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WASHINGTON, DC

WHEN: December 16, 1997 at 9:00 am.
WHERE: Office of the Federal Register
Conference Room
800 North Capitol Street, NW
Washington, DC
(3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

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Additional information, including a list of telephone numbers, finding aids, reminders, and a list of Public Laws appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board
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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–CE–37–AD; Amendment 39–10216; AD 97–24–09]

RIN 2120–AA64

Airworthiness Directives; Burkhart Grob, Luft-und Raumfahrt, Model G 103 C Twin III SL Sailplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to Burkhart Grob, Luft-und Raumfahrt (Grob), Model G 103 C Twin III SL sailplanes. This action requires repetitively inspecting the propeller bearing and upper pulley wheel for increased play and, if increased play is found, modifying the propeller bearing and pulley wheel with a part of improved design. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. The actions specified by this AD are intended to prevent the loss of the sailplane engine propeller and possible loss of the sailplane.

DATES: Effective January 5, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 5, 1998.

ADDRESSES: Service information that applies to this AD may be obtained from Burkhart Grob Luft-und Raumfahrt, D–86874 Mattsies, Germany. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 96–CE–37–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. J. Mike Kiesov, Project Officer, Sailplanes, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone (816) 426–6934, facsimile (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Events Leading to the Issuance of This AD

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to Grob Model G 103 C Twin III SL sailplanes was published in the **Federal Register** on January 29, 1997 (62 FR 4205). The action proposed to require inspecting the propeller bearing and pulley wheel for increased play, if there is no increased play in the propeller bearing and pulley wheel, continuing to inspect, and if increased play is found, modifying the propeller bearing and upper pulley wheel by installing a part of improved design. The modification would be considered a terminating action to the repetitive inspections. Accomplishment of this action would be in accordance with Grob Service Bulletin (SB) 869–18, dated March 7, 1996, and Grob SB 869–18/2, dated July 8, 1996, which is a revised page 6 of the Grob SB 869–18, dated March 7, 1996.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. The FAA has determined that these minor corrections will not change the meaning of the AD and will not add any additional burden upon the public than was already proposed.

Cost Impact

The FAA estimates that 8 sailplanes in the U.S. registry will be affected by this AD, that it will take approximately 1 workhour per sailplane to accomplish the initial inspection, and that the average labor rate is approximately $60 an hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $480 or $60 per sailplane.

Grob has informed the FAA that parts have been distributed to equip 7 of the 8 sailplanes in the United States, which would reduce the estimated impact on U.S. operators from $480 to $60.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

AD 97–24–09 Burkhart Grob, Luft-Und Raumfahrt: Amendment 39–10216; Docket No. 96–CE–37–AD.

Applicability: Model G 103 C Twin III SL Sailplanes (serial numbers 35002 through 35051), certificated in any category.

Note 1: This AD applies to each sailplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For sailplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD.

The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Note 2: The paragraph structure of this AD is as follows:

Level 1: (a), (b), (c), etc.
Level 2: (1), (2), (3), etc.
Level 3: (i), (ii), (iii), etc.

Level 2 and Level 3 structures are designations of the Level 1 paragraph they immediately follow.

Compliance: Required as indicated in the body of this AD, unless already accomplished.

To prevent the loss of the sailplane engine propeller and possible loss of the sailplane, accomplish the following:

(a) Within the next 5 engine operating hours after the effective date of this AD, do one of the following:

(1) Modify the propeller bearing and upper pulley wheel by installing parts of improved design in accordance with the ''Actions: 2.'' and the ''Installation Instructions'' sections of Grob service bulletin (SB) 869–18, dated March 7, 1996, and Grob SB 869–18/2, dated July 8, 1996; or,

(2) Inspect the propeller bearing and upper pulley wheel for increased play (movement that exceeds or is equal to 0.4 mm) in accordance with the ''Actions'' section of Grob service bulletin (SB) 869–18, dated March 7, 1996.

(i) If increased play is found, prior to further flight, accomplish the modification in paragraph (a)(1) of this AD or,

(ii) If no increased play is found, continue to repetitively inspect for increased play in the propeller bearing and upper pulley wheel every 5 engine operating hours in accordance with the ''Actions: 1.'' section in Grob SB 869–18, dated March 7, 1996, and Grob SB 869–18/2, dated July 8, 1996. If increased play is found during any inspection, then, prior to further flight, accomplish the modification in paragraph (a)(1) of this AD.

(b) Accomplishing the modification in paragraph (a)(1) of this AD is a terminating action to the repetitive inspection required in paragraph (a)(2)(ii) of this AD. This modification may be accomplished at any time, but must be accomplished if increased play is found.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the sailplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri, 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) The inspections and modifications required by this AD shall be done in accordance with Burkhart Grob, Luft-und Raumfahrt Service Bulletin 869–18, dated March 7, 1996, and Burkhart Grob, Luft-und Raumfahrt Service Bulletin 869–18/2, dated July 8, 1996, which is a revised page six of the Burkhart Grob, Luft-und Raumfahrt Service Bulletin 869–18, dated March 7, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained Burkhart Grob Luft-und Raumfahrt, D–86874 Mattsies, Germany. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD addresses German AD 96–206, April 4, 1996.

(f) This amendment (39–10216) becomes effective on January 5, 1998.

Issued in Kansas City, Missouri, on November 17, 1997.

Larry E. Werth,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–30869 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–CE–95–AD; Amendment 39–10215; AD 97–24–08]

RIN 2120–AA64

Airworthiness Directives; Burkhart Grob, Luft-und Raumfahrt, GmbH. Model G102 Astir CS Sailplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to Burkhart Grob, Luft-und Raumfahrt, GmbH. (Grob) Model G102 Astir CS sailplanes. This action requires replacing the elevator control lever with an improved elevator control lever. The discovery of cracks in the elevator control lever during a routine inspection of a Grob Model G102 Astir CS sailplane prompted this action. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. The actions specified by this AD are intended to prevent failure of the elevator control lever, which could result in loss of control of the sailplane.

DATES: Effective January 5, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 5, 1998.

ADDRESSES: Service information that applies to this AD may be obtained from Grob Luft-und Raumfahrt, GmbH, Postfach 1257, D–87712, Mindelheim, Germany. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket 95–CE–95–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. J. Mike Kiesov, Project Officer, Sailplanes, Small Airplane Directorate, Aircraft Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone (816) 426–6934; facsimile (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Events Leading to the Issuance of This AD

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would

apply to certain Burkhart Grob, Luft-und Raumfahrt, GmbH. Model G102 Astir CS sailplanes was published in the **Federal Register** on December 10, 1996 (61 FR 65001). The action proposed to require replacing the elevator control lever, part number (P/N) 102–3542 or an FAA-approved equivalent part number, with an improved elevator control lever, P/N 102–3543 or an FAA-approved equivalent part number.

Accomplishment of this action would be in accordance with Grob Service Bulletin (SB) TM 306–33, dated September 15, 1994, and Grob Installation Instructions No. 306–30/1, dated October 11, 1994. Grob has also issued SB TM 306–34, dated December 4, 1994, which expounds on the weight and balance procedure that is required in Item 4 of the Grob Installation Instructions No. 306–30/1, dated October 11, 1994.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. The addition of Grob Service Bulletin TM 306–34, dated December 12, 1994, was not included in the proposed action and is added to the final rule for clarification of the weight and balance procedures required in Item 4 of the Grob Installation Instructions 306–30/1, dated October 11, 994. The FAA has determined that this clarification and any minor corrections will not change the meaning of the AD and will not add any additional burden upon the public than was already proposed.

Compliance Time

The FAA has determined that it is more beneficial and less burdensome to the owners/operators to require a replacement of the elevator control lever within the next 20 hours time-in-service, instead of requiring an initial inspection for cracks and if cracks are found, replacing the part prior to further flight, and then if no cracks are found, replacing the part prior to a certain date, as required by the Luftfahrt-Bundesamt (LBA), the airworthiness authority for Germany and the manufacturer. The one time replacement is more time and labor efficient.

After reviewing the compliance times recommended by the manufacturer in the Grob SB 306–33, and by the German AD 94–317/2 Grob, dated April 21, 1995, the FAA has determined that one compliance time for all operators is less burdensome and would not present any undue burden on any of the owner/operators of any U.S. registered sailplanes. Therefore, the compliance time stated in the body of this AD takes precedence over the compliance time recommended by Grob and the LBA.

Cost Impact

The FAA estimates that 53 sailplanes in the U.S. registry will be affected by this AD, that it will take approximately 12 hours per sailplane to accomplish this action, and that the average labor rate is approximately $60 an hour. Parts cost approximately $180 per sailplane. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be $47,700.

Grob has informed the FAA that no parts have been distributed to equip any sailplane in the United States. The FAA has no way of determining how many owners/operators may have incorporated these actions on their sailplane.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

AD 97–24–08 Burkhart Grob Luft-Und Raumfahrt, GMBH: Amendment 39–10215; Docket No. 95–CE–95–AD.

Applicability: Model G102 Astir CS sailplanes (serial numbers 1001 through 1536), certificated in any category.

Note 1: This AD applies to each sailplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For sailplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 20 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished.

Note 2: The compliance time in this AD does not reflect the compliance time given in the Grob service bulletin or the LBA AD 94–317/2 Grob, dated April 21, 1995.

To prevent failure of the elevator control lever, which could result in loss of control of the sailplane, accomplish the following:

(a) Replace the elevator control lever, Burkhart Grob Luft-und Raumfahrt (Grob) part number (P/N) 102–3542 (or FAA-approved equivalent part number), with an elevator control lever of improved design (Grob P/N 102–3543 or FAA-approved equivalent part number) in accordance with the ''Procedure'' section of the Grob Installation Instructions No. 306–30/1, dated October 11, 1994, which are referenced in the ''Actions: 2'' section of Grob Service Bulletin (SB) TM 306–33, dated September 15, 1994.

(b) Accomplish the weight and balance procedure required in Item 4 of the ''Procedure'' section in Grob Installation Instructions No. 306–30/1, dated October 11, 1994, by following the ''Procedure'' and ''Actions'' section in Grob SB No. 306–34, dated December 4, 1994.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199

of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the sailplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, Aircraft Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) The replacement required by this AD shall be done in accordance with the Grob Luft-Und Raumfahrt Installation Instructions No. 306–30/1, dated October 11, 1994, Grob Luft-und Raumfahrt Service Bulletin TM 306–33, dated September 15, 1994, and Grob Luft-und Raumfahrt Service Bulletin Service Bulletin No. 306–34, dated December 4, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Grob Luft-und Raumfahrt, GmbH, Postfach 1257, D–87712, Mindelheim, Germany. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The actions specified in this AD are addressed in German AD 94–317/2 Grob, dated April 21, 1995.

(f) This amendment (39–10215) becomes effective on January 5, 1998.

Issued in Kansas City, Missouri, on November 17, 1997.

Larry E. Werth,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–30867 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–CE–96–AD; Amendment 39–10217; AD 97–24–10]

RIN 2120–AA64

Airworthiness Directives; Burkhardt Grob Luft-und Raumfahrt, GmbH. Model G 103 Twin Astir Sailplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to Burkhardt Grob Luft-und Raumfahrt, GmbH. (Grob) Model G 103 Twin Astir sailplanes. This action requires replacing the airbrake over-center lever and installing new inspection holes. The AD is the result of cracked airbrake over-center levers found during routine inspections. The actions specified by this AD are intended to prevent an asymmetrical airbrake deployment, which could result in an uncontrollable roll and possible loss of control of the sailplane.

DATES: Effective December 29, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 29, 1997.

ADDRESSES: Service information that applies to this AD may be obtained from Grob Luft-und Raumfahrt, GmbH., D–8939, Mattsies-am Flugplatz, Germany. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket 95–CE–96–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. J. Mike Kiesov, Project Officer, Sailplanes, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone (816) 426–6932; facsimile (816) 426–2165.

SUPPLEMENTARY INFORMATION:

Events Leading to the Issuance of This AD

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to Grob Model G 103 Twin Astir sailplanes was published in the **Federal Register** on December 23, 1996 (61 FR 67506). The action proposed to require replacing the airbrake over-center lever (Grob part number (P/N) 103–4123 (left) and P/N 103–4124 (right)) with a new part of improved design, (Grob P/N 103B–4123 (left) and 103B–4124 (right), or FAA-approved equivalent part numbers) and installing new inspection holes.

Accomplishment of the proposed action would be in accordance with Grob Service Bulletin TM 315–47/2, dated January 20, 1993, and Grob Repair Instructions No. 315–45/2, dated October 11, 1991.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

After examining all information related to this AD, the FAA has noticed two discrepancies in the NPRM that should be clarified in the final rule.

First, clarification is required regarding Grob Repair Instructions TM 315–45/2. There is a difference between the dimensions called out in Drawing 3 of Grob Repair Instructions TM 315–45/2 and the dimensions called out in the materials list on page one of the Repair Instructions for the composite sheet used for the 2 composite stops. Specifically, refer to the material list on page one of the repair instructions, which calls out 2 stops of 3mm × 30mm × 30mm composite sheet. Drawing 3 calls out the composite sheet material as 3mm × 30mm × 40mm, but should actually call out the composite sheet material as 3 × 30 × 30. The material list on page one is the correct dimension.

Second, there are only 18 Grob Model G 103 sailplanes in the U.S. registry rather than the figure of 60 sailplanes that was originally published in the NPRM. This would lower the cost impact on the U.S. operators, and would not have an adverse impact.

The FAA's Determination

After careful review of all available information related to the subject presented above, including the service information, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for the addition of a note to refer to the materials list for correct dimensions on the composite sheet, the lowering of the number of sailplanes affected, and minor editorial corrections. The FAA has determined that these corrections will not change the meaning of the AD and will not add any additional burden upon the public than was already proposed.

Cost Impact

The FAA estimates that 18 sailplanes in the U.S. registry will be affected by this AD, that it will take approximately 12 workhours per sailplane to accomplish the action, and that the average labor rate is approximately $60 an hour. Parts cost approximately $650 per sailplane. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $24,660 or $1,370 per sailplane.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and

responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

AD 97–24–10 Burkhardt Grob Luft-und Raumfahrt, GMBH: Amendment 39–10217; Docket No. 95–CE–96–AD.

Applicability: Model G 103 Twin Astir Sailplanes, (serial numbers 3000 through 3291, with or without the suffix ''T''), certificated in any category.

Note 1: This AD applies to each sailplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For sailplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 50 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished.

To prevent an asymmetrical airbrake deployment, which could result in an uncontrollable roll and possible loss of control of the sailplane, accomplish the following:

(a) Replace the airbrake over-center lever (Grob part number (P/N) 103–4123 (left) and 103–4124 (right), or FAA-approved equivalent part numbers) with a new part of improved design (Grob P/N 103B–4123 (left), and 103B–4124 (right), or FAA-approved equivalent part numbers) in accordance with the Procedures section of Grob Service Bulletin (SB) TM 315-47/2, dated January 20, 1993, and Grob Repair Instructions No. 315–45/2, dated October 11, 1991. Use the dimension called out in the materials list on page one of the Repair Instructions for the correct dimension of the composite sheet.

(b) Install inspection holes in accordance with the Procedure section of Grob Repair Instructions No. 315–45/2, dated October 11, 1991.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the sailplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) The modification and replacement required by this AD shall be done in accordance with Burkhardt Grob Luft-und Raumfahrt, GmbH G 103 Service Bulletin TM 315–47/2, dated January 20, 1993, and Burkhardt Grob Luft-und Raumfahrt, GmbH Repair Instructions No. 315–45/2, dated October 11, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may also be obtained from Grob Luft-und Raumfahrt, GmbH., D–8939, Mattsies-am Flugplatz, Germany. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD addresses German AD 92–309/2 Grob, dated February 26, 1993.

(f) This amendment (39–10217) becomes effective on December 29, 1997.

Issued in Kansas City, Missouri, on November 18, 1997.

Larry E. Werth,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–30870 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[CA–002–PP; FRL–5926–2]

Clean Air Act Approval and Promulgation of Title V Operating Permits Program Revisions; State Implementation Plan Revision, Santa Barbara County Air Pollution Control District, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing the approval of a revision to Rule 1301 of Regulation XIII proposed in the **Federal Register** on September 3, 1997, both as a revision to the federally-approved State Implementation Plan (SIP) and as a revision to the title V operating permit program adopted by the Santa Barbara County Air Pollution Control District (Santa Barbara, SBCAPCD, or District) on September 18, 1997. This approval action will incorporate this rule into the federally approved SIP. The intended effect of approving this revision is to allow Department of Defense (DoD) facilities to become exempt from title V of the Clean Air Act permit requirements, if the source implements an emission reduction plan that achieves a minimum reduction of 10 tons per year of ozone precursors.

Thus, EPA is finalizing the approval of this rule as a revision to the title V operating permit program, and as a revision into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

EFFECTIVE DATE: This action is effective on December 26, 1997.

ADDRESSES: Copies of the rule revision and EPA's evaluation report is available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revision is available for inspection during normal business hours at the following locations:

Permits Office (AIR–3), Air Division, U.S. Environmental Protection

Agency, Region IX, 75 Hawthorne Street, 17th Floor, San Francisco, CA 94105
Santa Barbara County Air Pollution Control District, 26 Castilian Drive B–23, Goleta, CA 93117
California Air Resources Board, 2020 L Street, Sacramento, CA 95814
U.S. Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, S.W., Washington, D.C. 20460

FOR FURTHER INFORMATION CONTACT: John Walser (telephone 415/744–1257), Permits Office (AIR–3), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

SUPPLEMENTARY INFORMATION:

I. Applicability

The following rule is being approved into the California SIP: SBCAPCD Rule 1301—Part 70 Operating Permit Program—General Information.

II. Background

On September 3, 1997, in 62 FR 46451, EPA proposed to approve the following rule in the California SIP and as a revision to the title V program: SBCAPCD Rule 1301—Part 70 Operating Permit Program—General Information. On behalf of the District, Rule 1301 was submitted by the California Air Resources Board to EPA on October 10, 1997 as a revision to the title V program, and on October 31, 1997 as a SIP-submittal. A detailed discussion of the background for the above rule is provided in the Proposed Rulemaking (NPRM) cited above.

EPA has evaluated the above rule for consistency with the requirements of the CAA and EPA regulations and EPA interpretation of these requirements as expressed in the various EPA policy guidance documents referenced in the NPRM cited above. EPA has found that the rule meets the applicable EPA requirements. On October 31, 1997, EPA reviewed this rule for completeness and found that the rule conformed to the completeness criteria in 40 CFR part 51, Appendix V.

III. Response to Comments

A 30 day public comment period was provided in 62 FR 46451. EPA received no comments.

IV. EPA Action

EPA is finalizing action to approve the above rule as a revision to the title V Operating Permit Program and for inclusion into the California SIP. EPA is approving the submittal under section 110(k)(3) as meeting requirements of section 110(a) and part D of the CAA. This approval action will incorporate this rule into the federally approved SIP and revise the title V program. These revisions apply to any source under jurisdiction of the SBCAPCD that qualifies as a Part 70 source and meets the requirements for exclusion of military tactical support and/or infrastructure building maintenance equipment at a Department of Defense facility. In Santa Barbara County, only Vandenberg Air Force Base (VAFB) meets these requirements.

The revision enables VAFB to comply with Rule 370, the District's prohibitory rule, which limits the Base's potential to emit to below the title V applicability thresholds and requires VAFB to reduce its annual emissions rate of ozone precursors by at least 10 tons through the ENVVEST initiative. The rule revision also includes emission reduction plan requirements and milestones to be approved by the District and made federally-enforceable by the EPA by incorporating the rule revisions into the SIP for California, if EPA finds that the planned emission reductions are real, quantifiable, surplus, and enforceable.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

V. Administrative Requirements

A. Docket

Copies of Santa Barbara's submittal and other information relied upon for final actions are contained in docket number CA–002-PP maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this final rulemaking. The docket is available for public inspection at the location listed under the **ADDRESSES** section of this document.

B. Regulatory Flexibility Act

The EPA's actions under section 502 of the Act do not create any new requirements, but simply address revisions to Santa Barbara's existing operating permits program that was submitted to satisfy the requirements of 40 CFR part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

C. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated today does not include a federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This federal action approves pre-existing requirements under state or local law, and imposes no new federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

D. Executive Order 12866

The Office of Management and Budget has exempted this action from review under Executive Order 12866.

E. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major'' as defined by 5 U.S.C. 804(2).

F. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 26, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not

be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds.

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Date Signed: November 14, 1997.

Felicia Marcus,

Regional Administrator.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart F—California

2. Section 52.220 is amended by adding and reserving paragraphs (c)(247) through (c)(249) and by adding paragraph (c)(250) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(247) [Reserved]

(248) [Reserved]

(249) [Reserved]

(250) New regulations for the following APCD were submitted on October 31, 1997, by the Governor's designee.

(i) Incorporation by reference.

(A) Santa Barbara County Air Pollution Control District.

(*1*) Rule 1301 adopted on September 18, 1997.

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

2. Appendix A to part 70 is amended by revising paragraph (aa) to the entry for California to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

California

* * * * *

(aa) Santa Barbara County Air Pollution Control District (APCD) submitted on November 15, 1993, as amended March 2, 1994, August 8, 1994, December 8, 1994, June 15, 1995, and September 18, 1997; interim approval effective on December 1, 1995; interim approval expires on October 1, 1998.

* * * * *

[FR Doc. 97–30951 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL162–1a; FRL–5926–6]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On September 8, 1997, the State of Illinois submitted a State Implementation Plan (SIP) revision request to the Environmental Protection Agency (EPA) which tightens Volatile Organic Material (VOM) regulations for cold cleaning degreasing operations in the Chicago and Metro-East ozone nonattainment areas. VOM, as defined by the State of Illinois, is identical to ''Volatile Organic Compounds'' (VOC), as defined by EPA. VOM combines with oxides of nitrogen in the atmosphere to form ground-level ozone, commonly known as smog. Exposure to ozone is associated with a wide variety of human health effects, agricultural crop loss, and damage to forests and ecosystems. The State intends to include the tightened cold cleaning degreasing regulations as part of its 1999 and 2002 Rate-Of-Progress (ROP) Plans. Illinois expects that the control measures specified in this SIP revision will reduce VOM emissions by 11.35 tons per day (TPD) by 1999 in the Chicago area and 0.79 TPD by 1999 in the Metro-East area. This rulemaking action approves, through direct final, the Illinois SIP revision request.

DATES: The ''direct final'' is effective on January 26, 1998, unless EPA receives written adverse or critical comments by December 26, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Copies of this SIP revision request is available for inspection at the following address:

U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (It is recommended that you telephone Mark J. Palermo, Environmental Protection Specialist at (312) 886–6082 before visiting the Region 5 Office.)

Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Mark J. Palermo, Environmental Protection Specialist, at (312) 886–6082.

SUPPLEMENTARY INFORMATION:

I. Background

Section 182(c)(2)(B) of the Clean Air Act (Act) requires any serious and above ozone nonattainment area to achieve post–1996 ROP reductions of 3 percent of VOC 1990 baseline emissions per year, averaged over each consecutive 3 year period, until the area has achieved attainment of the 1-hour ozone National Ambient Air Quality Standard. In Illinois, the Chicago area (Cook, DuPage, Kane, Lake, McHenry, Will Counties and Aux Sable and Goose Lake Townships in Grundy County and Oswego Township in Kendall County) is classified as ''severe'' nonattainment for the 1-hour ozone standard. As such, the Chicago nonattainment area is subject to the post–1996 ROP requirement.

The Act specifies under section 182(b)(1)(C) that emission reductions claimed under ROP plans must be achieved through the implementation of control measures through revisions to the SIP, the promulgation of Federal rules, or through permits under Title V of the Act. Control measures implemented before November 15, 1990, are precluded from counting toward ROP reduction.

Illinois has submitted tightened cold cleaning degreasing rules for the control of VOC as a revision to the SIP for the purpose of meeting post–1996 ROP requirements for the Chicago ozone nonattainment area. These tightened rules also apply to the Metro-East moderate ozone nonattainment area (Madison, Monroe, and St. Clair Counties), to help the area reach attainment.

A public hearing on the tightened rules was held on March 4, 1997, in Chicago, Illinois. The rules were adopted by the Illinois Pollution Control Board on June 5, 1997. The rules

became effective on June 9, 1997; they were published in the *Illinois Register* on June 20, 1997. The Illinois Environmental Protection Agency (IEPA) formally submitted the rules to EPA on September 8, 1997, as a revision to the Illinois SIP for ozone. EPA made a finding of completeness in a letter dated October 9, 1997.

The September 8, 1997, submittal includes the following new or revised rules:

Part 211: Definitions and General Provisions, Subpart B: Definitions, Section 211.1885 Electronic Component.

Part 218: Organic Material Emission Standards and Limitations for the Chicago Area, Subpart E: Solvent Cleaning, Section 218.182 Cold Cleaning.

Part 219: Organic Material Emission Standards and Limitations for the Metro-East St. Louis Area, Subpart E: Solvent Cleaning, Section 219.182 Cold Cleaning.

The cold cleaning rules contained in part 218 are identical to those in part 219 except for the areas of applicability. Part 218 applies to the Chicago area, while part 219 applies to the Metro-East area. EPA's evaluation of these rules is as follows.

II. Evaluation of Rules

Cold cleaning degreasing rules were originally implemented by Illinois as part of the State's Reasonably Available Control Technology (RACT) requirements for VOC control The rules are codified under 35 Illinois Administrative Code sections 218/219.182, which was incorporated into the SIP on September 9, 1994 (59 FR 46562). The September 8, 1997, SIP revision submittal amends sections 218/219.182 to tighten requirements for operators of cold cleaning degreasers and adds new requirements for sellers of solvent for use in cold cleaning degreasing operations.

As previously discussed, this SIP revision submittal is required by the Act to the extent that the rule was submitted to meet Illinois' post–1996 ROP requirements. A review of what emission reduction this SIP revision achieves for purposes of ROP will be addressed when rulemaking action on Illinois— post–1996 ROP plan is taken.

To determine whether the Illinois submittal meets the requirements for an approvable SIP revision, the rules were reviewed for their consistency with section 110 and part D of the Act. A discussion of the rules and EPA's evaluation follows.

Material Requirements

Sections 218/219.182(c) have been added to limit the vapor pressure of solvent used or sold for use in cold cleaning degreasing operations in the Chicago and Metro-East ozone nonattainment area. Beginning March 15, 1999, the vapor pressure limit is 2.0 millimeters of mercury (mmHg), or 0.038 pounds per square inch (psi) measured at 20 degrees Celsius (C) (68 degrees Fahrenheit (F)). On March 15, 2001, the vapor pressures limit is tightened to 1.0 mmHg (0.019 psi) measured at 20 degrees C (68 degrees F).

Exemptions

The supplier sales requirements under sections 218/219.182(c) do not apply to the sale of solvents in units less than or equal to 5 gallons. This provision is intended to exclude cleaning solvents sold at various stores specializing in auto products, including department stores with auto supply sections. The State submittal documentation indicates that due to the quantity of solvent used in commercial cold cleaning operations, and the lower per gallon costs offered by larger suppliers, facilities engaged in cold cleaning would not typically purchase their solvents at such auto supply stores.

Sections 218/219.182(f) exempt the cleaning of electronic components from the March 15, 1999, and March 15, 2001, vapor pressure limits under section 218/219.182(c). Illinois has defined ''electronic component'' under section 211.1885 as all portions of an electronic assembly, including, but not limited to, circuit board assemblies, printed wire assemblies, printed circuit boards, soldered joints, ground wires, bus bars, and associated electronic component manufacturing equipment such as screens and filters. The State submittal documentation indicates that this exemption was added based on concern that the 1.0 mmHg vapor pressure solvent would not adequately clean certain types of electronic equipment.

Sections 218/219.182(g) also exempt from section 218/219.182(c) any cold cleaning taking place in a Detrex cold batch degreaser Model # 2D-CC-SPL Size 24–4–10, or substantial equivalent, including automated loading of parts, totally enclosed operation (excluding loading or unloading) and permitted by IEPA. The State submittal documentation indicates that Detrex degreasers, and other substantially similar, large-scale degreasing operations, are highly controlled and specialized operations which provide emissions reductions that are equivalent or more stringent than the vapor pressure limits required under sections 218/219.182(c).

Compliance Testing

Sections 218/219.186 indicate that the test methods under sections 218/219.110 shall be used to determine vapor pressures to demonstrate compliance with Illinois' cold cleaning degreasing regulations under sections 218/219.182. These test method provisions were incorporated into the SIP on September 9, 1994 (59 FR 46562).

Recordkeeping

Sections 218/219.182(d) and (e) require subject solvent suppliers and users to maintain documents which indicate the solvent's vapor pressure at the prescribed temperature. The marketers of cold cleaning solvents to users must keep records indicating the name and address of the solvent purchaser, the date of purchase, the type of solvent purchased, the solvent unit quantity, the total volume purchased, and the vapor pressure of the solvent purchased measured in mmHg at 20 degrees C (68 degrees F). Solvent users must maintain records for each solvent purchase indicating the name and address of the solvent supplier, the date of the solvent purchase, the type of solvent purchased, and the vapor pressure of solvent measured in mmHg at 20 degrees C (68 degrees F). These records must be kept for three years.

III. EPA Rulemaking Action

The EPA is approving, through final rulemaking action, Illinois' tightened cold cleaning degreasing rules for the Chicago and Metro-East St. Louis ozone nonattainment areas.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603

and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *EPA*., 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must undertake various actions in association with any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. This Federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 26, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ozone, Volatile organic compounds, Incorporation by reference, Recordkeeping and reporting.

Dated: November 7, 1997.

David A. Ullrich,

Acting Regional Administrator.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart O—Illinois

2. Section 52.720 is amended by adding paragraph (c)(139) to read as follows:

§ 52.720 Identification of plan.

* * * * *

(c) * * *

(139) On September 8, 1997, the State of Illinois submitted tightened volatile organic material rules for cold cleaning degreasing operations in the Chicago and the Metro-East ozone nonattainment areas.

(i) *Incorporation by reference.* Illinois Administrative Code, Title 35: Environmental Protection, Subtitle B: Air Pollution, Chapter I: Pollution Control Board, Subchapter c: Emissions Standards and Limitations for Stationary Sources.

(A) Part 211: Definitions and General Provisions, Subpart B: Definitions, Section 211.1885, amended at 21 Ill. 7695, effective June 9, 1997.

(B) Part 218: Organic Material Emission Standards and Limitations for the Chicago Area, Subpart E: Solvent Cleaning, Section 218.182, amended at 21 Ill. 7708, effective June 9, 1997.

(C) Part 219: Organic Material Emissions Standards and Limitations for the Metro-East Area, Subpart E: Solvent Cleaning, Section 219.182, amended at 21 Ill. 7721, effective June 9, 1997.

[FR Doc. 97–31139 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[FRL–5927–4]

Standards of Performance for New Stationary Sources; Standards of Performance for Nonmetallic Mineral Processing Plants; Clarification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of policy; clarification.

SUMMARY: This action clarifies the applicability of the New Source Performance Standards for Nonmetallic Mineral Processing Plants (40 CFR part 60, subpart OOO). This action is necessary because of incorrect guidance and preamble language regarding the regulation's applicability to affected facilities in the nonmetallic mineral processing industry. The April 1991 Regulatory and Inspection Manual for Nonmetallic Mineral Processing Plants included the following incorrect statement: ''Subpart OOO affected facilities begin with the first crushing or grinding operation at the plant.'' The same incorrect statement was made in a response to a comment in the preamble to the June 9, 1997, **Federal Register** document for the final amendments to subpart OOO.

Section 60.670(a) of subpart OOO lists the affected facilities in fixed or portable nonmetallic mineral processing plants. This list includes each crusher, grinding mill, screening operation, bucket elevator, belt conveyor, bagging operation, storage bin, and enclosed truck or railcar loading station. The clear intent of the regulation is that *all* facilities listed in section 60.670(a) are subject to subpart OOO. While subpart OOO affected operations typically have crushers or grinding mills located at or near the beginning of the nonmetallic mineral processing line, this is not always the case (e.g., some plants may convey, screen or otherwise process materials without first utilizing a crusher located in the plant). Therefore, with this document, the EPA is clarifying that as long as crushing or grinding occurs anywhere at a non-metallic mineral processing plant, *any affected facility listed in § 60.670(a) is subject to subpart OOO regardless of its location within the plant. EPA expects that plants that have not considered facilities prior to the first crushing or grinding operation as affected facilities, will now ensure that those affected facilities will meet all of the applicable regulatory requirements.*

FOR FURTHER INFORMATION CONTACT: Mr. Scott Throwe at (202) 564–7013, Manufacturing, Energy, and Transportation Division (2223A), U.S. EPA, 401 M Street, Washington, D.C. 20460.

Dated: November 20, 1997.

Scott A. Throwe,

Environmental Protection Specialist.

[FR Doc. 97–30950 Filed 11–25–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300576; FRL–5754–9]

RIN 2070–AB78

Tefluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of tefluthrin and its metabolite in or on corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 parts per million (ppm). It also removes time limitations for tolerances for residues of tefluthrin on the same commodities that expire on November 15, 1997. Zeneca Ag Products requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300576], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300576], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300576]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Beth Edwards, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5400, e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On February 1, 1989 (54 FR 5080), EPA established time limited tolerances under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of tefluthrin on corn, grain, field, and pop; corn, forage and fodder, field and pop. As additional crop tolerances were established, they were also made time-limited. These tolerances expire on November 15, 1997. Zeneca Ag Products, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide tefluthrin in the corn commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of the registration. Zeneca Ag Products also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of September 25, 1997 (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petitions (PP 7F3521 and 4F4406) for tolerances by Zeneca Ag Products, P.O. Box 15458, Wilmington, DE, 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.440 be amended by removing the time-limitation for tolerances for combined residues of the insecticide and pyrethroid tefluthrin and its metabolite (*Z*)-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid, in or on corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 part per million (ppm).

The basis for the time-limited tolerances that expire November 15, 1997, was given in the **Federal Register** of October 20, 1993 (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and

children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by

pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of tefluthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for combined residues of tefluthrin and its metabolite on corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tefluthrin are discussed below.

1. Acute toxicity studies with the technical grade of the active ingredient tefluthrin: oral LD_{50} in the rat is 21.8 milligrams/kilogram (mg/kg) for males and 34.6 mg/kg for females - Toxicity Category I; dermal LD_{50} in the rat is 316 mg/kg in males and 177 mg/kg in females - Toxicity Category I; acute inhalation LC_{50} in the rat is 0.037 mg/l and 0.049 mg/l in male and female rats, respectively - Toxicity Category I; the primary eye irritation study in the rabbit was an invalid study; primary dermal irritation study in the rabbit showed slight irritation - Toxicity Category IV; dermal sensitization study in the guinea pig showed no skin sensitization; and the acute delayed neurotoxicity study did not show acute delayed neurotoxicity.

2. In an oral toxicity study, rats were dosed at 0, 25, 100, or 400 ppm (1.25, 5, or 20 milligrans/kilogram/day) (mg/kg/day) for 21 days. The LOEL for females for this 21-day oral toxicity study is 400 ppm (equivalent to approximately 20 mg/kg/day) based on decreased body weight gain, decreased platelet counts, and increased WBC and lymphocytes in the high-dose females. The NOEL for females is 100 ppm (equivalent to approximately 5 mg/kg/day). The NOEL in males was not observed.

3. In a subchronic oral toxicity study, rats were dosed at 0, 50, 150, or 350 ppm (2.5, 7.5, or 17.5 mg/kg/day) for 90 days. The LOEL for this 90-day feeding study is 150 ppm (equivalent to approximately 7.5 mg/kg/day) based on changes in hemoglobin, cholesterol, and liver weight in the mid-dose animals. The NOEL is 50 ppm (equivalent to approximately 2.5 mg/kg/day).

4. In a subchronic oral toxicity study, dogs were dosed at 0, 0.1, 0.5, or 1.5 mg/kg/day for 90 days. The LOEL for this 90-day oral toxicity study is 1.5 mg/kg/day based on thyroid changes, and increased levels of plasma triglycerides and aspartate transaminase observed at the high-dose. The NOEL is 0.5 mg/kg/day.

5. In an oral toxicity study, mice were dosed at 0, 25, 75, 200, or 400 ppm (0, 3.75, 11.3, 30.0, or 60.0 mg/kg/day) for 28 days. The LOEL is 400 ppm (equivalent to approximately 60 mg/kg/day) based on decreased body weight gains in both sexes and final body weights in females. The NOEL is 200 ppm (equivalent to approximately 30 mg/kg/day).

6. In a dermal toxicity study, rats were dosed at 0, 0.1, 1.0, or 50 mg/kg. The LOEL for skin effects for this 21-day dermal toxicity study is 50.0 mg/kg based on acanthosis, necrosis epidermis, and inflammatory cell infiltrate dermis observed in the high-dose animals. The NOEL for skin effects is 1.0 mg/kg). The NOEL for neurological effects (the observed postural effects) may be between 0.025 and 0.1 mg/kg.

7. In a chronic/oncogenicity study, mice were dosed at 0, 25, 100, or 400 ppm (actual dose levels were equivalent to 3.4, 13.5, or 54.4 mg/kg/day) for 104 weeks. The chronic LOEL is 13.5 mg/kg based on hemangiomatous changes of the uterus and liver necrosis observed in the mid- and high-dose females. The chronic NOEL is 3.4 mg/kg. Under the conditions of this study, there was no evidence of carcinogenic potential.

8. In a chronic toxicity study, dogs were dosed at dose levels of 0, 0.1, 0.5, and 2 mg/kg/day for 12 months. The LOEL for this chronic study is 2.0 mg/kg/day based on the increased incidence of ataxia in both sexes at the high-dose. The NOEL is 0.5 mg/kg/day.

9. In a chronic/oncogenicity study, rats were dosed for 24 months at 0, 25, 100, or 400 ppm (actual dose levels were equivalent to 1.1, 4.6, or 18.2 mg/kg/day). The chronic LOEL is 4.6 mg/kg/day based on decreased body weights, and neurotoxicity and clinical chemistry changes in the mid- and high-dose animals. The chronic NOEL is 1.1 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

10. In a developmental toxicity study, rats were dosed at 0, 1, 3, or 5 mg/kg/day from days 7 through 16 of gestation. The maternal LOEL is 3 mg/kg/day, based on treatment-related decrease body weight gains during dosing. The maternal NOEL is 1 mg/kg/day. Developmental toxicity was demonstrated at 5 mg/kg/day as an increase in the fetal incidence of bilaterally unossified calcanea (92.9% vs. 87.5% in controls, $p<0.05$; litter incidence was not shown) and a slight increase in the pes score (3.05 vs. 2.96 in controls) indicating slight inhibition of ossification at these sites. There were no treatment-related effects on the number, growth, and survival of the young in utero. In addition, the inter-group differences in the mean numbers of corpora lutea, implantations, pre- and post- implantation deaths, live fetuses, proportion of male fetuses, and fetal weights were not remarkable. The developmental LOEL is 5 mg/kg/day, based on inhibited ossification. The developmental NOEL is 3 mg/kg/day.

11. In a developmental toxicity study, rabbits were dosed at 0, 3, 6, or 12 mg/kg/day from days 7 through 19 of gestation. The maternal LOEL is 3 mg/kg/day, based on treatment-related clinical signs of toxicity (tremors). The maternal NOEL is <3 mg/kg/day. There was no developmental toxicity demonstrated at any dose level. There were no treatment-related effects on in utero survival and growth or on litter size and sex ratio of the fetuses. The skeletal variant data showed significant ($p<0.01$ or 0.05) increases in incidence of extra thoracic ribs and 27 pre-sacral vertebrae among fetuses in the dosed groups; however, when the litter was used as the unit for comparison, the incidences of these respective variants were comparable between all groups. The incidences of these variants were not biologically significant. The NOEL for developmental toxicity is 12 mg/kg/day. The developmental LOEL was not observed.

12. In a multi-generation reproduction study, rats were dosed at 0, 15, 50, or 250 ppm (0, 0.75, 2.5, or 12.5 mg/kg/day). The LOEL for parental toxicity is 12.5 mg/kg/day, based on lowered body

weight gains, and the NOEL is 2.5 mg/kg/day. The LOEL for neurotoxic effects is 2.5 mg/kg/day, based on abnormal, splayed, or high-stepping gait. The NOEL for neurotoxic effects is 0.75 mg/kg/day. Reproductive toxicity was demonstrated at the high-dose as lowered pup body weight gain throughout the study in all generations and in both sexes. Additionally, total litter weight was decreased on day 29 in all of the high-dose groups. The LOEL for reproductive toxicity is 12.5 mg/kg/day, based on lowered pup body weight gains. The reproductive NOEL is 2.5 mg/kg/day.

13. Mutagenicity. There is no mutagenicity concern. The submitted studies satisfy the pre-1991 mutagenicity test battery and the new mutagenicity testing requirements. There are seven acceptable studies: one dominant lethal study in mice; reverse mutation assay (*Salmonella typhimurium*); one forward mutation assay in mammalian cells; one mouse lymphoma assay, one *in vivo* chromosomal aberration assay, *in vitro* chromosome aberration study; one UDS assay in primary rat hepatocytes. All these studies were negative.

14. Metabolism. In both rats and dogs, when given either 1 or 10 mg/kg, most of the radioactivity was found in the feces unchanged and most urinary metabolites were conjugated. Approximately 30% of the administered dose was absorbed and excreted in the urine in both species. Single doses in both rats and dogs were excreted within 48 hours, 50–65% in feces and 20–30% in the urine. In rats, a biliary fistula experiment suggested that the radioactivity measured in the feces may be partially due to biliary excretion. Studies also suggest that oxidation precedes the ester body cleavage. In rats, the halflife in the liver is 4.8 days, in the fat is 13.3 days and in the blood is 10.6 days. In a study with rat fat, half of the radioactive residues could be attributed to the parent and the remaining residues consisted of a mixture of fatty acid esters of hydroxylated parent metabolites.

15. Neurotoxicity. No acceptable mammalian neurotoxicity studies are available. In a supplementary study, 10 animals/sex/group were given either vehicle, 2,5-hexanedione or 5 mg/kg or 15 mg/kg tefluthrin. The positive control, 2,5-hexanedione, elicited the appropriate neurotoxicological response. No consistent effects on motor or sensory nerve electrophysiology or function or clinical signs of neurotoxicity were evident in animals treated with either 5 or 15 mg/kg tefluthrin. A slight but significant increase in pull-up time was observed on day 12 in males which was accompanied by a significant decrease in both SNCV and the amplitude of the SNAP. Both quickly returned to values similar to control values, and did not decrease again.

Neurotoxicity studies will be required under a special Data Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data to support these tolerances and these additional studies are not expected to significantly change the risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of a NOEL of 0.5 mg/kg/day based on increased incidence of tremors and ataxia in both sexes of dogs at 2.0 mg/kg/day (LOEL) on day 1 of the study from the 1 year oral chronic toxicity study in dogs.

2. *Short - and intermediate - term toxicity.* For short- and intermediate term MOE's, EPA recommends use of a NOEL of 0.5 mg/kg/day based on increased incidence of tremors and ataxia in both sexes of dogs at 2.0 mg/kg/day (LOEL) from the one year oral toxicity study in dogs and use of a dermal absorption rate of 25%. A dermal absorption rate of 25% was recommended based on the weight-of-the-evidence available for structurally related pyrethroids.

3. *Chronic toxicity*. EPA has established the RfD for tefluthrin at 0.005 milligrams/kilogram/day (mg/kg/day). This RfD is based on increased incidence of tremors and ataxia in both sexes of dogs in a chronic toxicity study and an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. No evidence of carcinogenicity was demonstrated in studies conducted with mice or rats.

C. Exposures and Risks

1. *From food and feed uses.*Tolerances have been established (40 CFR 180.440) for the combined residues of tefluthrin and its metabolite, in or on corn. Risk assessments were conducted by EPA to assess dietary exposures and risks from tefluthrin as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. Percent of crop treated data and tolerance values were used in conjunction with Monte Carlo. The acute dietary MOE at the 99.9th percentile for the most highly exposed population subgroup (non-nursing infants <1 year old) is 691. The MOE at the 99.9th percentile for the general U.S. population is 1,469. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater. Therefore, the acute dietary risk assessment for tefluthrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk.* The chronic dietary exposure assessment used tolerance values and percent crop treated information. The RfD used for the chronic dietary analysis is 0.005 mg/kg/day. The risk assessment resulted in use of less than one percent (0.1%) of the RfD for the U.S. population. The percent of the RfD used for the most highly exposed population subgroup (children ages one to six) is 0.3%.

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating tolerance levels and percent of crop treated refinements. The chronic dietary risk assessments used tolerance levels and percent crop treated information.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided five years after the tolerance is established, modified or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a timeframe it deems appropriate. Section 408(b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for tefluthrin were derived from federal and market survey data. EPA considers these data reliable. A range of estimates

are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimate for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water.* Tefluthrin is immobile in soil and, therefore, will not leach into ground water. Additionally, due to the insolubility and lipophilic nature of tefluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential dietary exposure from drinking water.

A screening evaluation of leaching potential of a typical synthetic pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM). Based on this screening assessment, potential concentrations of a pyrethroid in ground water at depths of 1 to 2 meters are essentially zero (<0.001 ppb). Surface water concentrations for pyrethroids were estimated using PRZM1 and Exposure Analysis Modeling Systems (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulation pond was 0.052 ppb. Concentrations in actual drinking water would be much lower than the levels predicted in the hypothetical, small, stagnant farm pond model since drinking water derived from surface water would normally be treated before consumption. Based on these analyses, the contribution of water to the dietary risk estimate is negligible. Therefore, EPA concludes that together these data indicate that residues are not expected to occur in drinking water.

i. *Acute exposure and risk.* The acute drinking water exposure and risk estimates are 0.000040 mg/kg/day (MOE of 12,362) and 0.000078 mg/kg/day (MOE of 6,439) for the overall U.S. population and non-nursing infants <1 year old, respectively.

ii. *Chronic exposure and risk.* The chronic drinking water exposure and risk estimates are 0.000000 mg/kg/day (0.0% of RfD utilized) and 0.000002 mg/kg/day (0.0% of RfD utilized) for the overall U.S. population and non-nursing infants <1 year old, respectively.

3. *From non-occupational non-dietary exposure.* Tefluthrin is currently not registered for use on residential non-food sites; therefore, no non-occupational non-dietary exposure is expected.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether tefluthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tefluthrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tefluthrin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and water. The acute aggregate MOE calculated at the 99.9th percentile for the overall U.S. population is 1,316. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields an MOE of 100 or larger. Therefore, the Agency concludes that there is reasonable certainty that no harm will result from acute aggregate exposure to tefluthrin residues in food and drinking water.

2. *Chronic risk.* Using the Anticipated Residue Concentration (ARC) exposure assumptions described above, EPA has concluded that aggregate exposure to tefluthrin from food and water will utilize 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children age 1-6 years (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tefluthrin residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Based on tefluthrin not being registered for residential non-food sites, EPA concludes that the aggregate short- and intermediate-term risks do not

exceed levels of concern (MOE less than 100), and that there is reasonable certainty that no harm will result from aggregate exposure to tefluthrin residues.

E. Aggregate Cancer Risk for U.S. Population

No evidence of carcinogenicity was demonstrated in studies conducted mice or rats.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of tefluthrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the prenatal developmental toxicity studies in rats and rabbits, the developmental NOEL was greater than the maternal NOEL, indicating a lack of sensitivity to in utero exposure. In rats, the maternal NOEL (1 mg/kg/day), based on body weight decreases at the LOEL of 3 mg/kg/day, which was based on ossification reductions in the extremities at 5 mg/kg/day. In the rabbit study, maternal pyrethroid toxicity was observed at all dose levels (maternal NOEL <3 mg/kg/day), but no developmental toxicity was observed (developmental NOEL >12 mg/kg/day).

iii. *Reproductive toxicity study.* In the two-generation reproduction study in rats, offspring toxicity (reduced mean pup weight gain) was observed only at the highest dose level tested (250 ppm; 12.5 mg/kg/day), while evidence of neurotoxicity in parental animals was observed at the systemic LOEL of 50 ppm (2.5 mg/kg/day). The offspring toxicity NOEL was 50 ppm (2.5 mg/kg/day) and the parental systemic NOEL was 15 ppm (0.75 mg/kg/day).

iv. *Pre- and post-natal sensitivity.* The data demonstrated no indication of increased sensitivity of rats or to in utero and/or postnatal exposure with tefluthrin.

v. *Conclusion.* The data base related to pre- and post-natal sensitivity is complete. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* The acute aggregate MOE calculated at the 99.9th percentile for non-nursing infants <1 year old is 623. EPA concluded that aggregate dietary acute risk (food plus water) would not exceed levels of concern. Therefore, the Agency has no acute aggregate concern due to exposure to tefluthrin through food and drinking water.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to tefluthrin from food and water will utilize 0.3% of the RfD for children age 1-6 years. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. *Short- or intermediate-term risk.* Based on tefluthrin not being registered for residential non-food sites, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is reasonable certainty that no harm will result.

EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tefluthrin residues.

5. *Special Docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism In Plants and Animals

Plant metabolism studies indicate that tefluthrin *per se* is not translocated to plants but is degraded in soil to two principal metabolites that are capable of being taken up by plants. The metabolites are the products of the cleavage of the ester to the free acid (*Z*)-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylic acid (Metabolite Ia) and to 2,3,5,6-tetrafluoro-4-hydroxymethylbenzoic acid (Metabolite VI). The Agency concluded that Metabolite VI need not be regulated.

In animals, dosing with radioactive tefluthrin at level equivalent to 11 ppm in feed resulted in identifiable residues of tefluthrin and its metabolites in tissues but at levels below those capable of detection by proposed enforcement methods.

B. Analytical Enforcement Methodology

Validated enforcement analytical methods are available for tefluthrin parent (Method PPRAM No. 85/1, The Determination of Residues of Tefluthrin in Crops and Soil-A Gas-Liquid Chromatographic Method) and for Metabolite Ia (Method GRAM-028 A Gas Chromatography Method for the

Determination of Residues of the Tefluthrin Metabolite PP890 in Crops of High and Low Moisture Content). The limits of quantitation of these methods are 0.01 ppm for tefluthrin and 0.05 ppm for Metabolite Ia.

C. Magnitude of Residues

1. *Plant commodities— Field trial studies.* No residues were detected in field trials conducted at maximum label rates and minimum PHIs. Tolerances were established at the limit of quantitation of the analytical method (0.06 ppm). The 0.06 ppm tolerances were used to estimate chronic and acute dietary exposure to potential residues of tefluthrin.

2. *Animal commodities.* Studies conducted indicate that no residues are detected in animal tissues, milk, and eggs and therefore secondary residues would not be a concern. For that reason, no tolerances have been established on meat, milk, and eggs. Secondary residues were therefore not considered in these analyses.

D. International Residue Limits

There are no Codex Maximum Residue Levels established for tefluthrin. No Canadian MRLs have been established for residues of tefluthrin on corn commodities. Mexico has established a tolerance for residues of tefluthrin on corn grain (0.06 ppm) which is in harmony with the U.S. tolerance.

IV. Conclusion

Therefore, the tolerance is established for combined residues of tefluthrin and its metabolite in corn, grain, field and pop; corn, forage and fodder, field, pop and sweet; and corn, fresh (including sweet K and corn with husk removed (CWHR)) at 0.06 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300576] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in **ADDRESSES** at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances,

raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.440 is revised to read as follows:

§ 180.440 Tefluthrin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide tefluthrin (2,3,5,6 tetrafluroro-4-methylphenyl)methyl-(1 alpha, 3 alpha)-(*Z*)-(±)-3(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-diemthylcyclopropanecarboxylate) and its metabolite (*Z*)-3-(2-chloro-3,3,3-trifluroro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid in or on the following commodities:

Commodity	Parts per million
Corn, field, fodder and forage, pop and sweet	0.06
Corn, fresh (including sweet K and corn with husk removed (CWHR)	0.06
Corn, field, grain and pop	0.06

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–30946 Filed 11–25–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300579; FRL–5754–7]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide bifenthrin ((2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate), in or on the raw agricultural commodities (RAC) cottonseed at 0.5 parts per million (ppm); corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and meat by-products (mbyp) of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk) at 1.0 ppm; poultry, fat, meat, and mbyp at 0.05 ppm. It also removes time limitations for tolerances for residues of bifenthrin on the same commodities that expire on November 15, 1997. These tolerances were requested under pesticide petitions (PP) 6F3453, 7F3546, and OE3921. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300579], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300579], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300579]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Adam Heyward, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5418, e-mail: heyward.adam@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On August 15, 1988, EPA established a time-limited tolerance under section 408 of the FFDCA, 21 U.S.C. 346 a(d) and 348 for residues of bifenthrin on cottonseed (53 FR 30678). As additional crops were approved tolerances were also made time-limited. These tolerances will expire on November 15, 1997. FMC Corporation, on September 15, 1997, requested that the time limitations for

tolerances for residues of the insecticide bifenthrin in or on the commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of registration. FMC Corporation also submitted a summary of its petition as required under the FFDCA as amended by the FQPA of 1996 (Pub. L. 104–170).

In the **Federal Register** of Friday, September 25, 1997 (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 6F3453, 7F3546, and 0E3921) for tolerances by the FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 and from the Interregional Research Project No. 4 (IR–4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. This notice included a summary of the petitions prepared by the FMC Corporation and the Interregional Research Project No. 4 (IR–4), the registrants. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.442 be amended by removing the time limitation for tolerances of the insecticide bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on the raw agricultural commodities cottonseed at 0.5 ppm; corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and mbyp of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk) at 1.0 ppm, poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, and poultry mbyp at 0.05 ppm. Tolerances for corn (forage and fodder) and livestock commodities were inadvertently not listed in the proposal paragraph of the notice of filing but were included in the discussion under Aggregate Exposure of the notice. These tolerances were considered by EPA for risk assessment purposes.

The basis for time-limited tolerances that expire November 15, 1997, was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rational for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . ..''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no observed effect level'' or''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure

that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate-term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High-end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure and high-end residential exposure are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g., frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e. the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. Toxicity results at lower levels when the dosing duration is increased.

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of bifenthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), on cottonseed at 0.5 ppm; corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and mbyp of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk), poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, and poultry mbyp at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by bifenthrin are discussed below.

1. Acute toxicity. Acute toxicity studies with the technical grade of the active ingredient bifenthrin: Oral LD_{50} in the rats of 70.1 milligram/kilogram (mg/kg) (male) and 53.8 mg/kg (female): Toxic category II, dermal LD_{50} in the rats of > 2000 mg/kg (male and female): Toxic category II, primary dermal and eye showed no irritation: Toxic category IV. Bifenthrin is not a dermal senstizer.

2. Mutagenicity. The following genotoxicity tests were all negative: A *Salmonella typhimurium* reverse gene mutation assay, a mouse lymphoma forward gene mutation assay (HGPRT locus), a mouse lymphoma $TO^{\pm}$ assay, a CHO/HGPRT assay, an *in vitro* chromosomal aberration assay in CHO cells, a rat bone marrow cytogenetic assay, and 2 unscheduled DNA synthesis assays in primary rat hepatocytes. Bifenthrin tests positively both with and without metabolic activation in the mouse lymphoma forward gene mutation assay ($TO^{\pm}$). There is also presumptive evidence that bifenthrin is mutagenic with metabolic activation in the CHO gene mutation assay. However, this study appears to be unacceptable at this time. All the other studies tested negatively. The submitted studies satisfies both the pre 1991 and new mutagenicity test batteries. No further testing is required at this time.

3. A 13-week feeding study in dogs (by capsule) of doses at nominal dose levels of 0, 2.5, 5, 10, or 20 milligram/kilogram/day (mg/kg/day) (equivalent to 2.21, 4.42, 8.84, and 17.7 mg/kg/day, based on percent active ingredient (a.i.)) for 13 weeks. There was no mortality during the study. There were no treatment-related changes noted in food consumption, hematology, clinical chemistry, organ weight, gross or microscopic parameters. In addition,

there were no treatment-related ophthalmological changes. Tremors were noted in 3 dogs/sex at 4.42 mg/kg/day and in 4 dogs/sex at 8.84 and 17.7 mg/kg/day. Ataxia was noted in 4 dogs/sex at 8.84 and 17.7 mg/kg/day and in one female at 4.42 mg/kg/day. Languidness occurred primarily at 17.7 mg/kg/day in both sexes, but also occasionally at 8.84 mg/kg/day. All of these symptoms occurred more frequently during the last 3 weeks of the study. Other dose-related clinical signs included blinking, mydriasis, nystagmus, lacrimation, and polypnea. One high-dose female appeared thin and/or dehydrated during the final weeks of the study. A non-statistically significant, but possibly treatment-related reduction in body weight (bwt) gain was noted in females at 17.7 mg/kg/day (0.6 kilogram (kg)) relative to the controls (1.3 kg). None of the females at 8.84 or 17.7 mg/kg/day showed cyclic activity or signs of estrus, but cyclic activity was observed in 2, 2, and 1 female at 0, 2.21, and 4.42 mg/kg/day, respectively and 4/5 showed signs of estrus. The lowest observed effect level (LOEL) for this 13-week study is 4.42 mg/kg/day based on the increased incidence of tremors in both sexes. The NOEL is 2.21 mg/kg/day.

4. A 90-day feeding study in rats fed at doses of 0, 12, 50, 100, and 200 ppm (0, 0.6, 2.5, 5, or 10 mg/kg/day) with a NOEL of 2.5 mg/kg/day and LOEL of 5 mg/kg/day based on the increased incidence of tremors in both sexes.

5. A 21-day study in rabbits exposed dermally to doses of 0, 25, 50, 100, or 500 mg/kg/day for 21 days with a systemic NOEL of 100 mg/kg/day. Systemic LOEL is 500 mg/kg/day based on the loss of muscle coordination in both sexes.

6. A 1-year chronic/carcinogenicity study in dogs was administered in the diet at dose levels of 0, 0.75, 1.5, 3, or 5 mg/kg/day. No mortality occurred during the study and there were no treatment-related effects on bwt, food consumption, organ weights, and grossor microscopic pathology. In addition, there were no treatment-related ophthalmological changes. Tremors were noted in all males and females at 5 mg/kg/day during weeks 15–29 and in 1/4 males and 3/4 females at 3 mg/kg/day during weeks 16–23. A significant increase in platelets was noted at 52 weeks in 5 mg/kg/day males. Serum sodium levels were significantly increased in males at 3 and 5 mg/kg/day and serum chloride was increased in males at 5mg/kg/day. The LOEL for this 52-week study is 3 mg/kg/day based on the increased incidence of tremors in both sexes. The NOEL is 1.5 mg/kg/day.

7. A chronic/carcinogenicity study in mice fed at doses of 0, 50, 200, 500, or 600 ppm (0, 2.5, 10, 25, or 30 mg/kg/day) in the diet for 87 weeks (males) or 92 weeks (females). Chronic LOEL is 10 mg/kg/day based on the incidence of tremors in both sexes. Chronic NOEL is 2.5 mg/kg/day. Carcinogenic potential was evidenced by a statistically significant increased trend for hemangiopericytomas in the urinary bladders of males, a significant dose-related trend for combined hepatocellular adenomas and carcinomas in males, and a significantly higher incidence of combined lung adenomas and carcinomas in females.

8. Chronic/carcinogenicity study in rats was administered for in the diet at doses of 0, 12, 50, 100, or 200 ppm (0, 0.6, 2.5, 5, or 10 mg/kg/day). Chronic LOEL is 5 mg/kg/day based on the increased incidence of tremors in both sexes and possible increases in organ-to-body weight ratios in males. Chronic NOEL is 2.5 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

9. In a pilot developmental study in rats bifenthrin was administered in the diet at dose levels of 0, 0.5, 1.0, 2.0, or 2.5 mg/kg/day during days 6–15 of gestation. Three of 10 rats at 2.5 mg/kg/day died on days 14–15. Tremors were noted in all 10 rats at 2.5 mg/kg/day and in 9/10 at 2.0 mg/kg/day. Mean bwt gains were depressed at 2.5 mg/kg/day throughout the study, and food consumption was 20 percent lower at this dose level during days 6–13. There were no differences in mean bwt gains or food consumption in the lower dose groups with respect to the controls. There were no treatment-related differences from controls in the number of implantations or litter size. The mean number of resorptions was similar in the lower dose groups; at 2.5 mg/kg/day it was somewhat higher, but this was attributable to an excessive number of resorptions in a single rat. The maternal LOEL is 2.0 mg/kg/day based on sporadic tremors (gestation days 7–18) and 30 percent mortality at 2.5 mg/kg/day. The maternal NOEL is 1.0 mg/kg/day. The developmental LOEL and NOEL were not determined; fetuses were not examined.

10. A developmental study in rats given gavage doses of 0, 0.5, 1.0, or 2.0 mg/kg/day was administered. Developmental toxicity was noted at 2.0 mg/kg/day and was characterized as an increased fetal and litter incidence of hydroureter. Although not statistically significant, the incidence of hydroureter was double that of the vehicle control and the lower dose groups. Developmental LOEL is 2.0 mg/kg/day based on the increased fetal and litter incidence of hydroureter. Developmental NOEL is 1.0 mg/kg/day. Maternal toxicity NOEL was 1.0 mg/kg/day based on tremors at LOEL of 2.0 mg/kg/day.

11. A developmental study in rabbits given gavage doses of 0, 2.67, 4.0, or 8.0 mg/kg/day or with 3.0 gram/kilogram/day (g/kg/day) resulted in no developmental toxicity observed under the conditions of the study. The maternal NOEL is 2.67 mg/kg/day, based on head and forelimb twitching at LOEL of 4.0 mg/kg/day. The developmental NOEL is ≥ 8.0 mg/kg/day, the highest dose tested.

12. A 2-generation reproduction study in rats fed diets containing doses of 0, 30, 60, or 100 ppm (0, 1.5, 3 or 5 mg/kg/day). Systemic LOEL is 5 mg/kg/day based on the incidence of tremors and marginally lower bwts in P and F_1 generation females during gestation and lactation. Systemic NOEL is 3 mg/kg/day. A reproductive LOEL was not observed. The reproductive NOEL is 5 mg/kg/day.

13. Animal metabolism. Metabolism studies in rats demonstrated that distribution patterns and excretion rates in multiple oral dose studies are similar to single-dose studies. Accumulation of unchanged compound in fat upon chronic administration with slow elimination. Otherwise, bifenthrin was rapidly metabolized and excreted. Unchanged bifenthrin is the major residue component of toxicological concern in meat and milk.

14. In a dermal absorption study, the following doses of ^{14}C bifenthrin were administered dermally in aqueous suspension: 49.2, 514, or 5253 µg/rat. Bifenthrin is rapidly absorbed into and through the skin, with a direct correlation between the doses applied and the amount absorbed. Most of the label was recovered within the skin at the application site. Average amounts of activity absorbed at the skin site for each of the doses at the 0.5 hour sacrifice were 54.47 percent, 56.42 percent, and 52.54 percent; and at the 24-hour sacrifice were 71.34 percent, 45.33 percent, and 53.63 percent.

15. No neurotoxicity studies are available. These studies will be required under a special data call-in letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient data to support these tolerances and these additional studies will not significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For the purposes of assessing acute dietary risk, EPA has

used the maternal NOEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats. The maternal lowest effect level (LEL) of this study is 2.0 mg/kg/day, which was based on tremors from day 7–17 of dosing. This acute dietary endpoint is used to determine acute dietary risks to all population subgroups.

2. *Short- and intermediate-term toxicity*. The maternal NOEL of 1.0 mg/kg/day from the oral developmental toxicity study in rats is also used for short- and intermediate-term MOE calculations (as well as acute, discussed in Unit II.B.1. of this preamble). The maternal LEL of this study of 2.0 mg/kg/day was based on tremors from day 7–17 of dosing, which was observed at this dose level in the pilot study. In comparison to the other studies, tremors were observed at the earliest time period with the lowest dose level in this study. A dermal absorption rate of 25 percent was recommended based on the weight of the evidence for structurally related pyrethroids. Although a 21-day dermal study in the rabbit is available it was not used because the rat is considered to be more sensitive than the rabbit based on comparison of the maternal NOELs and LELs in the developmental studies.

For the inhalation endpoint, no appropriate studies were available. EPA determined that the risk assessment should be inclusive of oral and inhalation exposure components assuming 100 percent absorption via the inhalation route. An aggregate oral and inhalation risk assessment is appropriate due to the similarity in the toxicity endpoint (neurotoxicity) seen in rats via these routes. The inhalation study used for comparison purposes was an acute toxicity study in rats on the 25.1 percent formulation where tremors, convulsions, and loss of hindlimb motor control was observed among other clinical signs of toxicity.

3. *Chronic toxicity*. EPA has established the RfD for bifenthrin at 0.015 mg/kg/day. This RfD is based on a 1-year oral feeding study in dogs with a NOEL of 1.5 mg/kg/day, based on intermittent tremors observed at the LOEL of 3.0 mg/kg/day; an uncertainty factor of 100 is used.

For chronic dermal occupational and residential exposure, EPA recommended the NOEL of 1.5 mg/kg/day from the chronic oral study in the dog with a dermal absorption rate of 25 percent. The LEL for the dog study was 3.0 mg/kg/day based on intermittent tremors. The recommended MOE is 100.

4. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992) the Carcinogenicity Peer Review Committee (CPRC) has classified bifenthrin as a Group C chemical, possible human carcinogen, based on urinary bladder tumors in mice, but did not recommend assignment of a cancer potency factor Q* (Q star) for a linear quantitative cancer risk assessment, instead, the CPRC recommended the RfD approach. Based on CPRC's recommendation that the RfD approach be used to assess dietary cancer risk, a quantitative linear dietary cancer risk assessment was not performed. Human health risk concerns due to long term consumption of bifenthrin residues are adequately addressed by the dietary risk evaluation chronic exposure analysis using the RfD.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of bifenthrin on corn (grain, forage, and fodder), cottonseed, hops, and livestock commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from bifenthrin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The acute risk assessment used Monte Carlo modeling incorporating anticipated residue and percent crop treated refinements. The acute dietary (food only) MOE calculated at the 99.9th percentile for the most highly exposed population subgroup (children 1–6 years old) is 193. The MOE calculated at the 99.9th percentile for the general U.S. population is 466. EPA concludes that there is a reasonable certainty of no harm for MOE of 100 or greater. Therefore, the acute dietary risk assessment for bifenthrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk*. The chronic dietary exposure assessment used anticipated residues and percent crop treated information. The risk assessment resulted in use of 0.2 percent of the RfD for the U.S. population and 0.3 percent of the most highly exposed population subgroup (children 1–6 years old).

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinements. The chronic dietary risk assessment used percent crop treated information and anticipated residues.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the antipicated residue levels of pesticide chemicals that have been measure in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified or left in effect, and a demonstration must be made to show that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. Section 408 (b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

(1) That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues.

(2) That the exposure estimate does not underestimate the exposure for any significant subpopulation.

(3) Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for bifenthrin were derived from Federal and market survey data. EPA considers these reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Date Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water*. Laboratory and field data have demonstrated that bifenthrin is immobile in soil and will

not leach into ground water. Other data show that bifenthrin is virtually insoluble in water and extremely lipophilic. As a result, EPA concludes that residues reaching surface waters from field runoff will quickly absorb to sediment particles and be partitioned from the water column. Further, a screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM). Based on this screening assessment, the potential concentrations of a pyrethroid in groundwater at depths of 1 and 2 meters are essentially zero (<< 0.001 parts per billion (ppb)). Surface water concentrations for pyrethroids were estimated using PRZM2 and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 0.052 ppb. Concentrations in actual drinking water would be much lower than the levels predicted in the hypothetical, small, stagnant farm pond model since drinking water derived from surface water would normally be treated before consumption. Based on these analyses, the contribution of water to the dietary risk estimate is negligible. Therefore, EPA concludes that together these data indicate that residues are not expected to occur in drinking water.

i. *Acute exposure and risk*. The acute drinking water exposure and risk estimates are 0.000060 mg/kg/day (MOE 16,664) and 0.000115 mg/kg/day (MOE 8,658) for the overall population and non-nursing infants < 1 year old respectively.

ii. *Chronic exposure and risk*. The chronic drinking water exposure and risk estimates are 0.000001 mg/kg/day (0.0 percent RfD utilized) and 0.000002 mg/kg/day (0.0 percent of RfD utilized) for the overall population and non-nursing infants < 1 year old respectively.

3. *From non-dietary exposure*. Bifenthrin is currently registered for use on the following residential non-food sites: General indoor/outdoor pest control, termiticide, ornamental plants and lawns around homes, park, recreation areas and athletic fields, and golf courses turf. Application of this pesticide in and around these sites is mainly limited to commercial applicators. Analyses were conducted which included an evaluation of potential non-dietary (residential) applicator, post-application and chronic dietary aggregate exposures associated with bifenthrin products used for residential flea infestation control and agricultural/commercial applications. The aggregate analysis conservatively assumes that a person is concurrently exposed to the same active ingredient via the use of consumer or professional flea infestation control products and to chronic level residues in the diet.

In the case of potential non-dietary health risks, conservative point estimates of non-dietary exposures, expressed as total systemic absorbed dose (summed across inhalation and incidental ingestion routes) for each relevant product use category (i.e. lawn care) and receptor subpopulation (i.e. adults, children 1–6 years old and infants < 1 year old) are compared to the systemic absorbed dose NOEL for bifenthrin to provide estimates of the MOEs. Based on the toxicity endpoints selected by EPA for bifenthrin, inhalation and incidental oral ingestion absorbed doses were combined and compared to the relevant systemic NOEL for estimating MOEs.

In the case of potential aggregate health risks, the above-mentioned conservative point estimates of inhalation and incidental ingestion non-dietary exposure (expressed as systemic absorbed dose) are combined with estimates (arithmetic mean values) of chronic average dietary (oral) absorbed doses. These aggregate absorbed dose estimates are also provided for adults, children 1–6 years old and infants < 1 year old. The combined or aggregated absorbed dose estimates (summed across non-dietary and chronic dietary) are then compared with the systemic absorbed dose NOEL to provide estimates of aggregate MOEs.

The short and intermediate-term non-dietary and aggregate (non-dietary + chronic dietary (food and water) MOEs for bifenthrin indicate a substantial degree of safety. The total non-dietary (inhalation + incidental ingestion + dermal) MOEs for post-application exposure for the lawn care product evaluated was estimated to be > 51,000 for adults, 1,900 for children 1–6 years old and 1,800 for infants < 1 year. The aggregate MOE (inhalation + incidental oral + dermal + chronic dietary, summed across all product use categories) was estimated to be 417 for adults, 196 for children 1–6 years old and 200 for infants (< 1 year old).

It can be concluded that the potential non-dietary and aggregate (non-dietary + chronic dietary) exposures for bifenthrin are associated with substantial margins of safety.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether bifenthrin has a common mechanism of toxicity with other substances or how to include this pesticide in acumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, bifenthrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this

tolerance action, therefore, EPA has not assumed that bifenthrin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. The acute aggregate risk assessment takes into account exposure from food and water. The acute aggregate MOE calculated at the 99.9th percentile for the U.S. population is 453. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or large. Therefore, the Agency has no acute aggregate concern due to exposure to bifenthrin through food and drinking water.

2. *Chronic risk*. Using the Anticipated Residue Concentrations (ARC) exposure assumptions described in Unit II.C.1.ii. of this preamble, EPA has concluded that aggregate exposure to bifenthrin from food and water will utilize 0.2 percent of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1–6 year old (discussed in Unit II.F. of this preamble). EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, EPA does not expect the aggregate exposure to exceed 100 percent of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to bifenthrin residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. As indicated above the non-dietary and chronic dietary MOEs was estimated to be 417 for adults.

E. Aggregate Cancer Risk for U.S. Population

As indicated in Unit II.B.4. of this preamble, based on EPA's recommendation that the RfD approach be used, a quantitative dietary cancer risk assessment was not performed. Human health risk concerns due to long term consumption of bifenthrin residues are adequately addressed by the dietary risk evaluation chronic exposure analysis using the RfD.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of bifenthrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional 10-fold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the rabbit developmental study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOEL of 4 mg/kg/day. In the rat developmental study, the maternal NOEL was 1 mg/kg/day, based on tremors at the LOEL of 2 mg/kg/day. The developmental (pup) NOEL was also 1 mg/kg/day, based upon increased incidence of hydroureter at the LOEL 2 mg/kg/day. There were 5/23 (22 percent) litters affected (5/141 fetuses since each litter only had one affected fetus) in the 2 mg/kg/day group, compared with zero in the control, 1 and 0.5 mg/kg/day groups. According to recent historical data (1992–1994) for this strain of rat, incidence of distended ureter averaged 11 percent with a maximum incidence of 90 percent.

iii. *Reproductive toxicity study*. In the rat reproduction study, parental toxicity occurred as decreased bwt at 5.0 mg/kg/day with a NOEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (highest dose tested).

iv. *Pre- and post-natal sensitivity*.—a. *Pre-natal*. Since there was not a dose-related finding of hydroureter in the rat developmental study and in the presence of similar incidences in the recent historical control data, the marginal finding of hydroureter in rat fetuses at 2 mg/kg/day (in the presence of maternal toxicity) is not considered a significant developmental finding. Nor does it provide sufficient evidence of a special dietary risk (either acute or chronic) for infants and children which would require an additional safety factor.

b. *Post-natal*. Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special post-natal sensitivity to infants and children in the rat reproduction study.

v. *Conclusion*. The toxicological data base related to pre- and post-natal sensistivity is complete. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Aggregate acute risk*. The aggregate acute MOE calculated at the 99.9th percentile for children age 1–6 is 191. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to bifenthrin through food and drinking water.

3. *Aggregate chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 0.3 percent of the RfD for children 1–6 years old. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. As indicated above the non-dietary and chronic dietary MOEs was

estimated to be 196 for children 1–6 year old and 200 for infants (1 year old).

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to bifenthrin residues.

G. Endocrine Disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of bifenthrin in plants and animals is adequately understood. Studies have been conducted to delineate the metabolism of radio labelled bifenthrin in various crops and animals all showing similar results. The residue of concern is the parent compound only.

B. Nature of the Residue

Nature of the residue studies in corn, ruminants and poultry for bifenthrin have been adequately defined. The EPA Health Effect Division (HED) Metabolism Committee concluded that only the parent compound should appear in the tolerance expression for corn grain, forage, fodder, ruminant, and poultry commodities. No special concern was expressed about the principal metabolite in corn, 4′-hydroxy bifenthrin. The metabolite typically is found in corn forage or fodder at about 1/10 the concentration of parent and is also a rat metabolite of bifenthrin. Similarly, no concern was raised over biphenyl alcohol, the only metabolite predicted to be present in ruminant tissue in detectable concentrations. EPA estimated that the maximum concentration of this metabolite in ruminant tissue would be 0.04 ppm in fat. Neither bifenthrin nor its metabolites are likely to be present in poultry and eggs in detectable concentrations.

C. Analytical Enforcement Methodology

An enforcement method Gas Chromatography/Electron Capture Detector (GC/ECD) for the determination of residues of bifenthrin in cottonseed has been sent to the FDA for inclusion in Pesticide Analytical Method II (PAM II). Additionally, EPA has recently concluded that another method (Method P–2550M, GC/ECD large bore fused silica column) is suitable as an enforcement method for the determination of bifenthrin residues in corn matrices.

D. Magnitude of Residues

Crop field trial residue data from studies conducted at the maximum label rates for cotton, corn (field, seed, pop), strawberries, and hops show that the established bifenthrin tolerances on cottonseed of 0.5 ppm, corn, grain (field, seed, and pop) of 0.05 ppm, corn, fodder of 5.0 ppm, corn, forage of 2.0 ppm, strawberries of 3.0 ppm, and hops, dried of 10.0 ppm will not be exceeded when the bifenthrin products labeled for these uses are used as directed.

F. International Residue Limits

Codex Maximum Residue Levels (MRLs) for bifenthrin have been established which are in harmony with the U.S. tolerances for cattle meat (0.5 ppm), corn grain (0.05 ppm), poultry fat (0.05 ppm), poultry meat (0.05 ppm), and poultry meat byproducts (0.05 ppm). Codex MRLs have been established which exceed the U.S. tolerances for horse fat (10.0 vs. 1.0 ppm). Codex MRLs have been established which are below their U.S. counterparts for cattle fat (0.5 vs 1.0 ppm), cattle meat byproducts (0.05 vs. 0.10 ppm), corn forage (0.05 vs. 2.0 ppm), corn fodder (0.2 vs. 5.0 ppm), eggs (0.01 vs.0.05 ppm), and whole milk (0.05 vs. 0.1 ppm).

As indicated above there are differences between the section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods used to establish tolerances, calculate animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

No Canadian MRLs have been established for residues of bifenthrin. Mexico has established a tolerance for residues of bifenthrin on cottonseed (0.5 ppm) which is in harmony with the U.S. tolerance.

IV. Conclusion

Therefore, tolerances are established for bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on cottonseed at 0.5 ppm; corn, grain (field, seed, and pop) at 0.05 ppm; corn, forage at 2.0 ppm; corn, fodder at 5.0 ppm; hops, dried at 10.0 ppm; fat of cattle, goat, hogs, horses, and sheep at 1.0 ppm; meat of cattle, goat, hogs, horses, and sheep at 0.5 ppm; meat and meat by-products (mbyp) of cattle, goat, hogs, horses, and sheep at 0.10 ppm, eggs at 0.05 ppm; milk, fat (reflecting 0.1 ppm in whole milk), poultry, fat at 0.05 ppm, poultry, meat at 0.05 ppm, and poultry mbyp at 0.10 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by

40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300579] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.442 is amended by revising paragraph (a) and removing the entire entry for ''Raspberries'' in the table in paragraph (b) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of bifenthrin (2-methyl [1,1′-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on the raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	1.0
Cattle, mbyp	0.10
Cattle, meat	0.5
Corn, fodder	5.0
Corn, forage	2.0
Corn, grain (field, seed, and pop)	0.05
Cottonseed	0.5
Eggs	0.05
Goats, fat	1.0
Goats, mbyp	0.10
Goats, meat	0.5
Hogs, fat	1.0
Hogs, mbyp	0.10
Hogs, meat	0.5
Hops, dried	10.0
Horses, fat	1.0
Horses, mby	0.10

Commodity	Parts per million
Horses, meat	0.5
Milk, fat (reflecting 0.1 ppm in whole milk)	1.0
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	1.0
Sheep, mbyp	0.1
Sheep, meat	0.5
Strawberries	3.0

* * * * *

[FR Doc. 97–30948 Filed 11–25–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300587; FRL–5757–4]

RIN 2070–AB78

Fipronil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R,S*)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile) and its metabolites MB 46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]4-[(trifloumethyl) sulfonyl]-1*H*-pyrazole-3-carbonitrile) and MB 45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1*H*-pyrazole-3-carbonitrile) in or on field corn grain, stover, and forage; milk fat, (reflecting residues in whole milk); eggs; poultry fat, meat, and meat byproducts; hog fat, meat, meat byproducts, and liver; and liver, fat, meat, and meat byproducts of cattle, goat, horse, and sheep. In petition number 5F4426 Rhone Poulenc AG, Inc. requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170).

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300587], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300587], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300587]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Marion Johnson, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6788, e-mail: johnson.marion@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 1997 (62 FR 33641)(FRL–5723–7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of a pesticide petition for a tolerance (PP 5F4426) by Rhone Poulenc AG Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by Rhone Poulenc, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the insecticide fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R,S*)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile) and its metabolites MB 46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1*H*-pyrazole-3-carbonitrile) and MB 45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1*H*-pyrazole-3-carbonitrile) in or on the following items: corn, field, grain — 0.02 ppm; corn, field, stover — 0.30 ppm; corn, field, forage — 0.15 ppm; Milk, fat (reflecting 0.05 ppm in whole milk) — 1.50 ppm; Liver of cattle, goat, horse and sheep — 0.10 ppm; eggs — 0.03 ppm; Fat of cattle, goat, horse and sheep — 0.40 ppm; poultry fat — 0.05 ppm; meat of cattle, goat, horse and sheep — 0.04 ppm; poultry meat — 0.02 ppm; meat byproducts (except liver) of cattle, goat, horse and sheep — 0.04 ppm; poultry meat byproducts — 0.02 ppm; hog fat — 0.04 ppm; hog liver — 0.02 ppm; hog meat byproducts (except liver) — 0.01 ppm; hog meat — 0.01 ppm.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and

drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop

treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants <1 year old) was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of fipronil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of fipronil (5-amino-1-[2,6- dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R,S*)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile) and its metabolites MB 46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1*H*-pyrazole-3-carbonitrile) and MB 45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1*H*-pyrazole-3-carbonitrile) in or on the following items at the following levels:

Commodity	Tolerance (in parts per million)
Corn, field, grain	0.02
Corn, field, stover	0.30
Corn, field, forage	0.15
Eggs	0.03
Fat of cattle, goat, horse and sheep.	0.40
Hog fat	0.04
Hog liver	0.02
Hog meat byproducts (except liver).	0.01
Hog meat	0.01
Liver of cattle, goat, horse and sheep.	0.10
Milk, fat (reflecting 0.05 ppm in whole milk).	1.50
Meat of cattle, goat, horse and sheep.	0.04
Meat byproducts (except liver) of cattle, goat, horse and sheep.	0.04
Poultry fat	0.05
Poultry meat	0.02
Poultry meat byproducts	0.02

EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicology Data Base

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fipronil are discussed below.

1. *Acute studies.* i. A battery of acceptable acute toxicity studies place technical fipronil in toxicity Categories II and III. It is classified as a non-sensitizer.

ii. An acceptable acute neurotoxicity study in the rat using technical fipronil concluded the following: The no observed effect level (NOEL) was 0.5 mg/kg for males and females. The low observed effect level (LOEL) was 5.0 mg/kg for males and females based on decreased hind leg splay at the 7 hour post-treatment evaluation in males and females.

2. *Subchronic toxicity testing.* i. An acceptable subchronic toxicity study in the dog using technical fipronil concluded the following: The LOEL was 10.0 mg/kg/day for males (based on clinical signs of toxicity) and 2.0 mg/kg/day for females (based on clinical signs of toxicity and decreased body weight gain). The NOEL was 2.0 mg/kg/day for males and 0.5 mg/kg/day for females.

ii. A supplemental subchronic toxicity study in the rat using technical fipronil concluded the following: The LOEL was 30 ppm for males (1.93 mg/kg/day) and females (2.28 mg/kg/day) based on alterations in serum protein values and increased weight of the liver and thyroid. The NOEL was 5 ppm for males (0.33 mg/kg/day) and females (0.37 mg/kg/day).

iii. An acceptable 21–day dermal toxicity study in the rabbit using technical grade fipronil concluded the following: The Systemic LOEL was 10 mg/kg/day based on decreased body weight gain and food consumption; Dermal irritation LOEL > 10.0 mg/kg/day. The systemic NOEL was 5.0 mg/kg/day; Dermal irritation NOEL was greater than or equal to 10.0 mg/kg/day.

3. *Chronic toxicity studies.* i. An acceptable chronic toxicity study in the dog using technical fipronil concluded the following: The LOEL was 2.0 mg/kg/day based on clinical signs of neurotoxicity and abnormal neurological examinations. The NOEL was 0.2 mg/kg/day.

ii. An acceptable carcinogenicity study in the mouse using technical fipronil concluded the following: The LOEL was 10 ppm (1.181 mg/kg/day for males and 1.230 mg/kg/day for females) based on decreased body weight gain, decreased food conversion efficiency (males), increased liver weights and increased incidence of hepatic histopathological changes. The NOEL was 0.5 ppm (0.055 mg/kg/day for males and 0.063 mg/kg/day for females). The study demonstrated that Fipronil is not carcinogenic to CD-1 mice when administered at doses of 30 ppm.

iii. An acceptable combined chronic toxicity/carcinogenicity study in the rat using technical fipronil concluded the following: The LOEL was 1.5 ppm for males (0.059 mg/kg/day) and females (0.078 mg/kg/day) based on an increased incidence of clinical signs and alterations in clinical chemistry and thyroid parameters. The NOEL was 0.5 ppm for males (0.019 mg/kg/day) and females (0.025 mg/kg/day). The study demonstrated that fipronil is carcinogenic to rats at doses of 300 ppm in males (12.68 mg/kg/day) and females (16.75 mg/kg/day).

4. *Developmental and reproduction toxicity studies.* i. An acceptable developmental toxicity study in the rat using technical fipronil concluded the following: The maternal toxicity LOEL was 20 mg/kg/day based on reduced body weight gain, increased water consumption, reduced food consumption and reduced food efficiency. The maternal toxicity NOEL was 4 mg/kg/day. The developmental toxicity LOEL was greater than 20 mg/kg/day. The developmental toxicity NOEL was 20 mg/kg/day or higher.

ii. An acceptable developmental toxicity study in the rabbit using technical fipronil concluded the following: The maternal toxicity LOEL was less than or equal to 0.1 mg/kg/day based on reduced body weight gain, reduced food consumption and efficiency. The maternal toxicity NOEL was less than 0.1 mg/kg/day. The developmental toxicity LOEL was greater than 1.0 mg/kg/day. The developmental toxicity NOEL was greater than or equal to 1.0 mg/kg/day.

iii. An acceptable multigeneration reproduction study in the rat using technical fipronil concluded the following: The LOEL for parental (systemic) toxicity was 30 ppm (2.54 mg/kg/day for males and 2.74 mg/kg/day for females) based on increased weight of the thyroid glands and liver in males and females; decreased weight of the pituitary gland in females; and an increased incidence of follicular epithelial hypertrophy in the females. The NOEL for parental (systemic) toxicity was 3 ppm (0.25 mg/kg/day for

males and 0.27 mg/kg/day for females). The LOEL for reproductive toxicity was 300 ppm (26.03 mg/kg/day for males and 28.40 mg/kg/day for females) based on clinical signs of toxicity in the F_1 and F_2 offspring; decreased litter size in the F_1 and F_2 litters; decreased body weights in the F_1 and F_2 litters; decrease in the percentage of F_1 parental animals mating; reduction in fertility index in F_1 parental animals; reduced post-implantation survival and offspring postnatal survivability in the F_2 litters; and delay in physical development in the F_1 and F_2 offspring. The NOEL for reproductive toxicity was 30 ppm (2.54 mg/kg/day for males and 2.74 mg/kg/day for females).

iv. An acceptable developmental neurotoxicity study using technical fipronil concluded as follows: The maternal LOEL was 200 ppm (15 mg/kg/day), based on decreased body weight, body weight gain and food consumption. The maternal NOEL was 10 ppm (0.90 mg/kg/day). The developmental LOEL was 10 ppm (0.9 mg/kg/day), based on statistically significant decrease in group mean pup weights during lactation and significant increase in time of preputial separation in males. The developmental neurotoxicity LOEL was 10 ppm (0.9 mg/kg/day) based on a significant increase in mean motor activity counts in females on Postnatal Day 17. The NOEL for developmental and developmental neurotoxicity is 0.5 ppm (0.05 mg/kg/day). It is noted that developmental neurotoxicity occurred in the absence of maternal toxicity in this study.

5. *Mutagenicity studies*— i. *Studies conducted with fipronil.* a. An acceptable *Salmonella*/mammalian activation gene mutation assaying technical fipronil concluded as follows: fipronil was not mutagenic in 4 strains of S. typhimurium at concentrations up to 500 µg/plate in the presence or absence of S9 activation.

b. An acceptable *in vitro* gene mutation assay in mammalian cells/Chinese hamster V79 cells using technical fipronil concluded as follows: Fipronil was negative for inducing forward gene mutations at the HGPRT locus in cultured Chinese hamster V79 cells at concentrations up to 385.65 µg/ml both with and without S9 activation.

c. An acceptable *in vitro* micronucleus assay in the mouse using technical fipronil concluded as follows: fipronil was not cytotoxic to the target cell. There was, however, no evidence of a clastogenic or aneugenic effect at any dose or at any harvest time.

d. An acceptable cytogenic assay in human lymphocytes using technical fipronil concluded as follows: there was no evidence of a clastogenic effect when human lymphocytes were exposed *in vitro* to fipronil at doses of 75, 150 or 300 µg/ml with and without S9 activation.

ii. *Studies conducted with fipronil metabolite MB 46136.* a. An acceptable *Salmonella*/mammalian activation gene mutation assay using 98.7% pure metabolite showed that the fipronil metabolite was not mutagenic in 4 strains of *S. typhimurium* at concentrations of up to 200 µg/plate without S9 activation and up to 500 µg/plate in the presence of S9 activation.

b. An acceptable cytogenic assay with human lymphocytes using 98.7% pure metabolite showed that there was no evidence of a clastogenic effect when human lymphocytes were exposed *in vitro* to MB 46136 at doses of 75, 150 or 300 µg/ml with and without S9 activation.

6. *Metabolism study*. An acceptable metabolism study in the rat using ^{14}-C Fipronil showed the following: with oral dosing, the rate and extent of absorption appeared similar among all dose groups, but may have been decreased at the high dose. Distribution data showed significant amounts of residual radioactivity in carcass, G.I. tract, liver, adrenals, and abdominal fat at 168 hours post-dose for all rats in all dose groups. Repeated low oral dosing or a single high oral dose resulted in an overall decrease in the amount of residual radioactivity found, but an increase in the amount in abdominal fat, carcass, and adrenals. Feces appeared to be the major route of excretion for fipronil derived radioactivity, where 45–75% of an administered dose was excreted. Excretion in urine was between 5–25%. Increases in the percentages excreted in urine and feces were observed with repeated low oral dosing or a single high dose, while the percentage found in all tissues combined decreased. There were no significant sex-related differences in excretion. Major metabolites in urine included two ring-opened products of the metabolite MB 45897, two oxidation products (MB 46136 and RPA 200766), and parent chemical (MB 46030). In feces, parent MB 46030 was detected as a significant fraction of the sample radioactivity as well as the oxidation products MB 46136 and MB 45950.

7. *Special studies.* i. A supplemental thyroid function study in the rat using technical fipronil showed the following: Four groups of 27 male rats per group were administered either methylcellulose (vehicle control), 10 mg/kg/day fipronil, 200 mg/kg/day propylthiouracil (PTU) or 50 mg/kg/day Noxyflex for 14 days. On Day 15, each animal received Na^{125}I at a dose level of 1 µCi ^{125}I. Six hours later, 9 males per group received either 10 or 25 mg/kg potassium perchlorate or 0.9% saline solution. The treatment with fipronil or Noxyflex appeared to result in stimulation of the thyroid glands as evidenced by increased accumulation of ^{125}I in the thyroid glands and by increases in the ratios of radioactive distribution between the blood and thyroid. These changes were accompanied by increases in thyroid weight. Treatment with PTU produced decreases in the amount of ^{125}I incorporated in the thyroid and in the blood: thyroid ratios along with elevated levels of ^{125}I in the blood. However, the weights of the thyroids from these animals were increased by over 2.5 fold compared to the controls and therefore, the ratio of ^{125}I in the blood to thyroid weight was reduced. The administration of perchlorate produced further reductions in the ^{125}I content in the thyroids and in the blood: thyroid ^{125}I radioactivity ratio. There was no evidence of an inhibition of iodide incorporation by either fipronil or Noxyflex.

ii. A supplemental thyroxine clearance study in the rat using technical fipronil showed the following: Six groups of six male rats per group were administered either fipronil (10 mg/kg/day by gavage), phenobarbital (80 mg/kg/day intraperitoneally) or 0.5% methylcellulose (vehicle control at 5 ml/kg by gavage) for a duration of either 1 day or 14 days. Four hours after the final dose of either test substance, each rat received [^{125}I] thyroxine at a dosage of 10 µCi/kg. Fipronil had no effect on mortality or other ante mortem parameters. Phenobarbital-treated animals were observed to have collapsed posture, lethargy and shallow breathing on the first day of treatment. There was no effect of fipronil on clearance after 1 day of treatment, however after 14 days, there was a decrease in terminal half life (52% of control level) and increases in clearance and volume of distribution (261% and 137% of control level, respectively). The effects seen with phenobarbital treatment were similar, although quantitatively not as severe and were evident on Day 1 of treatment.

iii. An acceptable 28–day study in the rat by dietary administration using 96.2% pure fipronil metabolite RPA 200766 showed the following: The NOEL was 50 ppm (3.80 mg/kg/day for males and 4.44 mg/kg/day for females). The LOEL was 500 ppm (38.16 mg/kg/day for males and 43.97 mg/kg/day for females) based on decreased

hemoglobin values, increased cholesterol values and increased liver weights in both sexes.

iv. An acceptable 28–Day Study in the rat using technical fipronil showed that: the LOEL is ≤ 25 ppm (3.4 mg/kg/day in males; 3.5 mg/kg/day in females) based on clinical laboratory changes, increased absolute liver weights in females and histopathological alterations in the thyroid glands. The NOEL is < 25 ppm.

B. Toxicology Profile

The toxicology endpoints and dose levels of concern have been identified for use in this fipronil exposure and risk assessment as set forth below:

1. *Residential exposure—i. Short - and intermediate - term exposure (1 to 7 days).* a. A dermal absorption factor is set at less than 1% at 24 hours based on a dermal absorption study.

b. For short- and intermediate-term residential exposure for females age 13+ years, the NOEL is 5 mg/kg/day based on decreased body weight gain and food consumption in male and female rabbits observed at the LOEL of 10 mg/kg/day in the 21–day dermal study.

In the supporting study of developmental toxicity and developmental neurotoxicity, the developmental NOEL was 0.5 ppm (0.05 mg/kg/day) based on decreased mean pup weights during lactation and a significant increase in time to preputial separation in male rats observed at the developmental LOEL of 10 ppm (0.9 mg/kg/day). The developmental neurotoxicity LOEL was 10 ppm (0.9 mg/kg/day) based on an increase in mean motor activity counts for females on Postnatal Day 17.

It should be noted that the NOEL established after dermal administration in the 21–day dermal toxicity study is 5 mg/kg/day. When the co-critical study NOEL based on oral administration in the developmental neurotoxicity study, 0.05 mg/kg/day is corrected for the less than 1% dermal absorption, exposure is essentially the same as the critical study (5 mg/kg/day).

c. For short- and intermediate-term residential exposure for the general population, including infants and kids, the NOEL is 5.0 mg/kg/day, based on decreased body weight gain and food consumption in male and female rabbits observed at the LOEL of 10 mg/kg/day in the 21–day dermal toxicity study.

ii. *Chronic or residential exposure (several months to lifetime).* The NOEL is 0.5 ppm, based on an increased incidence of clinical signs (seizures and death) and alterations in clinical chemistry (protein) and thyroid parameters (increased TSH, decreased T4) at the LOEL of 1.5 ppm in a combined chronic toxicity/carcinogenicity study in the rat. Since the NOEL identified is from an oral study, a dermal absorption factor of < 1% should be used in risk calculations.

2. *Dietary exposure*—i. *Acute risk* . The NOEL is 0.5 mg/kg, based on decreased hind leg splay in male and female rats observed at LOEL = 5 mg/kg in the acute neurotoxicity study in rats.

ii. *Chronic risk.* The RfD (reference dose) for fipronil is 0.0002 mg/kg/day. This RfD is based on a NOEL of 0.019 mg/kg/day and an uncertainty factor of 100; the NOEL was established from the combined chronic toxicity/carcinogenicity study in rats where the LOEL was 1.5 ppm, based on an increased incidence of clinical signs (seizures and death) and alterations in clinical chemistry (protein) and thyroid parameters (increased TSH, decreased T4).

iii. *Cancer risk*. Fipronil has been classified as a Group C - Possible Human Carcinogen, based on increases in thyroid follicular cell tumors in both sexes of the rat, which were statistically significant by both pair-wise and trend analyses. The RfD methodology should be used to estimate human risk because the thyroid tumors appear to be related to a disruption in the thyroid-pituitary status. There was no apparent concern for mutagenicity (no mutagenic activity).

B. Exposures and Risks

1. *From food and feed uses*. In today's action, tolerances will be established (40 CFR 180.517) in or on a variety of raw agricultural commodities as follows:

Commodity	Tolerance (in parts per million)
Corn, field, grain	0.02
Corn, field, stover	0.30
Corn, field, forage	0.15
Eggs	0.03
Fat of cattle, goat, horse and sheep.	0.40
Hog Fat	0.04
Hog Liver	0.02
Hog Meat Byproducts (except liver).	0.01
Hog Meat	0.01
Liver of cattle, goat, horse and sheep.	0.10
Milk, fat (reflecting 0.05 ppm in whole milk).	1.50
Meat of cattle, goat, horse and sheep.	0.04
Poultry Fat	0.05
Poultry Meat	0.02
Meat Byproducts (except liver) of cattle, goat, horse and sheep.	0.04
Poultry Meat Byproducts	0.02

Risk assessments were conducted by EPA to assess dietary exposures and risks from fipronil as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The acute dietary exposure endpoint of concern for fipronil is neurotoxicological. As this endpoint is not developmental, all population subgroups are of potential concern. EPA calculated MOE values of 277 for the U.S. population, 167 for non-nursing infants (< 1 year old) and 167 for children (1–6 years years old). Anticipated residues were used for milk and corn commodities in this assessment.

ii. *Chronic exposure and risk.* Chronic dietary residues exposure estimates (DRES) for fipronil were calculated using anticipated residues derived from field-trial data for all commodities. In addition, an anticipated market share of 7% was used for corn grain, forage, and stover. The proposed fipronil tolerances result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percents of the RfD:

U.S. Population (48 States)	4.6%
Hispanics	5.9%
Non-Hispanic Others	5.2%
Non-Nursing Infants (< 1 year old).	10.1%
Females (13+ years, pregnant)	3.2%
Females (20+ years, not pregnant, not nursing).	3.0%
Females (13+ years, nursing)	4.1%
Children (1–6 years old)	11.1%
Children (7–12 years old)	7.4%

The subgroups listed above are: (1) the U.S. population (48 states); (2) infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is equal to, or greater than, that occupied by the subgroup U.S. population (48 states).

iii. *Percent crop treated and anticipated residues.* Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a timeframe it deems appropriate. Section 408(b)(2)(F) allows the Agency to use data on the actual

percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

a. That the data used are reliable and provide a valid a basis for showing the percentage of food derived from a crop that is likely to contain residues.

b. That the exposure estimate does not underestimate the exposure for any significant subpopulation.

c. Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for fipronil were derived from Federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To provide for the periodic evaluation of these estimates of percent crop treated and to meet the requirement for data on anticipated residues, EPA may require fipronil registrants to submit data on percent crop treated. Such evaluation will likely be conducted no sooner than 5 years after date of issuance of this tolerance. Further, as required by the FQPA, EPA will issue a Data Call-In under section 408(f) to all fipronil registrants for data on anticipated residues, to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *From drinking water.* EPA does not have monitoring data available to perform a quantitative drinking water risk assessment for fipronil at this time. EPA estimated ground and surface water exposure using the Generic Expected Environmental Concentration (GENEEC) model, a screening level model for determining concentrations of pesticides in surface water. GENEEC uses the soil/water partition coefficient, hydrolysis half life, and maximum label rate to estimate surface water concentration. In addition, the model contains a number of conservative underlying assumptions. Therefore, the drinking water concentrations derived from GENEEC for surface water are likely to be overestimated. As fipronil is relatively immobile in soil, residues in groundwater are expected to be less than those in surface water.

i. *Acute exposure and risk.* The exposure estimate for surface water is 247 ppt (peak concentration). Based on an acute NOEL of 0.5 mg/kg/day and water consumption of 1 L/d for a 10 kg child, the worst-case estimates of residues in drinking water (247 ppt) result in a child exposure of 2.5×10^{-5} mg/kg/day. This exposure value corresponds to a MOE of 20,000 for the most highly exposed subgroup for acute exposure (children 1–6 years old). As this value exceeds 100, fipronil residues in surface drinking water do not pose an acute risk.

ii. *Chronic exposure and risk.* The exposure estimate for surface water is 48.8 ppt (54–day average). Based on a RfD of 0.0002 $(mg/kg/day)^{-1}$ and water consumption of 2 L/d for a 70 kg adult (male) and of 1 L/d for a 10 kg child (1–6 years old), the worst-case estimates of residues in drinking water (48.8 parts per trillion (ppt)) result in the following exposures: Adult exposure is 1.4×10^{-6} mg/kg/day and exposure for children is 4.9×10^{-6} mg/kg/day. These exposure values correspond to 0.7% of the RfD for adult males and 2.4% of the RfD for children (1–6 years old).

3. *From non-dietary exposure.* Fipronil is currently registered for use on the following residential non-food sites: ant and cockroach bait traps ranging from 0.01 to 0.05% active ingredient; and flea and tick control products for dogs and cats, including a pump spray (0.29% RTU (ready to use) and a 9.7% RTU spot treatment in which a premeasured small amount is applied between the pet's shoulder blades. The flea and tick spray use is expected to result in the highest exposure of fipronil products. Based on the high MOE's resulting from these uses (see below), the application of small amounts between the pet's shoulder blades was not addressed. This use is expected to result in much lower exposure based on lower duration and a considerably smaller area being treated. Exposure from the use of fipronil in self contained bait stations is also expected to result in lower exposures since there is no contact with the pesticide.

i. *Acute exposure and risk.* For incidental non-dietary (acute) exposures, the endpoint selected for acute dietary (oral) assessments is used. The NOEL is 0.5 mg/kg/day. The MOE for a child/hand-to-mouth exposure after petting a wet or recently treated pet is 5,000 to 8,000.

ii. *Chronic exposure and risk.* Fipronil is reportedly strongly bound to the skin and does not come off the dog once dry. Therefore, the use of fipronil products in residential situations is not expected to result in chronic exposures. It should be noted that an exposure study assessing exposures resulting from the pet uses will be submitted in the fall of 1997. The risk assessment may be refined at that time.

iii. *Short- and intermediate-term exposure and risk.* Label directions on pet care products state that applications of fipronil are expected to occur several times per year in residential settings, resulting in acute and short- and intermediate-term exposures. The endpoint selected for short and intermediate-term non-occupational exposure assessments is based on the results of a 21–day dermal toxicity study. The systemic toxicity NOEL is 5.0 mg/kg/day. The MOE for applicators of the 0.29% ready-to-use formulation on dogs and cats is 50,000. The MOE for a child/dermal contact with a wet or recently treated pet is 1,000 to 2,000.

iv. *Cumulative exposure to substances with common mechanism of toxicity.* Fipronil is structurally similar to other members of the pyrazole class of pesticides (i.e., tebufenpyrad, pyrazolynate, benzofenap, etc.). Further, other pesticides may have common toxicity endpoints with fipronil. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific

understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether fipronil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative approach based on a common mechanism of toxicity, fipronil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fipronil has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* For the most highly exposed subgroup (children 1–6 years old), the calculated MOE value is 160 (the reciprocal of the sum of the reciprocal food, residential and water MOEs). (The MOE is 167 for food, 5,000 for residential (oral) and 20,000 for water). This aggregate MOE does not exceed the HED's level of concern for acute dietary exposure.

2. *Chronic risk.* Based on the available data and assumptions for dietary/water/residential exposure and risk estimates, the population group estimated to be most highly exposed is children (1–6 years old) with a risk estimate from combined sources equaling 13.5% of the RfD (11.1% dietary + 2.4% water). As previously noted, no chronic residential exposure is anticipated. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fipronil residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure should take into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. However, the short and intermediate term end points for fipronil are based on dermal exposure, and chronic endpoints are based on dietary exposure. The two exposure scenarios use different toxicological end points, and thus are not comparable in toxicological terms. At the present time, EPA does not know how to aggregate dermal and oral exposures for this chemical. For this reason, EPA has not developed a short and intermediate term risk assessment for fipronil. Further, as indicated above, when viewed independently, neither oral nor dermal exposure posed a risk of concern.

E. Aggregate Cancer Risk for U.S. Population

Based on the Cancer Peer Review Committee recommendation that the RfD approach be used to quantify carcinogenicity, a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of fipronil residues are adequately addressed by the chronic exposure analysis using the RfD.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children— i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of fipronil, EPA considered data from developmental toxicity studies in the rat and rabbit, a two-generation reproduction study in the rat, and a developmental neurotoxicity study. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. The developmental neurotoxicity study provided further information about the acute and chronic neurotoxic effects during prenatal and postnatal development.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

2. *FQPA considerations.* EPA has evaluated the chemical fipronil for FQPA considerations. The following discussion represents the information EPA considered.

i. *Developmental toxicity studies.* Acceptable prenatal developmental toxicity studies in rats and rabbits have been submitted to the Agency, meeting basic data requirements, as defined for a food-use chemical by 40 CFR part 158.

ii. *Reproductive toxicity study.* An acceptable two-generation reproduction study in rats has been submitted to the Agency, meeting basic data requirements, as defined for a food-use chemical by 40 CFR part 158.

iii. Developmental neurotoxicity study. An acceptable developmental neurotoxicity study was conducted with fipronil and reviewed by the Agency.

iv. Pre- and post-natal sensitivity. There are no data gaps for the assessment of the effects of fipronil on developing animals following *in utero* and/or early postnatal exposure.

v. *Conclusion.* The available data contained evidence of increased sensitivity of rats to alterations in functional development following pre- and/or postnatal exposure with fipronil. Specifically, in a developmental neurotoxicity study in rats, the developmental and developmental-neurotoxicity NOEL of 0.5 ppm (0.05 mg/kg/day) was lower than the maternal toxicity NOEL of 10 ppm (0.9 mg/kg/day). In the offspring, decreased pup weights, increased time of preputial separation in males, and increased

motor activity counts in female pups were observed at the developmental LOEL of 10 ppm (0.9 mg/kg/day), while maternal toxicity (decreased body weight, body weight gain, and food consumption) was observed at the maternal LOEL of 200 ppm (15 mg/kg/day).

Previously conducted studies with fipronil did not identify any issues of increased sensitivity in the fetuses or pups following pre- and/or postnatal exposure. In the prenatal developmental toxicity study in rats, there was no evidence of developmental toxicity at the highest doses tested (20 mg/kg/day). Maternal toxicity (decreased body weight gain, food consumption and/or water consumption) was observed at this dose (20 mg/kg/day) with the maternal NOEL established at 4 mg/kg/day. In the prenatal developmental toxicity study in rabbits, there was also no evidence of developmental toxicity at the highest doses tested (1.0 mg/kg/day). Maternal toxicity (decreased body weight gain, food consumption and/or water consumption) was observed at this same dose (1.0 mg/kg/day) and lower, with the maternal NOEL established at < 0.1 mg/kg/day.

Additionally, in the two-generation reproduction study in rats, offspring toxicity was observed only in the presence of parental toxicity. The offspring NOEL was 30 ppm (2.54–2.74 mg/kg/day), based upon clinical signs of toxicity, decreased litter size, decreased body weights, decreased pre- and postnatal survival, and delays in physical development at the LOEL of 300 ppm (26.0–28.4 mg/kg/day). In the parental animals, reproductive toxicity (reductions in mating and fertility) was also observed at the 30 ppm dietary level. The systemic NOEL for the parental animals was 3 ppm (0.25–0.27 mg/kg/day), based upon increased weight of the thyroid gland and liver in both sexes, decreased weight of the pituitary gland in the females, and increased incidence of thyroid follicular epithelial hypertrophy in the females at the LOEL of 30 ppm.

In considering whether additional uncertainty factors were needed to protect children, EPA noted that the developmental neurotoxicity NOEL of 0.05 mg/kg/day, when adjusted for 1% dermal absorption, yields an equivalent NOEL of 5 mg/kg/day, the value established as the systemic NOEL in the 21–day dermal study in rabbits. This value was selected for use in the short term and intermediate risk assessment calculations for fipronil. The NOEL used for the RfD calculation was 0.019 mg/kg/day from the combined chronic toxicity-carcinogenicity study in the rat, a value that is even lower than the NOEL used for short- and intermediate-term exposure. Therefore, it was concluded that the risk assessment calculations as defined, will provide adequate protection for sensitive subpopulations, including infants and children. The Committee determined that the third uncertainty factor in the risk assessment of fipronil, under the provisions of the FQPA mandate to ensure the protection of infants and children, was not warranted for chronic or less than life time exposure and could be removed.

EPA believes that reliable data support using the hundredfold margin/factor, rather than the thousandfold margin/factor, when EPA has a complete data base under existing guidelines, and when the severity of the effect in infants or children, the potency or unusual toxic properties of a compound, or the quality of the exposure data do not raise concerns regarding the adequacy of the tenfold margin/factor.

For the reasons outlined above, EPA has determined there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues of fipronil following its use on field corn and other uses registered to date.

III. Other Considerations

A. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inert ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

B. Metabolism In Plants and Animals

EPA considers the nature of the residue in corn to be understood. Fipronil is metabolized by: (1) hydrolysis to the amide (RPA 200766) with further hydrolysis to the carboxylic acid (RPA 200761) or (2) oxidation to the sulfone MB 46136. The EPA Metabolism Committee has concluded that the residues of concern for the tolerance expression and dietary risk assessment in corn and animal RACs are fipronil, MB 46136, and MB 45950.

C. Analytical Enforcement Methodology

Analytical methodology suitable for the enforcement of the proposed tolerance is available. For corn RACs, the registrant has submitted a proposed analytical enforcement method which measures the parent and its metabolites (MB 45950, and MB 46136) in a single chromatographic separation using GC with ECD. The limit of quantitation (LOQ) for each compound is 0.01 ppm in grain and 0.02 ppm in forage and fodder. This method has undergone a successful Petition Method Validation (PMV).

For animal RACs, the registrant has submitted a proposed analytical enforcement method which measures the parent and its metabolites (MB 45950 and MB 46136) in a single chromatographic separation using GC with ECD. The LOQ of cattle, goat, horse and sheep for each compound is < 0.02 ppm. This method has also undergone a successful PMV.

D. Magnitude of Residues

As a result of this use, residues of fipronil are not expected to exceed the following levels:

corn, field, grain	0.02 ppm
corn, field, stover	0.30 ppm
corn, field, forage	0.15 ppm

Secondary residues in animal commodities from this proposed use on corn are not expected to exceed the following levels:

Eggs	0.03 ppm
Fat of cattle, goat, horse and sheep	0.40 ppm
Hog Fat	0.04 ppm
Hog Liver	0.02 ppm
Hog Meat Byproducts (except liver)	0.01 ppm
Hog Meat	0.01 ppm
Milk, fat (reflecting 0.05 ppm in whole milk)	1.50 ppm
Liver of cattle, goat, horse and sheep	0.10 ppm
Meat Byproducts (except liver) of cattle, goat, horse and sheep	0.04 ppm
Meat of cattle, goat, horse and sheep	0.04 ppm
Poultry Fat	0.05 ppm
Poultry Meat	0.02 ppm
Poultry Meat Byproducts	0.02 ppm

E. International Residue Limits

There are no CODEX, Canadian, or Mexican MRLs established for fipronil

in/on corn and animal RACs. Therefore, no compatibility problems exist.

F. Rotational Crop Restrictions

The rotational crop restrictions specified on the labels (1 month for leafy vegetables, 5 months for root crops, 12 months for small grains and all other crops) are supported by the results of the confined rotational crop study.

IV. Conclusion

Therefore, the tolerance is established for combined residues of the insecticide fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R,S*)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile) and its metabolites MB 46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1*H*-pyrazole-3-carbonitrile) and MB 45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1*H*-pyrazole-3-carbonitrile) in or on the following items at the levels specified:

Commodity	Tolerances (in parts per million)
Corn, field, grain	0.02
Corn, field, stover	0.30
Corn, field, forage	0.15
Eggs	0.03
Fat of cattle, goat, horse and sheep	0.40
Hog fat	0.04
Hog liver	0.02
Hog meat byproducts (except liver)	0.01
Hog meat	0.01
Liver of cattle, goat, horse and sheep	0.10
Meat byproducts (except liver) of cattle, goat, horse and sheep	0.04
Meat of cattle, goat, horse and sheep	0.04
Milk, fat (reflecting 0.05 ppm in whole milk)	1.50
Poultry fat	0.05
Poultry meat	0.02
Poultry meat byproducts	0.02

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300587] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section

408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority : 21 U.S.C. 346a and 371.

2. By adding a new § 180.517 to read as follows:

§ 180.517 Fipronil; tolerances for residues.

(a) *General.* Therefore, tolerances are established for combined residues of the insecticide fipronil, (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1*R,S*)-(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile) and its metabolites 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1*H*-pyrazole-3-carbonitrile and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl) phenyl]-4-[(trifluoromethyl)thio]-1*H*-pyrazole-3-carbonitrile in or on the following items at the levels specified:

Commodity	Parts per million
Corn, field, grain	0.02
Corn, field, stover	0.30
Corn, field, forage	0.15
Eggs	0.03
Fat of cattle, goat, horse and sheep	0.40
Hog Fat	0.04
Hog Liver	0.02
Hog Meat	0.01
Hog Meat Byproducts (except liver)	0.01
Liver of cattle, goat, horse and sheep.	0.10
Milk, fat (reflecting 0.05 ppm in whole milk).	1.50
Meat Byproducts (except liver) of cattle, goat, horse and sheep.	0.04
Meat of cattle, goat, horse and sheep.	0.04
Poultry Fat	0.05
Poultry Meat	0.02
Poultry Meat Byproducts	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–30949 Filed 11–25–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300569; FRL–5751–1]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of tebufenozide in or on sugarcane. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on sugarcane. This regulation establishes a maximum permissible level for residues of tebufenozide in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and be revoked on December 31, 1998.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300569], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300569], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300569]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing request on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing

a tolerance for residues of the insecticide tebufenozide, in or on sugarcane at 0.3 part per million (ppm). This tolerance will expire and be revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Tebufenozide on Sugarcane and FFDCA Tolerances

On March 27, 1997, EPA received a request from the Louisiana Department of Agriculture and Forestry, requesting that EPA authorize emergency use of tebufenozide (Confirm 2F Agricultural Insecticide, EPA Registration No. 707–238, registered by Rohm and Haas Co.) on sugarcane to control sugarcane borer, under provisions of section 18 of FIFRA. Louisiana's request for this pesticide use asserted that the population of sugarcane borer has chronically attained levels that can inflict significant damage to the sugarcane crop. In the past the preferred method of control had been with the chemical azinphos-methyl. However, due to large-scale fish kills which have resulted from use of azinphos-methyl, EPA has restricted that chemical's use. Although Louisiana describes their efforts to develop an integrated pest management program to control sugarcane borer, they still require use of chemicals for this program to succeed. The state requested use of tebufenozide on up to 60,000 acres of sugarcane, at application rates of 0.12 lbs. active ingredient per acre, per application, with a maximum of two applications allowed during the use season of June 15 - September 15, 1997. This use was also requested and authorized by EPA during the growing season of 1996. EPA allowed the Louisiana Department of Agriculture and Forestry to exercise its authority to authorize the use of tebufenozide on sugarcane for control of sugarcane borer in Louisiana under crisis provisions of section 18, described in 40 CFR 166.40–160.53, on June 13, 1997.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebufenozide in or on sugarcane. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and be revoked on December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sugarcane after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether tebufenozide meets EPA's registration requirements for use on sugarcane or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of tebufenozide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Louisiana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebufenozide, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent (%) or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any

significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of tebufenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tebufenozide on sugarcane at 0.3 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tebufenozide are discussed below.

1. *Acute toxicity*. No acute dietary risk endpoint was identified by EPA, and is not of concern in this risk assessment.

2. *Chronic toxicity*. EPA has established the RfD for tebufenozide at 0.018 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 1–year feeding study in dogs with a NOEL of 1.8 mg/kg/day. An uncertainty factor of 100 was used to account for both the interspecies extrapolation and intraspecies variability. The LEL of 8.7 mg/kg/day was based on hematopoietic findings (decreased red blood cells, hematocrit, hemoglobin levels, and increased heinz bodies, MCV, MCH, reticulocytes, and platelets).

3. *Carcinogenicity*. Tebufenozide has been classified as a Group E, ''no evidence of carcinogenicity for humans,'' chemical by EPA.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.482) for the residues of tebufenozide, in or on a variety of raw agricultural commodities. The residue of concern in sugarcane is the parent compound, tebufenozide per se, as specified in 40 CFR 180.482. A permanent tolerance is established for the residues of tebufenozide in/on walnuts at 0.1 ppm and a time-limited tolerance in/on peppers at 0.5 ppm. A permanent tolerance at 1.0 ppm has also previously been established for imported apples. EPA has recently taken actions to establish time-limited tolerances in connection with section 18 uses on domestic apples (and time-limited tolerances on associated animal commodities), on cottonseed at 0.2 ppm, leafy vegetables (except Brassica) at 5.0 ppm, Brassica (cole) leafy vegetables at 5.0 ppm, sugar beets at 0.3 ppm, and turnip tops at 5.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebufenozide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. Since an acute dietary endpoint has not been identified in EPA's toxicology database, an assessment of acute dietary risk was not conducted for this Section 18 request.

ii. *Chronic exposure and risk.* In conducting this exposure assessment, EPA has made very conservative assumptions -- 100% of sugarcane and all other commodities having tebufenozide tolerances will contain tebufenozide residues and those residues would be at the level of the tolerance -- which result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment. The existing tebufenozide tolerances (published, pending, and including the necessary section 18 tolerances) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Population Subgroup	$TMRC_{food}$ (mg/kg/day)	%RfD
U.S. Population - 48 States	0.005516	31%
Nursing Infants (<1 year old)	0.007384	41%
Non-Nursing Infants (<1 year old)	0.014348	80%
Children (1–6 years old)	0.010646	59%
Children (7–12 years old)	0.007595	42%
Non-Hispanic Blacks	0.006063	34%
Non-Hispanic Others	0.007358	41%
Western Region	0.006033	34%

The subgroups listed above are: (1) the U.S. population (48 States); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 States).

For chronic dietary risk to tebufenozide, the population subgroup with the largest percentage of the RfD occupied is non-nursing infants (<1 year old) at 80% of the RfDs.

2. *From drinking water.* Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. There is no established Maximum Contaminant Level (MCL) for residues of tebufenozide in drinking water. No drinking water Health Advisories have been issued for tebufenozide. There is no entry for tebufenozide in the ''Pesticides in Groundwater Database'' (EPA 734–12–92–001, September 1992).

Chronic exposure and risk. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by

a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause tebufenozide to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with tebufenozide in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Tebufenozide is not currently registered for any indoor or outdoor residential uses; therefore, no non-dietary residential exposure is anticipated.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether tebufenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebufenozide has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 31% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is infants or children, which is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to tebufenozide in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Since there are no non-dietary non-occupational exposure scenarios for tebufenozide, there are no additional exposure from those routes. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebufenozide residues.

2. *Short- and intermediate-term risk.* Since there were no toxicity endpoints identified by the TES Committee for tebufenozide and no indoor/outdoor residential uses, no short- or intermediate-term risk assessment was required.

D. Aggregate Cancer Risk for U.S. Population

Since tebufenozide has been classified as a Group E chemical, ''no evidence of carcinogenicity for humans,'' no cancer risk assessment was required.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. This is generally the case -- edit if different studies. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies* — a. *Rats.* In the developmental toxicity study in rats, the maternal (systemic) NOEL was 250 mg/kg/day. The LOEL was 1,000 mg/kg/day, based on decreased body weight and food consumption. The developmental (pup) NOEL was >1,000 mg/kg/day (HDT).

b. *Rabbits.* In the developmental toxicity study in rabbits, the maternal and developmental NOELs were >1,000 mg/kg/day (HDT).

c. *Pre-Natal Sensitivity.* EPA has concluded that the developmental NOELs of >1,000 mg/kg/day (HDT) from the developmental toxicity studies in rats and rabbits demonstrate that there is no developmental (prenatal) toxicity present for tebufenozide. Additionally, these developmental NOELs are greater than 500-fold higher than the NOEL of 1.8 mg/kg/day from the 1-year feeding study in dogs which was the basis of the RfD.

iii. *Reproductive toxicity study — Rats.* In the multigeneration reproductive toxicity study in rats, the parental (systemic) NOEL was 0.85 mg/kg/day. Splenic pigmentation changes and extramedullary hematopoiesis occurred at the LOEL of 12.1 mg/kg/day (male, female; F_0, F_1). In addition to these effects, decreased body weight gain and food consumption occurred at 171.1 mg/kg/day. The reproductive (pup) NOEL was 125 mg/kg/day. The reproductive LOEL of 171.1 mg/kg/day, based on a slight increase in the number of pregnant females that either did not deliver or had difficulty and had to be sacrificed (F_1). Additionally at the LOEL, in F_1 dams, the length of gestation increased and implantation sites decreased significantly. Finally, the number of pups per litter decreased on Lactation Day (LD) 4 to 90% of the controls for the F_1 and on LD's 0 and 4 to 80% for the second generation.

iv. *Pre- and post-natal sensitivity.* In the reproductive toxicity study in rats, the reproductive NOEL (12.1 mg/kg/day) is 14-fold higher than the parental NOEL (0.85 mg/kg/day) and indicates that post-natal toxicity in the reproductive studies occurs only in the presence of significant parental toxicity. These developmental and reproductive studies indicate that tebufenozide does not have additional post-natal sensitivity for infants and children in comparison to other exposed groups.

2. *Chronic risk.* Using the conservative exposure assumptions described above, HED has concluded that the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of tebufenozide ranges from 41% for nursing infants (< 1 year old) up to 80% for non-nursing infants (< 1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to tebufenozide in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebufenozide residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of tebufenozide in/on plants is adequately understood. The residue of concern is the parent compound, tebufenozide per se, as specified in 40 CFR 180.482.

The metabolism of tebufenozide in animals is not adequately understood. However, for the purpose of this section 18 exemption only, EPA considers the residue of concern to be the parent compound, tebufenozide per se.

B. Analytical Enforcement Methodology

The HPLC/UV analytical method, TR 34–94–38 is adequate to detect residues of the parent compound in sugarcane to support this section 18 request. There is also an available extraction and GC/MS confirmatory technique described in the Rohm and Haas rice metabolism study.

There are no analytical methods available to the Agency, at this time, to detect secondary residues in animal matrices likely as a result of the proposed use.

C. Magnitude of Residues

Residues of tebufenozide per se are not expected to exceed the following levels as a result of this section 18 use:

Commodity	Parts per million
sugarcane	0.3

A time-limited tolerance for the residues of tebufenozide per se should be established at this level.

The summation of a sugarcane processing study submitted with this action indicates that residues of tebufenozide do not concentrate in sugarcane refined sugar (0.03x) or molasses (1.1x). Thus, tolerances for the residues of tebufenozide per se are not needed on these commodities. However, the following levels were used for the DRES analysis which EPA performed:

Commodity	Parts per million
sugar, refined	0.01
sugar cane molasses	0.35

Based on the summary data provided, residues of tebufenozide in ruminant commodities (cattle, sheep, horse, and goat) will not exceed the levels established for the use of tebufenozide on apples.

There are no poultry or swine feed items associated with these uses; consequently secondary residues of tebufenozide are not expected in poultry or swine commodities.

D. International Residue Limits

There are currently no CODEX, Canadian, or Mexican listings for tebufenozide residues, therefore there are no harmonization issues for this action.

E. Rotational Crop Restrictions

Sugarcane is not rotated to other crops, therefore a discussion of rotational crop restrictions is not germane to this action.

VI. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in sugarcane at 0.3 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the

grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300567] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 10, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180 — [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority : 21 U.S.C. 346a and 371.

2. In § 180.482(b), by adding alphabetically the following entry to the table:

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
* *	* * *	
Sugarcane	0.03	December 31, 1998
* *	* * *	

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[FR Doc. 97–31100 Filed 11–25–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300568; FRL–5750–9]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl in or on cotton, undelinted seed, and cotton gin byproducts. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cotton in California. This regulation establishes a maximum permissible level for residues of hexythiazox in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and be revoked on October 1, 1998.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300568], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300568], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300568]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of the insecticide hexythiazox (trans-5- (4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl, in or on cotton, undelinted seed at 0.1 part per million; and on cotton gin byproducts at 2.0 part per million (ppm). This tolerance will expire and be revoked on October 1, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the

requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for hexythiazox on Cotton and FFDCA Tolerances

The state of California submitted a request to EPA on April 1, 1997 for a specific exemption from the requirements of FIFRA, allowed under provisions of section 18 of FIFRA, for the emergency use of hexythiazox on cotton to control various spider mites (strawberry spider mite *Tetranychus turkestani*, twospotted spider mite *T. urticae*, Pacific spider mite *T. pacificus*, carmine spider mite *T. cinabarinus*). The state contended that an emergency condition was likely to develop during the 1997 growing season, due to conditions which have developed over the past several years favoring spider mite infestations on cotton. The state's request detailed the lack of effective non-chemical control measures for this pest. Additionally, three of the four mite species have been shown to have developed resistance to alternative registered chemicals. Spider mites attack plants primarily as foliage feeders. This action reduces plant vigor and growth, which can lead to reduced yields and/or nonproductive crops. During the last several years, wetter than normal conditions have resulted in more vegetation outside the irrigated cotton fields. This habitat has supported larger numbers of plant bugs, including mites, which have inflicted increased losses on cotton fields. On May 29, 1997 EPA allowed the state to invoke it's crisis authority under FIFRA section 18 for the use of hexythiazox on cotton for control of spider mites in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of hexythiazox in or on cotton. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and be revoked on October 1, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cotton, undelinted seed, and cotton gin byproducts after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA while these tolerances were in effect. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether hexythiazox meets EPA's registration requirements for use on cotton or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of hexythiazox by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for hexythiazox, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the

carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup nursing and non-nursing infants, <1 year old was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of hexythiazox and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl -4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl on cotton, undelinted seed at 0.1 ppm, and cotton gin byproducts at 2.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by hexythiazox are discussed below.

1. *Acute toxicity.* An acute dietary risk assessment is not required, since EPA did not identify an acute toxicological endpoint.

2. *Short - and intermediate - term toxicity.* For short and intermediate-term Margin of Exposure (MOE) calculations, EPA recommended use of the maternal NOEL of 240 mg/kg/day from the developmental toxicity study in rats. At the LEL of 740 mg/kg/day, there was decreased food consumption, decreased body weight and increased ovarian weights.

3. *Chronic toxicity.* EPA has established the RfD for hexythiazox at 0.025 milligrams/kilogram/day (mg/kg/day). This RfD is based on a one year feeding study in dogs with a NOEL of 2.5 mg/kg/day and an uncertainty factor

of 100. The LOEL of 12.5 mg/kg/day was based on hypertrophy of the adrenal cortex (both sexes).

4. *Carcinogenicity*. Hexythiazox has been classified as a Group C chemical (possible human carcinogen) by the Cancer Peer Review Committee (CPRC), based on an increased incidence of female mouse liver tumors. The Committee recommended using the Q_1* approach. The Q_1* is 0.039 mg/kg/day^{-1}.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.448) for the combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from hexythiazox as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary (food only) risk assessment is not required for this pesticide use, as the EPA did not identify an acute dietary risk endpoint.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made conservative assumptions -- 100% of cotton seed commodities (oil and meal) and apple commodities will contain residues of hexythiazox and its metabolites and those residues will be at the level of the tolerance. Percent crop treated data were utilized for pear commodities. These conservative assumptions result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The published tolerances for the regulated residue of hexythiazox, plus this proposed Section 18 use result in a Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

U.S. Population	<1%
Nursing Infants	<1%
Non-Nursing Infants (<1 year old)	<1%
Children (1–6 years old)	<1%
Children (7–12 years old)	<1%

The subgroups listed above are: (1) the U.S. population (48 states); and (2) those for infants and children.

2. *From drinking water.* Based on information currently available to EPA, hexythiazox is considered persistent in soil. EPA's current data also indicates that hexythiazox and soil metabolites are not likely to leach to groundwater. There are no established Maximum Contaminant Levels for residues of hexythiazox in drinking water. No health advisory levels for hexythiazox in drinking water have been established.

Chronic exposure and risk. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause hexythiazox to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with hexythiazox in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Hexythiazox is not currently registered for use on any residential non-food sites. The Agency does not expect there to be any meaningful non-dietary residential exposure to hexythiazox.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether hexythiazox has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hexythiazox does not appear to produce a toxic metabolite produced by other substances. According to information evaluated related to this action, hexythiazox is a member of the thiazolidinone class of pesticides and there are no other members of this class. For the purposes of this tolerance action, therefore, EPA has not assumed that hexythiazox has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Chronic risk.* Using the conservative exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure (food only) to hexythiazox will utilize <1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to hexythiazox in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to hexythiazox residues.

2. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. EPA believes that uses of hexythiazox may constitute a short- and/or intermediate-term exposure scenario. However, the Agency is not, at this time, able to complete a comprehensive residential risk assessment for many pesticides, including hexythiazox. Because there are no residential non-food uses registered for hexythiazox, and because there are no other chemicals that share its class, and based on the lack of an identified acute toxicological endpoint for hexythiazox, and the low percentage (<1%) of the RfD occupied by food and water, in the best scientific judgment of EPA, short- and intermediate-term aggregate risk will not exceed the Agency's level of concern.

D. Aggregate Cancer Risk for U.S. Population

Based on published tolerances (none are currently pending) and this proposed section 18 use, an upper bound lifetime dietary (food only) cancer risk estimate of 5.9×10^{-7} was calculated for the hexythiazox regulated residue. The calculation used the conservative exposure assumptions described above for generating ARC's and amortized the cancer risk over a 70-year lifetime (i.e., 5/70, for this first year section 18 use). This section 18 use contributes 8.0×10^{-8} to the upper bound lifetime dietary (food only) cancer risk and 5.7×10^{-9} if the cancer risk is amortized over a 70-year lifetime.

The cancer risk estimate for the existing hexythiazox uses plus the amortized risk estimate for cottonseed commodities does not exceed EPA's level of concern. EPA believes the registered uses do not constitute a chronic exposure scenario. Thus, no non-dietary, non-occupational chronic exposure to hexythiazox is expected, or is a factor in aggregate cancer risk.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children.* —i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of hexythiazox, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*— a. *Rats.* In the rat developmental study, the maternal (systemic) NOEL was 240 mg/kg/day. The maternal LOEL of 720 mg/kg/day was based on decreased food consumption and decreased body weight. The developmental (fetal) NOEL was 240 mg/kg/day. The developmental LOEL was based on slight delayed ossification.

b. *Rabbits.* In the rabbit developmental toxicity study, the maternal (systemic) NOEL was 1,080 mg/kg/day at the highest dose tested (HDT). The developmental (fetal) NOEL was 1,080 mg/kg/day at the highest dose tested.

iii. *Reproductive toxicity study. Rats.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL was 20 mg/kg/day. The LOEL of 120 mg/kg/day was based on decreased body weight and decreased food consumption. The developmental NOEL was 20 mg/kg/day. The developmental LOEL of 120 mg/kg/day was based on decreased body weight and delayed maturation. The reproductive NOEL was 120 mg/kg/day at the highest dose tested.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for hexythiazox is complete with respect to current toxicological data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study. In the developmental study in rats, the developmental NOEL and LOEL is the same as the maternal NOEL and LOEL demonstrating that no extra-sensitivity for infants and children is present. In rabbits, there are no maternal or developmental effects up to the limit dose of 1,080 mg/kg/day HDT. In the 2-generation reproductive toxicity study in rats, there are no pup effects at doses below maternal effects and the common effects in both pups and parental animals decreased body weight also demonstrates that there is no extra-sensitivity for infants and children.

v. *Conclusion.* Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor and that an the additional safety factor is not needed to protect the safety of infants and children.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to hexythiazox from food will utilize is less than 1% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to hexythiazox in drinking water and from non-dietary, non-occupational exposure, EPA does not

expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data, the conservative exposure assessment and the fact that residential uses do not fall under a chronic exposure scenario, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to hexythiazox residues.

V. Other Considerations

A. Metabolism In Plants and Animals

1. For the purpose of this section 18 request, the nature of the residue in plants is adequately understood. The residue of concern is hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (as specified in 40 CFR 180.448).

2. Although no livestock commodity tolerances are established, the nature of the residue in animals is considered to be understood. The residue of concern is hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety.

B. Analytical Enforcement Methodology

Adequate methods to enforce the tolerance expression have been submitted for publication in PAM II. The approved method is designated as AMR 985-87 which has been used in a variety of commodities. This method is available in PP 5F3254, and by request from U.S. EPA, IRSD/PIRIB (7502C), 401 M St., SW., Washington DC 20460.

C. Magnitude of Residues

1. Residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent compound) are not expected to exceed 0.10 ppm in/on cotton, undelinted seed. A time-limited tolerance is being established at this level.

2. It is unknown if residues will concentrate in processed products of cotton seed. Therefore, the tolerance level for the RAC has been adjusted to account for any possible concentration of the residue. Additional tolerances on processed products of cotton are not required for this section 18 request.

3. Residue data are not available for cotton gin byproducts. For the purpose of this section 18 request, EPA has estimated residue levels in cotton gin byproducts. A search by EPA of the data currently available indicates two chemicals for which tolerances are established on both cotton gin byproducts and cotton seed. One use is for an at-planting use of an insecticide. The other cotton seed/cotton gin byproducts tolerance pair, 6 ppm and 100 ppm respectively, was established for a preharvest desiccant use of a herbicide. Since this preharvest desiccant use would be considered a worst case scenario, the hexythiazox residues on cotton gin byproducts will be estimated based on the concentration factor from that use, $16.6 \times (100/6)$. Thus, EPA estimates that the residue level of hexythiazox on cotton gin byproducts will be 2 ppm. A time-limited tolerance is being established at 2 ppm for hexythiazox residues in/on cotton gin byproducts. EPA notes that residue data for hexythiazox in/on cotton gin byproducts will be required for a section 3 registration decision to be made.

4. Tolerances for secondary residues of hexythiazox in livestock commodities are not established. Livestock feedstuffs for cattle (dairy and beef), poultry (discussed below)and swine are derived from cotton (meal,seed, and hulls). The maximum dietary burden from established tolerances on apples and this time-limited tolerance are 0.53 ppm for beef cattle, and 0.51 ppm for dairy cattle. EPA has previously reviewed a hexythiazox feeding study in dairy cows, in which the only measurable residues were in kidney and liver. For the purpose of this time-limited tolerance, EPA has translated these data to swine commodities. Based upon available data, EPA would not expect detectable residues of hexythiazox and its metabolites in commodities derived from cattle (beef and dairy), and swine.

5. Poultry feedstuffs are derived from cotton (cotton seed meal). Data concerning the potential for secondary residues in poultry are available. The maximum dietary burden from poultry, resulting from use associated with this time-limited tolerance is 0.02 ppm. Hexythiazox tolerances are not established on other poultry feed items. Based upon the total radioactive residue levels from the poultry metabolism study, tolerances for secondary residues of hexythiazox in poultry commodities are not required for this section 18 request.

D. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits established for hexythiazox and its metabolites on cotton seed. Thus, harmonization is not an issue for this time-limited tolerance.

E. Rotational Crop Restrictions

As hexythiazox is not registered for use on crops that are typically rotated, rotational crop data are not available and rotation crop restrictions are not present on the hexythiazox label. Therefore, EPA cannot determine the potential for uptake of residues into crops that may be rotated into hexythiazox treated fields. In the absence of data, the following rotational crop restriction has been added to the section 18 product label: ''In order to avoid illegal residues, do not rotate treated fields to crops, other than cotton, for one year following application of hexythiazox. After one year following application of Hexythiazox, any crops may be rotated into treated fields.''

VI. Conclusion

Therefore, the tolerance is established for combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl in cotton, undelinted seed at 0.1 ppm, and on cotton gin byproducts at 2.0 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A

request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300568] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300568]. Electronic comments on this rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since this tolerance does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 29, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180 — [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.448 is amended as follows:

i. By designating the existing text as paragraph (a) and adding a heading.

ii. Adding paragraph (b) with a heading.

iii. Paragraphs (c) and (d) are added and reserved with headings.

§ 180.448 Hexythiazox; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the insecticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
cotton seed, undelinted	0.1	10/1/98
cotton gin byproducts	2.0	10/1/98

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–31104 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300584; FRL–5756–2]

RIN 2070–AB78

Deltamethrin and Tralomethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of deltamethrin and tralomethrin in or on: deltamethrin--cottonseed at 0.04 parts per million (ppm) and cottonseed oil at 0.2 ppm; and tralomethrin--broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm. It also removes time limitations for tolerances for residues of deltamethrin and tralomethrin on the same commodities that expire on November 15, 1997. AgrEvo USA Company requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104-170). These tolerances were established under petition numbers PP 2F4055, PP 6F3436, PP 4F2993, and PP 6F3309.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300584, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP–300584, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300584. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: John Hebert, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–3068, e-mail: hebert.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On August 16, 1995 and September 15, 1985, EPA established time limited tolerances under section 408 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of deltamethrin (60 FR 42455) (FRL–4966–3) and tralomethrin (50 FR 37851) respectively, on cottonseed. These tolerances expire on November 15, 1997. AgrEvo USA Company, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticides deltamethrin on cottonseed at 0.04 ppm and cottonseed oil at 0.2 ppm; and tralomethrin on broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm, be removed based on ecological and environmental effects data that they had submitted as a condition of the registration and time-limited tolerances. AgrEvo USA Company also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170). In the **Federal Register** of September 25, 1997 (62 FR 50337) (FRL–5848–2), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for a tolerance by AgrEvo USA Company. This notice included a summary of the petition prepared by AgrEvo USA Company (acting as registered US agent for Hoechst Schering AgrEvo, S. A., Little Falls Centre, 2711 Centerville Road, Wilmington, DE 19808, the registrant. There were no comments received in response to the notice of filing.

The basis for time limited tolerances that expire November 15, 1997, was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

Deltamethrin and tralomethrin are being combined for analysis under FQPA because tralomethrin is rapidly metabolized by animals to deltamethrin as a result of debromination. Results of the rat metabolism study supports this action.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes

exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects*. For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration*. The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and

children. The TMRC is a ''worst-case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants <1 year old) was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of deltamethrin and tralomethrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), to remove the time limitation for a tolerances for residues of deltamethrin--cottonseed at 0.04 ppm and cottonseed oil at 0.2 ppm; and tralomethrin--broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by deltamethrin and tralomethrin are discussed below.

Deltamethrin

1. A battery of acute toxicity studies places technical deltamethrin in Toxicity Category III for acute dermal (LD_{50} > 2,000 milligrams/kilograms (mg/kg)), acute inhalation (LC_{50} = 2.2 mg/l) and primary eye irritation; Category IV for acute oral (LD_{50} > 5,000 mg/kg) and primary dermal (non-irritating). Deltamethrin is a non-sensitizer. The NOEL for acute delayed neurotoxicity is greater than 5,000 mg/kg.

2. In a subchronic oral toxicity study deltamethrin was administered to 20 Sprague-Dawley rats/sex/dose in polyethylene glycol 200 by gavage at dose levels of 0, 0.1, 1.0, 2.5, or 10.0 milligrams/kilograms/day (mg/kg/day) for 13 weeks. The lowest observed effect level (LOEL) for males is 2.5 mg/kg/day, based on depressed body weights and body weight gains. The LOEL for females is 10 mg/kg/day, based on some hypersensitivity observed during neurotoxicity testing. The NOEL for males and females is 1.0 and 2.5 mg/kg/day, respectively. This subchronic oral toxicity study in rats is classified as core minimum.

3. In a subchronic oral toxicity study deltamethrin was administered to 3-5 beagle dogs/sex/dose in polyethylene glycol in gelatine capsules at dose levels of 0, 0.1, 1.0, 2.5, or 10 mg/kg/day for 13 weeks. The LOEL is 2.5 mg/kg/day, based on gastro-intestinal disturbance and stimulation of the nervous system as noted in the clinical signs of toxicity for both sexes. The NOEL is 1.0 mg/kg/day. This subchronic oral toxicity study in dogs is classified as core minimum. A NOEL of 1.0 mg/kg/day is supported. At higher levels stimulation of the nervous system is noted (the LOEL is set at 2.5 mg/kg/day, but effects were more definite at 10 mg/kg/day).

4. In a 21–day subchronic dermal toxicity study five Sprague-Dawley rats/sex/dose were dermally exposed to 6 ml/kg of deltamethrin for 6 hours/day at dose levels of 0, 100, 300, or 1,000 mg/kg/day (limit test). The LOEL for males is 300 mg/kg/day, based on slightly decreased body weight gain supported by marginally decreased food consumption. The NOEL for males is 100 mg/kg/day. The LOEL for females was not observed. The NOEL for females is >1,000 mg/kg/day (limit dose).

5. In a 3-week inhalation toxicity study deltamethrin was administered to eight CD rats/sex/dose at concentrations of 0.003, 0.0096, or 0.0563 mg/l for 6 hours/day for 5 days/week (14 exposures total). The LOEL is 0.0096 mg/l, based on signs of irritation (nerve stimulation) and reduced body weight gains in males and elevated Na+ levels in both males and females. The NOEL is 0.003 mg/l.

6. In a chronic toxicity study deltamethrin was administered to eight beagle dogs/sex/dose in the diet at dose levels of 0, 0.026, 0.261, or 1.134 mg/kg/day for males and 0, 0.024, 0.271, or 1.061 mg/kg/day for females for 24 months. The NOEL is ≥40 ppm (equivalent to 1.134 mg/kg/day for males and 1.061 mg/kg/day for females). A LOEL was not observed. Sufficient data to support a NOEL of >40 ppm have been generated.

7. In a chronic toxicity study deltamethrin was administered to 80 Charles River CD-1 mice/sex/dose in the diet at dose levels of 0, 0.12, 0.61, 3.1, or 12 mg/kg/day for males and 0, 0.15, 0.76, 3.8, or 15 mg/kg/day for females. The NOEL is ≥12 mg/kg/day for males or ≥15 mg/kg/day for females. A LOEL was not observed.

8. In a chronic toxicity study deltamethrin was administered to 90 Charles River CD rats/sex/dose in the diet at dose levels of 0, 0.1, 1.0, or 2.5 mg/kg/day. The LOEL is 2.5 mg/kg/day based on decreased body weight gains noted in both sexes. The NOEL is 1.0 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

9. In a developmental toxicity study deltamethrin was administered to 16 New Zealand White rabbits/dose in 0.5% carboxymethylcellulose by gavage at dose levels of 0, 10, 25, or 100 mg/kg/day from days 7 through 19 of gestation. The maternal LOEL is 25 mg/kg/day, based on treatment-related clinical findings (decreased defecation). The maternal NOEL is 10 mg/kg/day. The developmental LOEL is 100 mg/kg/day, based on treatment-related increases in the fetal incidence of several skeletal variations and a positive trend for litter incidence of two of these variations (unossified pubic and tail bones). The developmental NOEL is 25 mg/kg/day. The developmental toxicity study in the rabbit is classified core minimum.

10. In a developmental toxicity study deltamethrin was administered to 25 Charles River Crl:CD VAF/Plus rats/dose in corn oil by gavage at dose levels of 0, 1.0, 3.3, or 11 mg/kg/day from days 6 through 15 of gestation. Because of excessive toxicity at 11 mg/kg/day, an additional group of 25 rats dosed at 7 mg/kg/day was added. The maternal

LOEL is 7 mg/kg/day, based on treatment-related increases in mortality, clinical findings (increased salivation), and decreased body weight gains during dosing. The maternal NOEL is 3.3 mg/kg/day. There were no treatment-related effects on fetal deaths or resorptions, altered growth, or developmental malformations or variations (external, visceral, and skeletal) noted at any dose level. The developmental NOEL is ≥11 mg/kg/day. A developmental LOEL was not observed.

11. In three different developmental toxicity studies deltamethrin was administered to mice, rats, and rabbits. *Mice:* Mice were dosed at 0, 0.1, 1.0, or 10 mg/kg/day on gestational days 6-17 and were sacrificed on day 18. The maternal NOEL is ≥10 mg/kg/day. There was no maternal LOEL observed. The developmental LOEL is 1.0 mg/kg/day based on increase incidence (fetal and/or litter) of delayed ossification of the sternebrae and paws together with decreased fetal body weights. The developmental NOEL is 0.1 mg/kg/day.

Rats: Rats were dosed at 0, 0.1, 1.0, or 10 mg/kg/day on days 6-18 of gestation and were sacrificed on day 21. The maternal LOEL is 10 mg/kg/day based on slightly reduced body weights. The maternal NOEL is 1.0 mg/kg/day. The developmental LOEL is equivocally set at 10 mg/kg/day, based only on a statistically significant increased incidence (fetal and/or litter) of delayed ossification of the sternebrae. The developmental NOEL is 1.0 mg/kg/day.

Rabbits: Rabbits were dosed at 0, 1, 4, or 16 mg/kg/day on days 6-19 of gestation and were sacrificed on day 28; two separate groups of rabbits received 16 mg/kg/day. The maternal NOEL is ≥16 mg/kg/day. There was no maternal LOEL observed. The developmental LOEL is 16 mg/kg/day based on increased fetal losses and decreased fetal weights. The developmental NOEL is 4 mg/kg/day.

12. In a 3-generation reproduction study deltamethrin was administered to 10 male and 20 female Charles River CD rats/dose in the diet at doses of 0, 0.1, 1.0, or 2.5 mg/kg/day. Parental toxicity was not demonstrated at any dose level. The NOEL for systemic toxicity is ≥2.5 mg/kg/day. The LOEL for systemic toxicity was not observed. Reproductive toxicity was not demonstrated at any dose level. The NOEL for reproductive toxicity is ≥2.5 mg/kg/day. The reproductive LOEL was not observed.

13. There is no mutagenicity concern. There are three acceptable studies: one reverse mutation assay; one *in vitro* chromosome aberration study; one UDS assay in primary rat hepatocytes. All these studies were negative. A dominant lethal study is also available but has not been officially reviewed. A quick assessment indicated that it is also negative.

14. Studies on metabolism: Deltamethrin ^{14}C-labeled at either the benzyl (BD) or the dimethyl (DMD) portion of the molecule was relatively well absorbed. Urine and fecal excretions were almost complete at 48 hours post-dosing. Seven days after dosing, 31-56% of the radioactivity administered was recovered in the urine, 36-59% recovered in the feces, < 0.2% recovered in tissues (fat was highest) and < 1.2% recovered in carcass. Fecal extracts contained mostly unabsorbed, unchanged deltamethrin (17-46% of BD dose and 21-35% of DMD dose).

15. Studies on neurotoxicity: With the exception of the acute delayed neurotoxicity study, no neurotoxicity studies are available.

16. The following studies are considered data gaps in the toxicology data base: 2-generation reproduction study and acute, chronic and developmental mammalian neurotoxicity. These studies will be required under a special Data Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

Tralomethrin

1. A battery of acute toxicity studies places technical tralomethrin in Toxicity Category II for acute oral (LD_{50} in males = 84.9 mg/kg; LD_{50} in females = 95.4 mg/kg), acute inhalation (LC_{50} > 2,000 mg/kg) and primary eye irritation (corneal opacity which reversed within 14 days); Category III for acute dermal (LD_{50} > 2,000 mg/kg); Category IV for primary dermal irritation (non-irritating). Tralomethrin is not a sensitizer. The NOEL for Acute Delayed Neurotoxicity is greater than 6,000 mg/kg.

2. In a rat oral toxicity study, tralomethrin was administered to 20 CD rats/sex/dose via gavage at dose levels of 0, 1, 6, or 18 mg/kg/day for 13 weeks (91 days). The LOEL for this 13-week rat oral toxicity study is 6 mg/kg/day based on decreased liver weights. The NOEL is 1 mg/kg/day.

3. In a 13-week dog feeding study, tralomethrin in polyethylene glycol was administered to 5 beagle dogs/sex/group via capsule at dose levels of 0, 0.1, 1.0, or 10 mg/kg/day. The LOEL for this 13-week dog feeding study is 10 mg/kg/day based on neurological and hematological effects. The NOEL is 1 mg/kg/day.

4. In a 1-year dog feeding study, tralomethrin in corn oil was administered to eight beagle dogs/sex/group by capsule at dose levels of 0.75, 3.0, and 10.0 mg/kg/day. The high dose level was excessively toxic and was reduced to 8.0 mg/kg/day at 4 weeks and to 6.0 mg/kg/day on week 14. The low dose level was increased from 0.75 to 1.0 mg/kg/day during week 14. The LOEL in this 1-year dog feeding study is 3.0 mg/kg/day, based on reduced body weight gain, tremors, and ptyalism. The NOEL is 0.75/1.0 mg/kg/day.

5. In a mouse oncogenicity study, tralomethrin in corn oil was administered to 80 CD-1 mice/sex/dose by gavage at dose levels of 0.75, 3.0, or 10.0 mg/kg/day for up to 2 years. The systemic LOEL in this mouse oncogenicity study is 3 mg/kg/day, based on skin lesions in male and female mice. The systemic NOEL is 0.75 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

6. In a rat chronic toxicity/oncogenicity study, tralomethrin in corn oil was administered to 80 CD rats/sex/dose by gavage at dose levels of 0.75, 3.0, or 12.0 mg/kg/day for up to 2 years. The LOEL is 3.0 mg/kg/day in male and female rats based on decreased body weight gain in males and decreased food and water consumption in males and females at 3.0 mg/kg/day. The NOEL is 0.75 mg/kg/day. Under the conditions of this study, there was no evidence of carcinogenic potential.

7. In a rat developmental study, tralomethrin in corn oil was administered to 25 female Sprague-Dawley CD rats per group at 0, 2, 6, or 18 mg/kg/day via gavage on days 6-17 of gestation. On day 21 the rats were sacrificed and pups delivered by cesarean section. The maternal LOEL 18 mg/kg/day based on one treatment-related death at this dose level. The maternal NOEL is 6 mg/kg/day. There was no developmental toxicity noted at any dose level. There were no treatment-related increases in malformations or variations found upon external, internal, and skeletal examination of the fetuses. A developmental LOEL was not observed. The developmental NOEL is ≥18 mg/kg/day.

8. In a developmental study, tralomethrin in corn oil was administered to 15 female New Zealand white rabbits per group at 0, 2, 8, or 32 mg/kg/day via gavage on days 6-18 of gestation. There was no maternal toxicity noted at any dose level. In a

developmental study, tralomethrin (purity not indicated) in corn oil was administered to 15 female New Zealand white rabbits per group at 0, 2, 8, or 32 mg/kg/day via gavage on days 6-18 of gestation. On day 28 the dams were sacrificed and pups delivered. A maternal LOEL was not observed. The maternal NOEL is ≥32 mg/kg/day. There was no developmental toxicity noted at any dose level. A developmental LOEL was not observed. The developmental NOEL is ≥32 mg/kg/day.

9. In a two-generation rat reproductive toxicity study, tralomethrin in corn oil was administered to COBS CD rats by gavage at dose levels of 0, 0.75, 3.0, or 12.0 mg/kg/day. The LOEL for parental toxicity is 3.0 mg/kg/day, based on decreased body weight gains. The NOEL for parental toxicity is 0.75 mg/kg/day. Reproductive toxicity was demonstrated at the mid- and high-doses. The LOEL for reproductive toxicity is 0.75 mg/kg/day, based on litters with smaller than normal pups. A reproductive NOEL was not observed.

10. There does not appear to be a concern for mutagenicity, however, all studies should be revisited, particularly, the mouse lymphoma. There are three reviewed studies that are not classified for acceptability: one mouse lymphoma assay (Accession No. 072115; one *in vitro* chromosome aberration study in CHO cells and one UDS assay in primary rat hepatocytes (MRID 41138803). The mouse lymphoma assay tested negatively without activation and was moderately positive with activation. The other two assays tested negatively.

11. The metabolism studies indicate that tralomethrin is rapidly debrominated to deltamethrin. It is then further metabolized to alcohols, carboxylic acids, glucuronides, glycine and sulfate conjugates.

12. No mammalian neurotoxicity studies are available. The acute delayed neurotoxicity study in the hen is summarized in section one.

13. The following studies are considered data gaps in the toxicology data base: acute, chronic and developmental mammalian neurotoxicity. These studies will be required under a special Data Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

Tralomethrin is rapidly metabolized to deltamethrin. The toxicology data bases for deltamethrin and tralomethrin were combined in order to determine appropriate endpoints for risk assessment. Results of the rat metabolism study support this action.

1. *Acute toxicity*. EPA has established an NOEL of 1.0 mg/kg/day based on combined acute dietary dog studies with a combined deltamethrin/tralomethrin data base. This NOEL is based on an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

2. *Short - and intermediate-term toxicity*. There is no concern for short- and intermediate-term toxicity. There is no dermal or systemic toxicity at 1,000 mg/kg/day in 21–day dermal study in rats.

3. *Chronic toxicity*. EPA has established the RfD for deltamethrin and tralomethrin at 0.01 (mg/kg/day). This RfD is based on a NOEL of 0.75/1.0 mg/kg/day from a 1 year toxicity study in dogs. The NOEL is based on decreased body weight gain, tremors, and ptyalism. This RfD is based on an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in either rats or mice.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.422 and 180.435) for the residues of tralomethrin and deltamethrin in or on a variety of raw agricultural commodities. For purposes of the risk assessment the data bases for deltamethrin and tralomethrin have been combined. EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA's June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinements. Field trial data and FDA monitoring data were used to generate anticipated residues or residue distribution for Monte Carlo analyses. Chronic dietary risk assessments used anticipated residues and percent crop treated refinements. Risk assessments were conducted by EPA to assess dietary exposures and risks from deltamethrin and tralomethrin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The NOEL used for the acute dietary exposure was 1.0 mg/kg/day. Potential acute exposures from food commodities were estimated using a Tier 3 acute dietary risk assessment (Monte Carlo Analysis). The MOE's (99.9th percentile) for the U.S. population based on an acute dietary exposure of 0.000728 mg/kg/day are 1,373. For children 1-6 years old (most highly exposed population), the MOE's based on an acute dietary exposure of 0.001855 mg/kg/day are 539. The Agency has no cause for concern if total exposure calculated for the 99.9th percentile yields an MOE of 100 or larger.

ii. *Chronic exposure and risk*. Potential chronic exposures were estimated using NOVIGEN's DEEM (Dietary Exposure Evaluation Model). The RfD used for the chronic dietary analysis is 0.01 mg/kg/day. Using tolerance values and anticipated residues discussed above, the risk assessment resulted in use of 0.2% of the RfD for the general U.S. population and 0.5% of the RfD for children 1-6 years.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate.

Section 408(b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used. The percent of crop treated estimates for deltamethrin and tralomethrin were derived from federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further,

regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under FIFRA.

2. *From drinking water*. Deltamethrin and tralomethrin are immobile in soil and will not leach into ground water. Additionally, due to their insolubility and lipophilic nature, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment. A screening evaluation of leaching potential of a typical potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM1). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at depths of 1 and 2 meters are essentially zero (much less than 0.001 ppb). Therefore, EPA concludes that residues are not expected to occur in drinking water.

i. *Acute exposure and risk*. Acute drinking water exposure is estimated for the U.S. population to be 0.000014 mg/kg/day with an MOE of 69,093. For Non-nursing infants less than 1 year old the exposure is 0.000028 with and MOE of 35,895.

ii. *Chronic exposure and risk*. Chronic drinking water exposure is estimated for the U.S. population to be zero and for the non-nursing infants 0.000001 mg/kg/day. Zero percent of the RfD is occupied by both population groups.

3. *From non-dietary exposure*. Deltamethrin and tralomethrin are broad spectrum insecticides registered for use on a variety of food and non-food agricultural commodities. Non-agricultural registered uses include turf and lawn care treatments, broadcast carpet treatments, indoor fogger, spot, crack and crevice treatment, insect baits, lawn and garden sprays and indoor and outdoor residential, industrial, and food/feed handling establishments.

To evaluate non-dietary exposure, the ''flea infestation control'' scenario was chosen to represent a plausible but worst-case non-dietary (indoor and outdoor) non-occupational exposure. This scenario provides a situation where deltamethrin and/or tralomethrin is commonly used and they can be used concurrently for a multitude of uses, e.g., spot and/or broadcast treatment of infested indoor surfaces such as carpets and rugs, treatment of pets and treatment of the lawn. This hypothetical situation provides a very conservative, upper bound estimate of potential non-dietary exposures. Consequently, if health risks are acceptable under these conditions, the potential risks associated with other more likely scenarios would also be acceptable.

Because tralomethrin is rapidly metabolized to deltamethrin, and the toxicology profiles of deltamethrin and tralomethrin are virtually identical, a non-dietary and aggregate (non-dietary + chronic dietary) exposure/risk assessment has been conducted for the combination of both active ingredients. The total exposure to both materials was expressed as ''deltamethrin equivalents'' and these were compared to the toxicology endpoints identified from the combined deltamethrin/tralomethrin toxicology data base.

The total aggregate non-dietary exposure including lawn, carpet, and pet uses (in mg/kg/day) are: 0.00002 for adults; 0.000503 for children aged 1-6 years; and 0.000543 for infants less than 1 year old.

4. Cumulative exposure to substances with common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Although deltamethrin and tralomethrin are similar to other members of the synthetic pyrethroid class of insecticides, EPA does not have, at this time, available data to determine whether deltamethrin and tralomethrin have common methods of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed, a cumulative risk approach based on a common mechanism of toxicity, deltamethrin and tralomethrin do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that deltamethrin and tralomethrin have a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. The acute aggregate risk assessment takes into account exposure from food and drinking water. The potential acute exposure from food and water to the US population for deltamethrin and tralomethrin is 0.000742 mg/kg/day with an MOE of 1,348. This acute dietary exposure estimate is considered conservative, using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis.

2. *Chronic risk*. Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to deltamethrin and tralomethrin from food and drinking water will utilize 0.2% of the RfD for the U.S. population. The major

identifiable subgroup with the highest aggregate exposure are children 1-6 years old (discussed in Unit II.F. of this preamble). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Short- and intermediate-term risk*. Short- and intermediate aggregate exposure takes into account chronic dietary food and drinking water (considered to be a background exposure level) plus indoor and outdoor residential exposure. The potential short- and intermediate-term aggregate risk for the U.S. population is an exposure 0.000042 mg/kg/day with an MOE of 49,000.

EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to deltamethrin and tralomethrin residues.

E. Aggregate Cancer Risk for U.S. Population

Deltamethrin and tralomethrin do not yet have carcinogenicity classification; however, there is no evidence of carcinogenicity in any of the chronic studies. Therefore, a carcinogenicity risk analysis is not required.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of deltamethrin and tralomethrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. See toxicological profile in Unit II.A. of this preamble.

iii. *Reproductive toxicity study*. See toxicological profile in Unit II.A. of this preamble.

iv. *Pre- and post-natal sensitivity*. There is no evidence of additional sensitivity to young rats or rabbits following prenatal exposure to deltamethrin or tralomethrin.

v. *Conclusion*. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk*. The potential acute exposure from food and drinking water to the most sensitive population subgroup, children 1-6 years old is 0.001867 mg/kg/day with an MOE of 535. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to deltamethrin and tralomethrin from food will utilize 0.5% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. *Short- or intermediate-term risk*. EPA has concluded that potential short- or intermediate-term aggregate exposure of deltamethrin or tralomethrin from chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure to infants (less than 1 year old) is 0.000057 mg/kg/day with an MOE of 1,800. For children (1-6 years old) the exposure is 0.000055 mg/kg/day with and MOE of 2,700.

5. *Special docket*. The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

EPA concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to deltamethrin and tralomethrin.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . .'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism In Plants and Animals

The absorption of deltamethrin appears to be highly dependent upon the route and vehicle of administration. Once absorbed, deltamethrin is rapidly and extensively metabolized and excreted through urine and feces, almost completed within the first 48 hours. Tralomethrin is rapidly metabolized to deltamethrin after debromination. The metabolic pattern of the debrominated tralomethrin is exactly the same as that of the metabolic pattern of deltamethrin.

B. Analytical Enforcement Methodology

The analytical method designated HRAV-7B is adequate for enforcement purposes. Multi residue methods data for tralomethrin, deltamethrin, and trans-deltamethrin have been sent to the Food and Drug Administration.

C. Magnitude of Residues

Based on the low level of deltamethrin residues expected in the diet of cattle from the use on cotton, the ruminant metabolism study, and an available cattle feeding study, measurable residues are not expected in the milk or meat of ruminants. A poultry metabolism or feeding study is not required because cottonseed meal is

not a major poultry feed item and deltamethrin residues are predicted to be non-detectable. For dietary exposure analyses, field trial data and FDA monitoring data were used to generate the appropriate anticipated residues or residue distribution for Monte Carlo analysis.

D. International Residue Limits

No CODEX maximum residue levels (MRL) are established for deltamethrin and tralomethrin tolerances addressed in this document. For deltamethrin on cottonseed, Mexico has an established tolerance of 0.1 ppm (vs. U.S. tolerance of 0.04 ppm). For tralomethrin on broccoli and soybeans Mexico has established tolerances of 0.02 ppm (vs. U.S. tolerance of 0.50) and 0.05 ppm (vs. U.S tolerance of 0.05ppm) respectively. As indicated above, there are small differences between the section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods to establish tolerances, calculation of animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, the tolerance is established for residues of deltamethrin in cottonseed at 0.04 ppm and cottonseed oil at 0.2 ppm and tralomethrin broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm.

In addition to the tolerances being established, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerance for cottonseed oil that now appears in § 185.1580 with the tolerances that appear in §180.435.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number OPP–300584 (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at: opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule removes time limitations for tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of

a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests. requirements.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By revising § 180.422 to read as follows:

§ 180.422 Tralomethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the pesticide chemical tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate) and its metabolites (*S*)-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate and (*S*)-*alpha*-cyano-3-phenoxybenzyl(1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylate calculated as the parent in or on the following agricultural commodities:

Commodity	Parts per million
Broccoli	0.5
Cottonseed	0.02
Cottonseed oil	0.20
Lettuce, head	1.00
Lettuce, leaf	3.00
Soybeans	0.05
Sunflower seed	0.05

(2) A food additive tolerance of 0.02 part per million is established for the combined residues of the insecticide tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(RS)-1,2,2,2-tetrabromoethyl] cyclopropanecarboxylate) and its metabolites *cis*-deltamethrin [(*S*-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-[2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and trans-deltamethrin [(*S*)-*alpha*-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] as follows:

(i) In or on all food items (other than those covered by a higher tolerance as a result of use on growing crops) in food-handling establishments.

(ii) The insecticide may be present as a residue from application of tralomethrin in food-handling establishments, including food service, manufacturing, and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries in accordance with the following prescribed conditions:

(A) Application shall be limited to a general surface and spot and/or crack and crevice treatment in food-handling establishments where food and food products are held, processed, prepared, and served. General surface application may be used only when the facility is not in operation provided exposed food has been covered or removed from the area being treated. All food-contact surfaces and equipment must be thoroughly cleaned after general surface applications. Spot and/or crack and crevice application may be used while the facility is in operation provided exposed food is covered or removed from the area being treated prior to application. Spray concentration shall be limited to a maximum of 0.06 percent active ingredient. Contamination of food and food-contact surfaces shall be avoided.

(B) To assure safe use of the insecticide, its label and labelling shall conform to that registered with the U.S. Environmental Protection Agency and shall be used in accordance with such label and labelling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

c. By revising § 180.435 to read as follows:

§ 180.435 Deltamethrin, tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the pesticide chemical deltamethrin [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid (*S*)-*alpha*-cyano-3-phenoxybenzyl ester and its major metabolites, *trans* deltamethrin [(*S*)-*alpha*-cyano-*m*-phenoxybenzyl(1R,3S)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and *alpha-R*-deltamethrin [(*R*)-*alpha*-cyano-*m*-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] in or on the following agricultural commodities:

Commodity	Parts per million
Cottonseed	0.04
Cottonseed oil	0.2
Tomatoes	0.2
Tomato (products) concentrated.	1.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.1580 [Removed]

b. By removing § 185.1580.

§ 185.5450 [Removed]

c. By removing § 185.5450.

[FR Doc. 97–31103 Filed 11–25–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300581; FRL–5755–5]

RIN 2070–AB78

Lambda-Cyhalothrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of the pyrethroid lambda-cyhalothrin and its epimer in or on broccoli, cabbage, corn (grain, fodder and forage), corn (sweet), cottonseed, dry bulb onion, garlic, lettuce, head, peanuts, rice, soybeans, sorghum, sunflower, tomatoes, wheat, sunflower, and livestock commodities. It also removes time limitations for tolerances for residues of lambda-cyhalothrin on the same commodities that expire on November 15, 1997. The Zeneca Ag Products requested these tolerances under the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 28, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300581], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300581], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300581]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Adam Heyward, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–6100, e-mail: heyward.adam@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On May 24, 1988, EPA established a time limited tolerance under section 408 of the FFDCA, 21 U.S.C. 346 a(d) and 348 for residues of lambda-cyhalothrin and its epimer on cottonseed (53 FR 18558). As additional crops tolerances were established, they were also made time-limited. These tolerance expire on November 15, 1997. Zeneca Ag Products, on September 15, 1997, requested that the time limitation for tolerances for residues of the insecticide lambda-cyhalothrin and its epimer in or on the commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of registration. Zeneca Ag Products also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of Friday, September 25, 1997 (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 6F3318, 7F3560, 7H5543, 7F3488, 1F3952, 1H5607, 1F3992, 2F4109, 2F4100, 2F4114, 1F3985, 9F3770 and 6F4769) for tolerances by Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, Delaware 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.438 be amended by removing time limitatioins for tolerances for the combined residue of the insecticide, lambda-cyhalothrin and its epimer in or on the following crops and commodities: broccoli at 0.4 parts per millions (ppm); cabbage at 0.4 ppm; cattle, fat at 3.0 ppm; cattle, meat at 0.2 ppm; cattle, meat and meat by-products (mbyp) at 0.2 ppm; corn, grain (field and pop) at 0.05 ppm; corn, fodder at 1.0 ppm; corn, forage at 6.0 ppm; corn, sweet (k+kwhr) at 0.05 ppm; cottonseed at 0.05 ppm; dry bulb onion at 0.1 ppm; eggs at 0.01 ppm; garlic at 0.1 ppm; goats, fat at 3.0 ppm; goats, meat at 0.2 ppm; goats, mbyp at 0.2 ppm, hogs, fat at 3.0 ppm; hogs, meat at 0.2 ppm; hogs, mbyp at 0.2 ppm; horses, fat at 3.0 ppm; horses, meat at 0.2 ppm; horses, mbyp at 0.2 ppm; lettuce, head at 2.0 ppm; milk, fat (reflecting 0.2 ppm in whole milk) at 5.0 ppm; peanuts at 0.05 ppm; peanuts, hulls at 0.05 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, mbyp at 0.01 ppm; rice, grain at 1.0 ppm; rice, hulls at 5.0 ppm; rice, straw at 1.8 ppm; sheep, fat at 3.0 ppm; sheep, meat at 0.2 ppm; sheep, mbyp at 0.2 ppm; soybeans at 0.01 ppm; sorghum, grain at 0.02 ppm; sorghum, grain dust at 1.5 ppm; sunflower, seeds at 0.2 ppm; sunflower, forage at 0.2 ppm; tomatoes at 0.1 ppm; wheat, grain at 0.05 ppm; wheat, forage at 2.0 ppm; wheat, hay at 2.0 ppm; wheat, straw at 2.0 ppm; wheat, grain dust at 2.0 ppm; corn, grain flour at 0.15 ppm; sunflower, oil at 0.30 ppm; sunflower, hulls at 0.50 ppm; tomato pomace (dry or wet) at 6.0 ppm; and wheat, bran at 0.2 ppm.

In the Notice of Filing the established tolerance level for sorghum grain was inadvertently listed as 0.02 ppm. The correct tolerance level for this commodity if 0.2 ppm. The correct tolerance was considered by EPA for risk assessment purposes. In the latest CFR, 40 CFR 180.438 (revised as of July 1, 1997), the tolerance for garlic was incorrectly listed as 0.02 ppm. The correct level if 0.1 ppm. This error occurred when the CFR was updated. The 0.1 ppm level was considered by EPA for risk assessment.

The basis for time limited tolerances that expire November 15, 1997 was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional

due to lack of certain environmental effects data. The rational for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) if none of the conditions of registration had any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months

to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of lambda-cyhalothrin and its epimer, and to make a determination on aggregate exposure, consistent with section 408(b)(2) in or on the crops and commodities listed above under SUPPLEMENTARY INFORMATION. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by lambda-cyhalothrin and its epimer are discussed below. Note that the studies discussed below were conducted using either cyhalothrin or lambda-cyhalothrin. Cyhalothrin and lambda-cyhalothrin are basically the same chemical, the differences are found in their stereo chemistry and the number of isomers in each mixture. Cyhalothrin consists of four stereo isomers in each mixture. Cyhalothrin consists of four steno isomers while lambda-cyhalothrin is a mixture of the two iomers. The two lambda-cyhalothrin isomers are contained in cyhalothrin, they represent 40% of the cyhalothrin mixture. The major studies submitted to the Agency were conducted with cyhalothrin. However, these studies are used in support of registration for both mixtures. There is evidence, based on subchronic studies in rats, that the two mixtures are not biologically different with respect to their mammalian toxicity.

1. Acute toxicity studies with the technical grade of the active ingredient lambda-cyahothrin: oral LD_{50} in the rat of 79 milligrams/kilogram (mg/kg) (males) and 56 mg/kg (females)(Tox Category II), dermal LD_{50} in the rat of 632 mg/kg (males) and 696 mg/kg females (Tox Category II), primary eye irritation study showed mild irritation (Tox Category II) and primary dermal irritation study showed no irritation (Tox Category IV).

2. The following genotoxicity tests were all negative: a gene mutation assay (Ames), a mouse micronucleus assay, an *in vitro* cytogenetics assay, and a gene mutation study in mouse lymphoma cells.

3. In a three-generation reproduction study, rats were fed diets containing cyhalothrin at 0, 10, 30 or 100 ppm (approximately 0, 0.5, 1.5 or 5.0 mg/kg/day). Parental toxicity was observed as decreased mean body weight and body weight gain during the premating and gestation periods at 5.0 mg/kg/day. There were no other treatment-related effects. Offspring toxicity was observed as reduced mean pup weight and pup weight gains during lactation, again at 5.0 mg/kg/day. No other treatment-related effects were observed. The reproductive and parental NOELs are 1.5 mg/kg/day and the reproductive and parental LOELs are 5.0 mg/kg/day. The developmental NOEL is 5.0 mg/kg/day (highest dose tested).

4. In a developmental toxicity study, rabbits were given gavage dose levels of cyhalothrin at: 0, 3, 10, 30 mg/kg/day during the gestation period (days 6 through 18). The maternal NOEL was 10 mg/kg/day and the maternal LOEL was 30 mg/kg/day based on decreased body weight gain (48% of controls) during the dosing period. The developmental NOEL was 30 mg/kg/day highest dose tested (HDT). No developmental effects were observed.

5. In a developmental study rats were given gavage dose levels of cyhalothrin at: 0, 5, 10, 15 mg/kg/day during the gestation period (days 6 through 15). The maternal NOEL was 10 mg/kg/day and the maternal LOEL was 15 mg/kg/day based on reduced body weight gain (70% of control) and food consumption (as low as 76%) during the dosing period. The developmental NOEL was greater than 15 mg/kg/day (HDT). No developmental effects were observed.

6. In a 90–day feeding study in rats, lambda-cyhalothrin was fed at doses of, 0, 10, 50 or 250 ppm (0,0.5, 2.5, 12.5 mg/kg/day). The animals were examined once daily for clinical signs of toxicity. Bodyweights, food consumption, hematological and clinical chemistry parameters, urinalysis parameters, organ weights, and macroscopic and microscopic observations were recorded. Body weight gain and food consumption were significantly reduced for both sexes at 12.5 mg/kg/day. There was also a slight but statistically significant reduction in food efficiency in females at this dose level. The NOEL is 2.5 mg/kg/day and the LEL is 12.5 mg/kg/day based on reduction in bodyweight gain and food consumption in both sexes and food efficiency in females.

7. In another 90–day feeding study in rats cyhalothrin was fed at doses of 0, 10, 50 or 250 ppm (0, 0.5, 2.5, 12.5 mg/kg/day). The animals were examined for clinical signs of toxicity. Bodyweights, food consumption, hematological and clinical chemistry parameters, urinalysis parameters, organ weights, and macroscopic and microscopic observations were recorded. Body weight gain was significantly reduced in males at 12.5 mg/kg/day. Body weight gain was also significantly reduced in females at this level, but only during the first week. Body weight gain was not significantly affected at lower dose

levels. The NOEL is 2.5 mg/kg/day and the LEL is 12.5 mg/kg/day based on decreased bodyweight gain.

8. A In 28–day study in the mouse cyhalothrin was fed to mice in the diet as a range-finding study for the carcinogenicity study at 0, 5, 25, 100, 500, or 2,000 ppm (0, 0.65, 3.30, 13.5, 64.2 or 309 mg/kg/day for males and 0, 0.80, 4.17, 15.2, 77.9 or 294 mg/kg/day for females).The NOEL is 500 ppm and the LEL is 2,000 ppm based on mortality, clinical signs of toxicity, decreases in body weight gain and food consumption, changes in hematology and organ weights and minimal centrilobular hepatocyte enlargement.

9. In a 21 day dermal toxicity study rats were exposed dermally to doses of 1, 10, or 100 mg/kg of lambda-cyhalothrin (reduced to 50 mg/kg after two or three applications) 6 hours/day for 21 consecutive days. No significant signs of skin irritation was observed at any dose level. Two male rats were found dead after 3 applications of 100 mg/kg. There was no evidence prior to death, at postmortem examination, or from histopathology, of the possible cause of death, but it is thought likely to be due to pyrethroid toxicity. Animals dosed with 50 mg/kg/day displayed clinical signs of slight general toxicity (bizarre behavior, paw flicking, splayed gait, sides pinched in, thin, tip-toe gait, reduced stability, dehydration and reduced splay reflex). Effects on body weight gain and food consumption were also seen in males at this dose level. No toxicologically significant treatment-related effects were observed at any other dose level. The NOEL is 10 mg/kg/day and the LEL is 100/50 mg/kg/day based on death, clinical signs of toxicity and decreased bodyweight gain and food consumption.

10. In a 21–day inhalation study rats were exposed nose-only 6 hours/day, 5 days/week for 21 days to lambda-cyhalothrin at 0.3, 3.3, or 16.7 µg/L. The NOEL was 0.3 µg/L and the LOEL was 3.3 µg/L based on decreased bodyweight gains (high dose males) and food consumption (high dose, both sexes), clinical signs of toxicity (paw flicking, tail erections, tiptoe gait, lachrymation or salivation), punctate foci on cornea (both sexes, mid- and high dose), raised prothrombin time, changes in hematology, clinical chemistry and urinalysis parameters and a slight increase in the incidence of alveolitis in females.

11. In a 12–month chronic/carcinogenicity feeding study, dogs were fed dose (by capsule) levels of lambda-cyhalothrin at 0, 0.1, 0.5, 3.5 mg/kg/day with a NOEL of 0.1 mg/kg/day. The LOEL for this study is established at 0.5 mg/kg/day based upon clinical signs of neurotoxicity.

12. In a 24–month chronic feeding/carcinogenicity study rats were fed diets containing 0, 10, 50, and 250 ppm (0, 0.5, 2.5 or 12.5 mg/kg/day) of cyhalothrin. The LEL for chronic toxicity in rats is 12.5 mg/kg/day and the NOEL is 2.5 mg/kg/day. There was no indication of carcinogenic effects observed under the conditions of the study.

13. In a carcinogenicity study, mice were fed dose levels of 0, 20, 100, or 500 ppm (0, 3, 15, or 75 mg/kg/day) of cyhalothrin in the diet for 2 years. A systemic NOEL was established at 100 ppm and systemic LOEL at 500 ppm based on decreased body weight gain in males throughout the study at 500 ppm. The EPA has classified lambda-cyhalothrin as a Group D carcinogen (not classifiable due to an equivocal finding in this study). No treatment-related carcinogenic effects were observed under the conditions of the study.

14. Metabolism studies in rats demonstrated that distribution patterns and excretion rates in multiple oral dose studies are similar to single-dose studies. Accumulation of unchanged compound in fat upon chronic administration with slow elimination. Otherwise, lambda-cyhalothrin was rapidly metabolized and excreted. The metabolism of lambda-cyhalothrin in livestock has been studied in the goat, chicken, and cow.

15. No neurotoxicity studies are available. These studies will be required under a special data call-in letter pursuant to Section 3(c)(2)(B) of FIFRA. Although these data are lacking EPA has sufficient toxicity data to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, EPA used a systemic NOEL of 0.5 mg/kg/day based on gait adnormalities in dogs on day 2 in the chronic toxicity study.

2. *Short - and intermediate - term toxicity*. For short-and intermediate-term dermal risk assessment, EPA recommends use of a NOEL of 10.0 mg/kg/day from the 21–day dermal toxicity study based on systemic toxicity at 50 mg/kg/day (LOEL). A dermal absorption rate of 25% was used based on weight of the evidence available for all structurally related pyrethroids. EPA used a NOEL of 0.3 µg/L from the 21–day inhalation study in rats based on clinical signs indicative of neurotoxicity (paw slicking) tail erections, and tiptoe gait) at 3.3 µg/L.

3. *Chronic toxicity*. EPA has established the reference dose (RfD) for lambda-cyhalothrin at 0.001 mg/kg/day. This RfD is based on a 1–year oral study in dogs with a NOEL of 0.1 mg/kg/day and an uncertainty factor (UF) of 100. The LEL of 0.5 mg/kg/day was based on clinical signs of neurotoxicity (convulsions, ataxia, muscle tremors) and a slight increase in liquid feces.

4. *Carcinogenicity*. Based on the available carcinogenicity studies in two rodent species, lambda-cyhalothrin has been classified as a Group ''D'' chemical, ''not classifiable as to human carcinogenicity.'' Although lambda-cyhalothrin was not shown to be carcinogenic in either the mouse or rat, the EPA Health Effects Division (HED) RfD/PEER review committee based the ''D'' classification on: (1) Lambda-cyhalothrin was not tested at adequate dose levels for carcinogenicity testing in the mouse, and (2) the equivocal nature of the findings with regard to the incidence of mammary adenocarcinomas. No additional cancer studies are being required at this time.

C. Exposures and Risks

1. *From food and feed uses.* The primary source of human exposure to lambda-cyhalothrin will be from ingestion of both raw and processed food commodities treated with lambda-cyhalothrin. Tolerances have been established in 40 CFR 180.438 and 40 CFR 186.3765 for combined residues of lambda-cyhalothrin and its epimer in or on a variety of food commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from lambda-cyhalothrin as follows:

i. *Acute exposure and risk.* An acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The acute dietary exposure used Monte Carlo modeling incorporating anticipated residue and percent crop treated refinements. The acute dietary Margin of Exposure (MOE) calculated at the 99.9th percentile for the most highly exposed population subgroup (non-nursing infants < 1 year old) is 139. The MOE calculated at the 99.9th percentile for the general U.S. population is 311. EPA concludes that there is a reasonable certainty of no harm for MOE of 100 or greater. Therefore, the acute dietary risk assessment for lambda-cyhalothrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk.* The RfD used for the chronic dietary analysis is

0.001 mg/kg/day from the lambda-cyhalothrin chronic dog study and an uncertainty factor of 100. The chronic dietary exposure assessment used anticipated residues and percent crop treated information. The chronic dietary exposure estimate for the overall U.S. population was calculated to be 0.000068 mg/kg/day (6.8% of the RfD utilized) and for children 1–6 years was calculated to be 0.000192 mg/kg/day (19.2% of the RfD utilized).

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinements. The chronic dietary risk assessment used percent crop treated information and anticipated residues. Section 408(b)(2)(E) authorizes EPA to consider available data and information on the antipicated residue levels of pesticide chemicals that have been measure in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified or left in effect, demonstration that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a timeframe it deems appropriate. Section 408 (b)(2)(F) allows the agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for lambda-cyhalothrin were derived from federal and market survey data. EPA considers these reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Date Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water.* Laboratory and field data have demonstrated that lambda-cyhalothrin is immobile in soil and will not leach into groundwater. Other data show that lambda-cyhalothrin is virtually insoluble in water and extremely lipophilic. As a result, EPA concludes that residues reaching surface waters from field runoff will quickly adsorb to sediment particles and be partitioned from the water column. Further, a screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM1). Based on this screening assessment, the potential concentrations of a pyrethroid in groundwater at depths of 1 and 2 meters are essentially zero (<<0.001 parts per billion (ppb)). Surface water concentrations for pyrethroids were estimated using PRZM3 and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 0.052 ppb. Concentrations in actual drinking water would be much lower than the levels predicted in the hypothetical, small, stagnant farm pond model since drinking water derived from surface water would normally be treated before consumption.

i. *Acute exposure and risk.* The acute drinking water exposure and risk estimates are 0.000022 mg/kg/day (MOE 22,876) and 0.000042 mg/kg/day (MOE 11,956) for the overall U.S. population and non-nursing infants < 1 year old, respectively.

ii. *Chronic exposure and risk.* The chronic drinking water exposure and risk estimates are 0.000000 mg/kg/day (0.0% of RfD utilized) and 0.000000 mg/kg/day (0.0% of RfD. Utilized) for the overall U.S. population and non-nursing infants < 1 year old, respectively.

3. *From non-dietary exposure.* Lambda-cyhalothrin is currently registered for use on the following residential non-food sites: general indoor/outdoor pest control (crack/crevice/spot), termiticide, ornamental plants and lawns around homes, parks, recreation areas and athletic fields, and golf course turf. Application of this pesticide in and around these sites is mainly limited to commercial applicators. Analyses were conducted which included an evaluation of potential non-dietary (residential) applicator, post-application and chronic dietary aggregate exposures associated with lambda-cyhalothrin products used for residential flea infestation control and agricultural/commercial applications. In the case of potential non-dietary health risks, conservative point estimates of non-dietary exposures, expressed as total systemic absorbed dose (summed across inhalation and incidental ingestion routes) for each relevant product use category (i.e. lawn care) and receptor based on the toxicity endpoints selected by EPA for lambda-cyhalothrin, inhalation and incidental oral ingestion absorbed doses were combined and compared to the relevant systemic NOEL for estimating MOEs.

4. *Short- and intermediate-term exposure and risk.* EPA used a NOEL of 0.3 µg/L (0.05 mg/kg/day) from the 21–day inhalation toxicity study in rats. The LOEL of 3.3 µg/L was based on decreased body weight gains and clinical signs of toxicity including paw flicking, tail erections and tiptoe gait. For short- and intermediate-term dermal exposure MOE calculations, EPA used a NOEL of 10.0 mg/kg/day based on systemic toxicity at 50 mg/kg/day (LOEL). MOE = 100.

The short and intermediate-term non-dietary aggregate (non-dietary + chronic dietary (food and water)) MOEs for lambda-cyhalothrin indicate a substantial degree of safety. The total non-dietary (inhalation + incidental ingestion + dermal) MOEs for post-application exposure for the lawn care product evaluated was estimated to be > 15,000 for adults, 7,200 for children 1–6 years old and 7,000 for infants < 1 year. It can be concluded that the potential non-dietary and aggregate (non-dietary + chronic dietary) exposures for lambda-cyhalothrin are associated with substantial margin of safety.

5. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry,

and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Although lambda-cyhalothrin is structurally similar to other members of the synthetic pyrethroids class of insecticide, EPA does not have, at this time, available data to determine whether lambda-cyhalothrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, lambda-cyhalothrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that lambda-cyhalothrin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and water. The acute aggregate MOE calculated at the 99.th percentile for the U.S. population is 307. In a conservative policy, the Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or large. EPA concludes that there is a reasonable certainty that no harm will result from acute aggregate exposure to lambda-cyhalothrin residues.

2. *Chronic risk.* Aggregate chronic exposure is the sum of chronic exposure from food and chronic water. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food and water will utilize 6.8% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.. EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to lambda-cyhalothrin residues.

3. *Short- and intermediate-term risk.*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. For lambda-cyhalothrin the aggegrate MOE (inhalation + incidental oral + chronic dietary summed across all product use category was estimated to be 14,000 for the U.S. population. EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is reasonable certainty that no harm will result from aggregate exposure to lambda-cyhalothrin residues.

E. Aggregate Cancer Risk for U.S. Population

Lambda-cyhalothrin has been classified by EPA as a Group ''D'' chemical, ''not classifiable as to human carcinogenicity.'' Therefore, this risk assessment was not conducted.

F. Aggregate Risks and Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of lambda-cyhalothrin, EPA considered data from developmental toxicity studies in rats and rabbits and a three-generation reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during prenatal development. Reproduction studies provide information relating to pre- and post-natal effects from exposure to the pesticide, information on the reproductive capability of mating animals, and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor is designed to account for inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the standard hundredfold factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard factor.

1. *Developmental toxicity studies. i.* From the developmental toxicity study in rats, the maternal (systemic) NOEL was 10 mg/kg/day. The maternal LEL of 15 mg/kg/day was based on decreased body weight gain and decreased food consumption. The developmental (fetal) NOEL was > 15 mg/kg/day at the HDT.

ii. From the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 10 mg/kg/day. The maternal LEL of 30 mg/kg/day was based on decreased body weight gain. The developmental (fetal) NOEL was ≥ 30 mg/kg/day (HDT).

2. *Reproductive toxicity study.* From the three-generation reproductive toxicity study in rats, both the parental (systemic) and reproductive (pup) NOEL's were 1.5 mg/kg/day. Both the parental (systemic) and reproductive (pup) LEL's were 5 mg/kg/day. They were based on a significant decrease in

parental body weight (systemic) or a significant decrease in pup body.

3. *Pre- and post-natal sensitivity.* The toxicology data base for lambda-cyhalothrin is complete with respect to current toxicological data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the three-generation reproductive toxicity study in rats.

The toxicological database relative to pre- and post- natal sensitivity is complete. Based on the above, EPA concludes that reliable data support the use of the standard hundredfold margin of uncertainty factor and that an additional uncertainty factor is not warranted at this time.

4. *Acute risk.* The aggregate acute MOE calculated at the 99.9th percentile for non-nursing infants < 1 year old is 138. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to lambda-cyhalothrin through food and drinking water.

5. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food will utilize 19.2% of the RfD for children 1–6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to lambda-cyhalothrin residues.

6. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background level) plus short-term and intermediate term residential exposure. The aggregate MOE was estimated to be 6,300 for children 1–6 years old and 6,800 for infants (< 1 year old). EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is reasonable certainty that no harm will result from aggregate exposure to lambda-cyhalothrin residues.

G. Endocrine Disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism in Plants and Animals

The metabolism of lambda-cyhalothrin in plants and animals is adequately understood for the purpose of this tolerance. EPA has determined that plant and animal metabolites do not need to appear in the tolerance expression at this time. The residues to be regulated are lambda-cyhalothrin and its epimer as specified in 40 CFR 180.438.

B. Analytical Enforcement Methodology

There is a practical analytical method available for determination of residues of lambda-cyhalothrin and its epimer. Adequate enforcement methodology (gas chromatography/electron capture detector) for plant and animal commodities is available to enforce the tolerances. EPA will provide information on this method to FDA. In the interim, the analytical method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

C. Magnitude of Residues

A report entitled ''Reanalysis of Chronic and Acute Exposure and Risk for Lambda-Cyhalothrin Residues'' contains revisions to the originally submitted report: ''Chronic and Acute Dietary Exposure Analyses and Risk Assessment for Lambda-Cyhalothrin Residues in Food.'' The report dated October 10, 1997 contains a list of all residue values used in the chronic and acute dietary exposure analyses (including drinking water). The residue values have been verified by EPA and are appropriate.

D. International Residue Limits

No Codex MRLs for residues of lambda-cyhalothrin have been established. Canadian MRLs have been established for residues of lambda-cyhalothrin. Mexico has established tolerances for residues of lambda-cyhalothrin on cottonseed (0.05 ppm) which is in harmony with the U.S. tolerance. Mexico has established tolerances which are below their U.S. counterparts for corn grain (0.01 vs. 0.05 ppm) and sorghum grain (0.1 vs. 0.2 ppm).

As indicated above there are differences between the section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods used to establish tolerances, calculate animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, tolerances are established for lambda-cyhalothrin and its epimer in or on broccoli at 0.4 ppm; cabbage at 0.4 ppm; cattle, fat at 3.0 ppm; cattle, meat at 0.2 ppm; cattle, meat and meat by-products (mbyp) at 0.2 ppm; corn, grain (field and pop) at 0.05 ppm; corn, fodder at 1.0 ppm; corn, forage at 6.0 ppm; corn, sweet (k+kwhr) at 0.05 ppm; cottonseed at 0.05 ppm; dry bulb onion at 0.1 ppm; eggs at 0.01 ppm; garlic at 0.1 ppm; goats, fat at 3.0 ppm; goats, meat at 0.2 ppm; goats, mbyp at 0.2 ppm, hogs, fat at 3.0 ppm; hogs, meat at 0.2 ppm; hogs, mbyp at 0.2 ppm; horses, fat at 3.0 ppm; horses, meat at 0.2 ppm; horses, mbyp at 0.2 ppm; lettuce, head at 2.0 ppm; milk, fat (reflecting 0.2 ppm in whole milk) at 5.0 ppm; peanuts at 0.05 ppm; peanuts, hulls at 0.05 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, mbyp at 0.01 ppm; rice, grain at 1.0 ppm; rice, hulls at 5.0 ppm; rice, straw at 1.8 ppm; sheep, fat at 3.0 ppm; sheep, meat at 0.2 ppm; sheep, mbyp at 0.2 ppm; soybeans at 0.01 ppm; sorghum, grain at 0.02 ppm; sorghum, grain dust at 1.5 ppm; sunflower, seeds at 0.2 ppm; sunflower, forage at 0.2 ppm; tomatoes at 0.1 ppm; wheat, grain at 0.05 ppm; wheat, forage at 2.0 ppm; wheat, hay at 2.0 ppm; wheat, straw at 2.0 ppm; wheat, grain dust at 2.0 ppm; corn, grain flour at 0.15 ppm; sunflower, oil at 0.30 ppm; sunflower, hulls at 0.50 ppm; tomato pomace (dry or wet) at 6.0 ppm; and wheat, bran at 0.2 ppm.

In addition to the tolerance being amended, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerances that now appear in §§ 185.3765 and 186.3765 with the tolerances in § 180.438 and is removing §§ 185.3765 and 186.3765.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300581] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Feed additives, Pesticides and pests.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. Section 180.438 is amended by revising paragraph (a) to read as follows:

§ 180.438 Lambda-cyhalothrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the pyrethroid lambda-cyhalothrin, 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3- phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, on plants and livestocks, as indicated in the following table.

Commodity	Parts per million
Broccoli	0.4
Cabbage	0.4
Cattle, fat	3.0
Cattle, meat	0.2
Cattle, mbyp	0.2
Corn, grain (field and pop)	0.05
Corn, fodder	1.0
Corn, forage	6.0
Corn, grain flour	0.15
Corn, sweet (K+kwhr)	0.05
Cottonseed	0.05
Dry bulb onion	0.1
Eggs	0.01
Garlic	0.1
Goats, fat	3.0
Goats, meat	0.2
Goats, mbyp	0.2
Hogs, fat	3.0
Hogs, meat	0.2
Hogs, mbyp	0.2
Horses, fat	3.0
Horses, meat	0.2
Horses, mbyp	0.2
Lettuce, head	2.0
Milk, fat (reflecting 0.2 ppm in whole milk).	5.0
Peanuts	0.05
Peanuts, hulls	0.05
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, mbyp	0.01
Rice, grain	1.0
Rice, hulls	5.0
Rice, straw	1.8
Sheep, fat	3.0
Sheep, meat	0.2
Sheep, mbyp	0.2
Soybeans	0.01
Sorghum, grain	0.2
Sorghum, grain dust	1.5
Sunflower, forage	0.2
Sunflower, hulls	0.50
Sunflower, oil	0.30
Sunflowers, seeds	0.2
Tomatoes	0.1
Tomato pomace (dry or wet)	6.0
Wheat, grain	0.05
Wheat, forage	2.0
Wheat, hay	2.0
Wheat, straw	2.0
Wheat, grain dust	2.0
Wheat, bran	0.2

(2) A food additive tolerance of 0.01 part per million is established for residues of the insecticide [1α(*S**),3α(*Z*)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate (lambdacyhalothrin) as follows:

(i) In or on all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food-handling establishments where food products are held, processed, or prepared.

(ii) Application shall be limited solely to spot and/or crack and crevice treatment with a spray solution maximum of a 0.06-percent active ingredient by weight. Food must be removed or covered during treatment. Spray should not be applied directly to surfaces or utensils that may come into contact with food. Food-contact surfaces and equipment should be thoroughly cleaned with an effective cleaning compound and rinsed with potable water before using.

(iii) For spot treatment, a coarse low-pressure spray shall be used. Limit individual spot treatments to an area no larger than 20 percent of the surface area. Any individual spot treatment shall not exceed 2 square feet.

(iv) For crack and crevice treatment, equipment capable of delivering a pin-stream of spray directly into the cracks and crevices shall be used.

(v) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(3) A food additive tolerance is established for residues of the insecticide [1α (*S**),3α(*Z*)]-(±)-cyano-(3-phenoxylphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate as follows:

Commodity	Parts per million
Hops, dried	10.0

* * * * *

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 348.

§ 185.3765 [Removed]

b. Section 185.3765 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

§ 186.3765 [Removed]

b. Section 186.3765 is removed.

[FR Doc. 97–30959 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300582; FRL–5755–2]

RIN 2070–AB78

Cyfluthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyfluthrin in or on the raw agricultural commodities in or on the following raw agricultural commodities: alfalfa; alfalfa, hay; aspirated grain fractions; carrots; cattle, fat; cattle, meat; cattle, meat by-products (mbyp); citrus, crop group; citrus dried pulp; citrus oil; cottonseed; cottonseed,

hulls; cottonseed, oil; eggs; goats, fat; goats, meat; goats, mbyp; hogs, fat; hogs, meat; hogs, mbyp; horses, fat; horses, meat; horses, mbyp; milkfat; peppers; poultry, fat; poultry, meat; poultry, mbyp; radishes; sheep, fat; sheep, meat; sheep, mbyp; sorghum, fodder; sorghum, forage; sorghum, grain; sugarcane; sugarcane, molasses; sunflower, forage; sunflower, seed; tomato; tomato, concentrated products; and tomato, pomace (wet and dry). It also removes time limitations for tolerances for residues of cyfluthrin on the same commodities. Bayer Ag Corporation requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300582], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300582], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300582]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 25, 1988 (53 FR 1924), EPA established time-limited tolerances under Section 408 and 409 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) and 348 for residues of cyfluthrin. These tolerances expire on November 15, 1997. On September 15, 1997, Bayer requested that the time limitation for tolerances established for residue of the insecticide cyfluthrin in the above mentioned commodities be removed based on environmental effects data that they had submitted as a condition of the registration and time-limited tolerances. Bayer also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of Thursday, September 25, 1997 (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (4F3046, 9F3731, 3F4204, 4F4313, 2F4137, and 4F4313 and food/feed additive petitions 4H5427, 9H5574, 3H5670, 4H5686, and 4H5687) for tolerances by the Bayer Ag Corporation, 8400 Hawthorn Rd., Kansas City, MO 64120. This notice included a summary of the petitions prepared by the Bayer Ag Corporation. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.436 be amended by establishing permanent tolerances for residues of the insecticide cyfluthrin, in or on alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sugarcane, sweet corn, sunflowers and tomatoes at the following levels part per million (ppm): alfalfa, 5.0 ppm; alfalfa, hay, at 10.0 ppm; aspirated grain fractions at 300 ppm; carrots at 0.2 ppm; cattle, fat, at 5.0 ppm; cattle, meat, at 0.4 ppm; cattle, mbyp at 0.4 ppm; citrus, crop group, at 0.2 ppm; citrus, dried pulp at 0.3 ppm; citrus oil, at 0.3 ppm; cottonseed at 1.0 ppm; cottonseed, oil, at 2.0 ppm; cottonseed, hulls, at 2.0 ppm; eggs at 0.01 ppm; goats, fat, at 5.0 ppm; goats, meat, at 0.4 ppm; goats, mbyp at 0.4 ppm; hogs, fat, at 5.0 ppm; hogs, meat, at 0.4 ppm; hogs, mbyp at 0.4 ppm; horses, fat, at 5.0 ppm; horses, meat, at 0.4 ppm; horses, mbyp at 0.4 ppm; milkfat, at 15.0 ppm (representing 0.5 ppm in whole milk); peppers, at 0.5 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, mbyp at 0.01 ppm; radishes at 1.0 ppm; sheep, fat, at 5.0 ppm; sheep, meat, at 0.4 ppm; sheep, mbyp at 0.4 ppm; sorghum, fodder, at 5.0 ppm; sorghum, forage, at 2.0 ppm; sorghum, grain at 4.0 ppm; sugarcane, at 0.05 ppm; sugarcane, molasses, at 0.2 ppm; sunflower, forage, at 1.0 ppm; sunflower, seed, at 0.02 ppm; tomato, at 0.2 ppm; tomato, concentrated products, at 0.5 ppm; and tomato, pomace (wet and dry) at 5.0 ppm.

In the Notice of Filing, the established tolerance levels for cattle, fat; goat, fat; hog, fat; and horse, fat were incorrectly listed as 1.0 ppm. The correct tolerance level for these commodities is 5.0 ppm as stipulated in PP No. 2F4137 in the **Federal Register** of July 31, 1996 (61 FR 39883)(FRL–5387–2). A tolerance level of 5.0 ppm was considered by EPA for risk assessment purposes.

The basis for time-limited tolerances that expire November 15, 1997 was given in the **Federal Register** of October 20, 1993 (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limed due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerances with expiration dates if none of the conditions of registration have any bearing on human dietary risk. This current action meets that condition and thus expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a

reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if

each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of cyfluthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of cyfluthrin on alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sugarcane, sunflowers and tomatoes at the following levels (ppm): alfalfa, forage, at 5.0 ppm; alfalfa, hay, at 10.0 ppm; aspirated grain fractions at 300 ppm; carrots at 0.2 ppm; cattle, fat, at 5.0 ppm; cattle, meat, at 0.4 ppm; cattle, mbyp at 0.4 ppm; citrus, crop group, at 0.2 ppm; citrus dried pulp, at 0.3 ppm; citrus oil, at 0.3 ppm; cottonseed at 1.0 ppm; cottonseed, hulls, at 2.0 ppm; cottonseed, oil, at 2.0 ppm; eggs at 0.01 ppm; goats, fat, at 5.0 ppm; goats, meat, at 0.4 ppm; goats, mbyp at 0.4 ppm; hogs, fat, at 5.0 ppm; hogs, meat, at 0.4 ppm; hogs, mbyp at 0.4 ppm; horses, fat, at 5.0 ppm; horses, meat, at 0.4 ppm; horses, mbyp at 0.4 ppm; milkfat, at 15.0 ppm (representing 0.5 ppm in whole milk); peppers, at 0.5 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, mbyp at 0.01 ppm; radishes at 1.0 ppm; sheep, fat, at 5.0 ppm; sheep, meat, at 0.4 ppm; sheep, mbyp at 0.4 ppm; sorghum, fodder, at 5.0 ppm; sorghum, forage, at 2.0 ppm; sorghum, grain at 4.0 ppm; sugarcane, at 0.05 ppm; sugarcane, molasses, at 0.2 ppm; sunflower, forage, at 1.0 ppm; sunflower, seed, at 0.02 ppm; tomato, at 0.2 ppm; tomato, concentrated products, at 0.5 ppm; and tomato, pomace (wet and dry) at 5.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cyfluthrin are discussed below.

1. *Acute toxicity*. The required toxicity battery studies for acute oral (LD_{50} ≥16.2 mg/kg), dermal (LD_{50} >5,000 mg/kg), inhalation (LC_{50} ≥0.468 mg/L), primary eye irritation (category III), primary dermal irritation (category IV), and dermal sensitization have been conducted and were found adequate. Cyfluthrin is not a dermal sensitizer.

2. *Mutagenicity*. There are seven acceptable studies upon which the Agency based its evaluation: three reverse mutation assays (*Salmonella typhimurium* , *E. coli* and *Saccharomyces cerevisiae*); one reverse mutation, mitotic recombination and conversion assay in *Saccharomyces cerevisiae* ; one CHO/HGPRT assay; one sister chromatid exchange assay in CHO cells; and one UDS assay in primary rat hepatocytes. All these studies were negative. There is no mutagenicity concern.

3. *Reproductive and developmental toxicity*— i. *Oral developmental study in rats.* Cyfluthrin was administered via gavage to pregnant female rats during days 6-15 of gestation at dose levels of 0, 1, 3, or 10 milligrams/kilograms/day (mg/kg/day). A maternal LOEL was not observed. (i.e. the maternal NOEL is >10 mg/kg/day). A developmental LOEL was not observed. The developmental NOEL is >10 mg/kg/day. This developmental study in rats was classified core guideline.

ii. *Oral developmental study in rabbits.* Cyfluthrin was administered via gavage to pregnant female rabbits during days 6-18 of gestation at dose levels of 0, 20, 60, or 180 mg/kg/day. The maternal LOEL is 60 mg/kg/day based on decreased body weight gain and food consumption during the dosing period. The maternal NOEL is 20 mg/kg/day. The developmental LOEL is 60 mg/kg/day based on increased numbers of resorptions and percent incidence of postimplantation loss. The developmental NOEL is 20 mg/kg/day. This study was classified core guideline.

iii. *Rat developmental studies via inhalation.* In the first two studies, pregnant female rats at day 0 gestation were exposed head-only to cyfluthrin concentrations of 0, 1.1, 4.7 or 23.7 mg/m^3/day (milligrams/per cubic meter/day) for 6 hours/day on gestation days 6 through 15. In the second study, the dams were exposed to analytical concentrations of 0, 0.09, 0.25, 0.59 or 4.2 mg/m^3 of the test material. The dams were sacrificed on day 20 and their pups removed by caesarian section. The maternal NOEL was 1.1 mg/m^3 and the maternal LOEL was 4.7 mg/m^3 (reduced motility, dyspnea, piloerection, ungroomed coats and eye irritation. The developmental NOEL was 0.59 mg/m^3 and the developmental LOEL was 1.1 mg/m^3 (increases in the incidence of runts and skeletal anomalies in the sternum (1.1 mg/m^3 and above); increases in post-implantation losses and decreases in pup weights (4.7 mg/m^3 and above) and increased incidences of late embryonic deaths, in skeletal anomalies in the extremities, pelvis and skull and in microphthalmia (23.7 mg/m^3). The study was graded core minimum.

In a third study, In a developmental toxicity study via inhalation, cyfluthrin was administered to female rats at 0.46, 2.55, 11.9 or 12.8 mg/m^3 exposure levels for gestational days 6 through 15 in a nose only inhalation chamber. The rats were exposed to the test material 6 hours per day, 7 days per week. The maternal NOEL/LOEL were < 0.46/<0.46 mg/m^3 based on decreased body weight gain and reduced relative food efficiency. The developmental NOEL/LOEL were 0.46/2.55 mg/m^3 based on reduced fetal and placental weight, reduced ossification in the phalanx, metacarpals and vertebrae. This study was classified as core guideline.

iv. *3-Generation reproduction study.* Cyfluthrin was administered in the diet to male and female rats dose levels of 0, 50, 150, or 450 ppm (actual animal intake; 0, 2.5, 7.5, or 22.5 mg/kg/day). The LOEL for parental toxicity was 450 ppm (22.5 mg/kg/day) based on decreased body weight gains. The NOEL for parental toxicity is 150 ppm (7.5 mg/kg/day). The LOEL for reproductive toxicity was 150 ppm (7.5 mg/kg/day) based on decreased viability and lactational indices and decreased pup body weight gains. The reproductive NOEL was 50 ppm (2.5 mg/kg/day). The multigeneration reproductive study in the rat was classified core minimum.

4. *Subchronic toxicity*— i. *28-Day oral toxicity study in rats.* Cyfluthrin was administered to SPF-Wistar rats via gavage at 0, 5, 20, or 80 (40) mg/kg/day. The high dose was 80 mg/kg/day during

the first and third weeks and 40 mg/kg/day during the second and fourth weeks. The LOEL was 80 (40) mg/kg/day in both sexes based on clinical signs of nerve toxicity, decreases in body weight gain, and changes in liver and adrenal weights. The NOEL was 20 mg/kg/day. This study was classified as core minimum.

ii. *28-Day oral toxicity study in rats.* Rats were dosed with cyfluthrin in the diet at 0, 100, 300, or 1,000 ppm (equivalent to 0, 5, 15, or 50 mg/kg/day). The LOEL was 15 mg/kg/day in both sexes based on decreased blood glucose. The NOEL was 5 mg/kg/day. This study was classified core supplementary.

iii. *3 Month feeding study in rats.* SPF Wistar rats were dosed with cyfluthrin in the diet at 0, 30, 100, or 300 ppm (equivalent to 0, 1.5, 5, or 15 mg/kg/day) for 3 months. No treatment related effects were observed at any of the levels tested, thus the NOEL for this 3-month rat feeding study was 15 mg/kg/day for both sexes. This study was classified core minimum.

iv. *6 Month dog feeding study.* Cyfluthrin was administered in the diet to dogs at 0, 65, 200 or 600 ppm (equivalent to 0, 1.62, 5 or 15 mg/kg/day) for 26 weeks. The LOEL for this study was 15 mg/kg/day for both sexes, based on neurological effects (hindlimb abnormalities) and gastrointestinal disturbances. The NOEL was 5 mg/kg/day for males and females. The study was classified as core minimum.

v. *21-Day dermal study in rats.* In a 21-day repeated dose dermal toxicity study, male and female rats were treated with cyfluthrin by dermal occlusion at target doses of 0, 100, 340, or 1,000 mg/kg/day for 6 hours/day (average actual dose levels were 0, 113, 376 or 1,077 mg/kg/day). No mortality was observed, and there were no treatment-related effects on body weight, ophthalmology, organ weights, clinical biochemistry, or hematology. The LOEL for dermal effects was 376 mg/kg/day for male and female Sprague-Dawley rats based on gross and histological skin lesions. The NOEL for dermal effects was for technical Baythroid was 113 mg/kg/day. The LOEL for systemic effects was 1,077 mg/kg/day based on decreased food consumption, red nasal discharge and urine staining. The NOEL for systemic effects was 376 mg/kg/day. This study was classified as acceptable.

vi. *3-Week inhalation toxicity studies in rats*— a. Wistar rats were dynamically exposed by nose-only inhalation to cyfluthrin in at concentrations of 0, 2.3, 11.5, or 69.6 mg/ for 6 hours/day, 5 consecutive days/week for 3 weeks (total of 15 exposures). The LOEL was 2.3 mg/m ^{3}, based on the treatment-related effects on body weight and temperature observed during the 3-week exposure period. A NOEL was not established; therefore, this study was repeated using lower doses.

b. Wistar rats were dynamically exposed by nose-only inhalation to cyfluthrin at concentrations of 0, 0.4, 1.4, or 10.5 mg/m^3 for 6 hours/day, 5 consecutive days/week for 3 weeks (total of 15 exposures). The LOEL was 10.5 mg/m^3, based on the treatment-related behavioral effects as well as effects on body and organ (spleen) weights. The NOEL is 1.4 mg/m^3. These studies were classified as core minimum.

vii. *4-Week inhalation toxicity study in rats.* Rats were dynamically exposed by inhalation (nose only) to cyfluthrin at concentrations of 0, 0.44, 6.04, or 46.6 mg/m^3 for 6 hours/day, 5 consecutive days/week for 4 weeks (20 exposures). The LOEL is 6.04 mg/m^3 based on the decrease in body and thymus weights, hypothermia, reduction in leukocytes counts (females), and low serum protein. The NOEL is 0.44 mg/m^3. This subacute inhalation toxicity study in rats was classified as supplementary.

viii. *13-Week inhalation toxicity study in rats.* Rats were dynamically exposed by head-only inhalation to cyfluthrin at concentrations of 0, 0.09, 0.71, or 4.51 mg/m^3 for 6 hours/day, 5 consecutive days/week for 13 weeks. All animals survived the 13-week study, and no treatment-related changes were observed in organ weight, gross pathology, and histopathology. The LOEL was 0.71 mg/m^3, based on the treatment-related behavioral effects in females as well as the increased urinary protein in males. The NOEL was 0.09 mg/m^3. This study was classified as core minimum.

5. *Chronic toxicity*— i. *1 Year dog study.* Cyfluthrin was fed to beagle dogs at 0, 40, 160, or 640 ppm (equivalent to 0, 1, 4, or 16 mg/kg/day) for 52 weeks. The NOEL was 4 mg/kg bw/day. The LOEL was 16 mg/kg/day for both sexes, based on slight ataxia in two dogs on single occasions, decreased body weight in males, and on observations of increased vomiting and diarrhea at the high dose. The NOEL is 4 mg/kg/day. This study was classified as core minimum.

ii. *Chronic/carcinogenicity-rat.* Cyfluthrin was administered for 24 months in the diet to rats at dose levels of 0, 50, 150, or 450 ppm (equivalent to 2.02, 6.19, or 19.20 mg/kg/day in males and 2.71, 8.15, or 25.47 mg/kg/day in females based on food consumption and body weights). The chronic LOEL was 150 ppm (equivalent to 6.19 mg/kg/day in males and 8.15 mg/kg/day in females) based on decreased body weights in the high-dose animals and the mid-dose males. The chronic NOEL was 50 ppm (equivalent to 2.02 mg/kg/day in males and 2.71 mg/kg/day in females). Under the conditions of this study, there was no evidence of carcinogenic potential. The study was classified core minimum for both chronic toxicity and oncogenicity.

iii. *Chronic/carcinogenicity- mouse.* In a chronic/carcinogenicity study, cyfluthrin was administered in the diet for 23 months to mice at dose levels of 0, 50, 200, or 800 ppm (equivalent to 11.6, 45.8, or 194.5 mg/kg/day in males and 15.3, 63.0, or 259.9 in females based on food consumption and body weights). There were no treatment related changes noted in the clinical observation, food consumption, hematology, gross observation, organ weight, and microscopic data. The chronic LOEL is 50 ppm (equivalent to 11.6 mg/kg/day in males and 15.3 mg/kg/day in females) based on increased alkaline phosphatase activity in the dosed males. A chronic NOEL was not established in male and female mice. Under the conditions of this study, there was no evidence of carcinogenic potential. This study was classified core minimum for carcinogenicity and supplementary for chronic toxicity.

6. *Animal metabolism*. Metabolism studies in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

7. *Neurotoxicity*. Other studies evaluated included a subacute oral neurotoxicity study in rats (LOEL of 50/mg/kg/day; no NOEL observed); a second subacute oral neurotoxicity study (NOEL of 40 mg/kg/day); a subchronic neurotoxicity study in rats (NOEL <60 mg/kg/day), and a subacute inhalation study in mice NOEL for pups, 0.006 mg/L; parental NOEL 0.058 mg/L HDT). These studies were all graded acceptable/guideline. Additional neurotoxicity data may be required under a special Data-Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has a sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. To assess acute dietary risk, the Agency used an endpoint of 20 mg/kg/day, the NOEL from the oral developmental toxicity study in rabbits.

2. *Short - and intermediate - term toxicity.* For the short and intermediate

term dermal exposures, the Agency used a NOEL of 20 mg/kg/day from the rabbit developmental study. The dermal absorption rate was 25%. This factor is based on the weight of evidence available for structurally related pyrethroids. For the short term inhalation exposures, the Agency used a NOEL of 0.00044 mg/L based on decreases in body and thymus weights, hypothermia, and clinical pathology at 0.00604 mg/L in a 28-day inhalation study. The recommended MOE is 300 which includes FQPA considerations. For the intermediate term inhalation exposure, the Agency used a NOEL of 0.00009 mg/L based on behavioral effects in rats at 0.00071 mg/L in a 90-day inhalation study. The additional certainty factor was included for inhalation because an inhalation study is available in the mouse which indicates increased sensitivity of the pups in comparison to the dams.

3.*Chronic toxicity*. EPA has established the RfD for cyfluthrin at 0.008 mg/kg/day. This RfD is based on a chronic/carcinogenicity feeding study in the rat with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 300.

4. *Carcinogenicity*. Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Agency. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.436) for the parent residues of cyfluthrin, in or on a variety of raw agricultural commodities. For purposes of dietary risk assessment, residue data generated from residue field trials conducted at maximum application rates and minimum preharvest intervals were used. To assess secondary exposure from edible animal commodities, animal dietary burdens were calculated using mean field trial residues, adjusted for percent crop treated and applying appropriate processing factors for all feed items. Risk assessments were conducted by EPA to assess dietary exposures and risks from cyfluthrin as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a day or single exposure. For the acute dietary exposure analysis for cyfluthrin treated raw agricultural commodities and processed food items, residue field trial data incorporating percent crop treated refinement and anticipated residues were used in Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document). The acute exposure via food was estimated as 0.004917 mg/kg/day for adults in the U.S., and 0.010687 mg/kg/day for nonnursing infants < 1 year old (most highly exposed subgroup. To assess acute dietary risk, the Agency used an endpoint of 20 mg/kg/day, the NOEL from the oral developmental toxicity study in rabbits. The resulting margin of exposure (MOE) is 4,068 for the general U.S. population, and 1,871 for nonnursing infants < 1 year old. For cyfluthrin, EPA generally has no concern for MOEs over 300.

ii. *Chronic exposure and risk*. The chronic dietary exposure assessment incorporated tolerance values and percent crop treated information. The RfD used was 0.008 mg/kg/day. Exposure was estimated at 0.000076 mg/kg/day for the U.S. population, and 0.000151 mg/kg/day for nonnursing infants < 1 year old. The percent RfD occupied is 1.0 % for the U.S. population, and 1.9% for infants < 1 year old. EPA generally has no concern for RfD of less than 100%

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticides residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided five years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for cypermethrin were derived from federal and market basket survey data. EPA considers these data reliable. A range of estimates supplied by this data and upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer based model for evaluating exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under FIFRA.

2. *From drinking water.* There is no established Maximum Concentration Level for residues of cyfluthrin in drinking water. Although data indicate little potential for soil mobility or leaching, cyfluthrin is moderately persistent. Estimates were generated with the PRZM I and EXAMS computer models in 1993 for comparative ecological risk assessment for these chemicals.

i. *Acute exposure and risk.* The acute drinking water exposure and risk estimates for cyfluthrin for the general U.S. population as estimated by the Agency was 0.000054 mg/kg/day. The acute drinking water exposure and risk estimate for non-nursing infants <1 year old was 0.000104 mg/kg/day. Using these values and an endpoint of 20 mg/kg/day, the margin of exposure (MOE) for the U.S. population is estimated at 368,982. For non-nursing infants <1 year old, the MOE is estimated at 192,308. For cyfluthrin, the Agency general has concern for risk estimates only below 300.

ii. *Chronic exposure and risk.* For the U.S. population, exposure is estimated at 0.000001 mg/kg/day, resulting in negligible risk. For nonnursing infants < 1 year old, exposure is estimated as 0.000005 mg/kg/day, which occupies 0.1% of the RfD.

3. *From non-dietary exposure.* Cyfluthrin is currently registered for use on non-food sites including golf courses, ornamental shrubs, indoor foggers, wood surfaces, lawns, and carpet. Nonoccupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses.

Short- and intermediate-term exposure and risk. Exposure is estimated at 0.00524 mg/kg/day for the

U.S. population, and 0.00810 mg/kg/day for nonnursing infants < 1 year old.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Cyfluthrin is a member of the synthetic pyrethroid class of pesticides. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA doe not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluation the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Four members of the insecticide class Pyrethroids produce a common metabolite known as DCVA. These insecticides are cyfluthrin, cypermethrin, z-cypermethrin and permethrin. Although the residues of DCVA can be estimated, no toxicology data on the compound per se are available to directly conduct a hazard evaluation and thereby establish an appropriate endpoint for use in a joint risk assessment. To date, for the purpose of assessing the risk of the parent compound the toxicity of DCVA has been assumed to be equivalent to the parent compound. However, due to the different toxicological profiles of cyfluthrin, cypermethrin, z-cypermethrin, and permethrin, EPA does not believe that it would be appropriate to cumulate DCVA for these pesticides, or DCVA residues from one of these pesticides with the parent of another of these pesticides, in conducting the risk assessment for these pesticides.

Accordingly, EPA does not have, at this time, available data to determine whether cyfluthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyfluthrin does not appear to produce a toxic metabolite produces by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyfluthrin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

The Agency has determined that an aggregate systemic (oral) and dermal exposure risk assessment is appropriate for cyfluthrin because of concern for the developmental effects seen after oral exposure. An aggregate oral and inhalation exposure risk assessment is also appropriate due to similarity in systemic toxicity observed in rats via these routes.

1. *Acute risk.* Aggregate acute dietary exposure is estimated at 0.004971 mg/kg/day resulting in a MOE of 4,023 for the U.S. population.

2. *Chronic risk.* EPA has concluded that aggregate exposure to cyfluthrin from food and water is estimated at 0.000076 mg/kg/day and will utilize 1% of the RfD for the U.S. population.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. For the general U.S. population, exposure is estimated at 0.0053 mg/kg/day, resulting in an MOE of 3,800.

E. Aggregate Cancer Risk for U.S. Population

Cyfluthrin has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Agency. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse. Therefore there is no concern for cancer in humans.

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children— In general.* In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, EPA considered data from a developmental toxicity study in the rat (see unit II.A.3. of this preamble). In addition, data from a 7-day inhalation study conducted with mouse dams and their offspring were considered (see also unit II.A.3.). There were no data gaps for the assessment of the effects of cyfluthrin following in utero or early postnatal exposure. Suggested sensitivity of rats to in utero exposure to cyfluthrin was hypothetically linked to bradypnea in the dams and was judged not be a valid consideration in the calculation of risk. However, evidence of increased sensitivity of young rats following pre- and/or postnatal exposure to cyfluthrin was observed in the two-generation reproduction study and in the 7-day inhalation study in mice.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes a 3-fold safety factor for children is appropriate for cyfluthrin based on lack of severity of the effect.

Based on the submitted studies, EPA concludes that reliable data support the use of a 300-fold uncertainty factor for infants and children.

2. *Acute exposure.* For nonnursing infants <1year old, the aggregate acute exposure is 0.010791 mg/kg/day, with a resulting MOE of 1,853. For cyfluthrin, EPA has no concern for MOEs over 300.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to cyfluthrin from food and water will utilize 2% of the RfD for infants and children (nonnursing infants <1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a

lifetime will not pose appreciable risks to human health.

4. *Short- or intermediate-term risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate nondietary exposure to cyfluthrin to infants <1 year is 0.008255 mg/kg/day. The MOE is estimated at 2,400.

Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to cyfluthrin residues.

5. *Special Docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement the program. Congress has allowed 3 years from passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disruption effects.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of cyfluthrin in plants and animals is adequately understood. Studies have been conducted to delineate the metabolism of radio labeled cyfluthrin in various crops and animals all showing similar results. The residue of concern is cyfluthrin.

B. Analytical Enforcement Methodology

Adequate analytical methodology (gas/liquid chromatography with an electron capture detector) is available for enforcement purposes.

C. Magnitude of Residues

Field trial residue and feeding study data have been submitted and reviewed in support of tolerances on alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sugarcane, sunflowers and tomatoes. Tolerances to support these uses were proposed in pesticide petitions 4F3046, 9F3731, 3F4204, 4F4313, 2F4137, and 4F4313 and food/feed additive petitions 4H5427, 9H5574, 3H5670, 4H5686, and 4H5687.

D. International Residue Limits

Codex maximum residue levels (MRLs) are establish for residues of cyfluthrin in milk, whole (0.01 ppm) ; cottonseed (0.05 ppm); peppers, sweet (0.2 ppm); and tomatoes (0.5 ppm). Mexico has established a tolerance on cottonseed at 1 ppm. There are no Canadian tolerances for cyfluthrin. As indicated in unit II. of this preamble there are differences between the section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods to establish tolerances, calculation of animal dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, the tolerances are established for residues of cyfluthrin in/on alfalfa, 5.0 ppm; alfalfa, hay, at 10.0 ppm; aspirated grain fractions at 300 ppm; carrots at 0.2 ppm; cattle, fat, at 5.0 ppm; cattle, meat, at 0.4 ppm; cattle, mbyp at 0.4 ppm; citrus, crop group, at 0.2 ppm; citrus dried pulp, at 0.3 ppm; citrus oil, at 0.3 ppm; cottonseed at 1.0 ppm; cottonseed, oil, at 2.0 ppm; cottonseed, hulls, at 2.0 ppm; eggs at 0.01 ppm; goats, fat, at 5.0 ppm; goats, meat, at 0.4 ppm; goats, mbyp at 0.4 ppm; hogs, fat, at 5.0 ppm; hogs, meat, at 0.4 ppm; hogs, mbyp at 0.4 ppm; horses, fat, at 5.0 ppm; horses, meat, at 0.4 ppm; horses, mbyp at 0.4 ppm; milkfat, at 15.0 ppm (representing 0.5 ppm in whole milk); peppers, at 0.5 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, mbyp at 0.01 ppm; radishes at 1.0 ppm; sheep, fat, at 5.0 ppm; sheep, meat, at 0.4 ppm; sheep, mbyp at 0.4 ppm; sorghum, fodder, at 5.0 ppm; sorghum, forage, at 2.0 ppm; sorghum, grain at 4.0 ppm; sugarcane, at 0.05 ppm; sugarcane, molasses, at 0.2 ppm; sunflower, forage, at 1.0 ppm; sunflower, seed, at 0.02 ppm; tomato, at 0.2 ppm; tomato, concentrated products, at 0.5 ppm; and tomato, pomace (wet and dry) at 5.0 ppm. tomatoes at ppm.

In addition to the tolerances being amended, since for purposes of establishing tolerances FQPA has eliminated distinctions between raw and processed food, EPA is combining the tolerances that appear in §§ 185.1250 and 186.1250 with § 186.436 and is removing tolerances under §§ 185.1250 and 186.1250.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection

with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300582] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* , or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.436 is amended as follows:

i. By designating the text following the heading in paragraph (a) as paragraph (a)(1) and by revising the table in newly designated paragraph (a)(1).

ii. Paragraph (b) is redesignated as paragraph (a)(2).

iii. New paragraphs (b), (c), and (d) are added and reserved with headings.

The revised table to § 180.436 reads as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Alfalfa	5.0
Alfalfa, hay	10.0
Aspirated grain fractions	300
Carrots	0.20
Cattle, fat	5.0
Cattle, mbyp	0.40
Cattle, meat	0.40
Citrus, crop group	0.2
Citrus, dried pulp	0.3
Citrus, oil	0.3
Cottonseed	1.0
Cottonseed hulls	2.0
Cottonseed oil	2.0
Eggs	0.01
Goats, fat	5.0
Goats, mbyp	0.40
Goats, meat	0.40
Hogs, fat	5.0
Hogs, mbyp	0.40
Hogs, meat	0.40
Hops, dried	20.0
Hops, fresh	4.0
Horses, fat	5.0
Horses, mbyp	0.40
Horses, meat	0.40
Milkfat (reflecting 0.5 ppm in whole milk)	15.0

Commodity	Parts per million
Peppers	0.50
Poultry, fat	0.01
Poultry, mbyp	0.01
Poultry, meat	0.01
Radishes	1.0
Sheep, fat	5.0
Sheep, mbyp	0.40
Sheep, meat	0.40
Sorghum, fodder	5.0
Sorghum, forage	2.0
Sorghum, grain	4.0
Sugarcane	0.05
Sugarcane, molasses	0.20
Sunflower, forage	5.0
Sunflower, seed	0.02
Tomato	0.20
Tomato, concentrated products	0.5
Tomato, pomace	5.0

(2) * * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.1250 [Removed]

b. In § 185.1250:

i. Paragraph (c) introductory text, (c)(1), (c)(2), and (c)(3) are transferred to § 180.436 and redesignated as paragraph (a)(3) introductory text, (a)(3)(i), (a)(3)(ii), and (a)(3)(iii), respectively.

ii. The remainder of § 185.1250 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.1250 [Removed]

b. In § 186.1250:

i. Paragraph (c) introductory text, (c)(1), (c)(2), and (c)(3) are transferred to § 180.436 and redesignated as paragraph (a)(4) introductory text, (a)(4)(i), (a)(4)(ii), and (a)(4)(iii), respectively.

ii. The remainder of § 186.1250 is removed.

[FR Doc. 97–31101 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300575; FRL–5754–6]

RIN 2070–AB78

Fenvalerate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenvalerate, including the S,S-enriched isomer esfenvalerate in or on cottonseed at 0.2 parts per million (ppm). It also removes time limitations for tolerances for residues of fenvalerate on the same commodities that expire on November 15, 1997. DuPont Agricultural Products requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170). This tolerance was established under petition number PP 7F2013.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300575], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed withthe Hearing Clerk identified by the docket control number, [OPP–300575], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300575]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: John Hebert, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–3068, e-mail: hebert.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On October 20, 1993 EPA established time limited tolerances under Section 408 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of esfenvalerate on cottonseed. These tolerances expire on November 15, 1997. DuPont Agricultural Products, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide fenvalerate, including the S,S-enriched isomer esfenvalerate in or on cottonseed at 0.2 parts per million (ppm) be removed based on ecological and environmental effects data that they had submitted as a condition of the registration. DuPont Agricultural Products also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of September 25, 1997 (62 FR 50337)(FRL 5748–2), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by DuPont Agricultural Products, P.O. Box 80038, Wilmington, DE 19880–0038. This notice included a summary of the petition prepared by DuPont Agricultural Products. There were no comments received in response to the notice of filing.

The basis for time limited tolerances that expire November 15, 1997 was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and

environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

The petition requested that 40 CFR 180.379 be amended by removing the time limitation for a tolerance for residues of the pyrethroid insecticide esfenvalerate, in or on: cottonseed at 0.2 parts per million (ppm). Tolerances are based on the sum of all isomers of fenvalerate. Fenvalerate is a racemic mixture of four isomers (about 25% each). This product was registered as Pydrin®. However since 1992, an S,S-isomer enriched formulation, Asana (esfenvalerate), has been the only fenvalerate formulation sold in the U.S. for agricultural use. Since the S,S-isomer is the insecticidally active isomer, the use rate for Asana® is four times lower than that for Pydrin®. A petition is pending (PP 4F4329), to convert tolerances (still to be expressed as the sum of all isomers) based on the use rates for Asana®. Bridging residue studies have shown Asana® residues to be 3–4 times lower than Pydrin® residues.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(I) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection

of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of esfenvalerate and to make a determination on aggregate exposure, consistent with section 408(b)(2), to remove the time limitation for a tolerances for residues of esfenvalerate on cottonseed at 0.2 parts per million (ppm). EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by esfenvalerate are discussed below.

1. A battery of acute toxicity studies places technical esfenvalerate in Toxicity category II for acute oral (LD_{50} = 87.2 mg/kg), Category III for acute dermal (LD_{50} > 2000 mg/kg) and primary eye irritation, Category IV for primary skin irritation. Esfenvalerate is a non-sensitizer. Acute inhalation on technical grade active ingredient is waived due to negligible vapor pressure. The Acute Delayed Neurotoxicity (Guideline 81–8) remains a data gap.

2. In a 90–day feeding study, rats were administered 0, 4.7, 6.2, 7.8 or 18.7 mg/kg/day of esfenvalerate. The Lowest Observed Effect Level (LOEL) is 18.7 mg/kg/day based on neurological dysfunction. The NOEL is 7.8 mg/kg/day.

In another 90–day feeding study, rats were administered 0, 5, 15, 30 or 50 mg/kg/day of esfenvalerate. The LOEL is 15 mg/kg/day based on neurological dysfunction. The NOEL is 5 mg/kg/day.

Esfenvalerate was administered to mice at dose levels of 0, 10.5, 30.5 or 106 mg/kg/day (male) and 0, 12.6, 36.8 or 113 mg/kg/day (female). The LOEL for esfenvalerate is 106 mg/kg/day. The NOEL is 30.5 mg/kg/day.

3. In a chronic/onco feeding study (MRID 00082244, 00111888), rats were administered 0.050, 0.25, 1.25 or 12.5 mg/kg/day of fenvalerate in the diet for 2 years. The LOEL was ≥ 12.5 mg/kg/day. There was no increase in tumors at 12.5 mg/kg/day. The NOEL was determined to be 12.5 mg/kg/day (the Highest Dose Tested (HDT) in the 2 year study.) The study is supplementary and does not satisfy the requirement for a guideline series 83–5 combined chronic/carcinogenicity study in rats.

In a lifetime feeding study (MRID 00079877), rats were administered 0 or 50.0 mg/kg/day of fenvalerate in the diet. Spindle cell sarcomas were produced in male rats only. The LOEL was 50.0 mg/kg/day based on loss of weight and neurological effects. The NOEL was 12.5 mg/kg/day.

The conclusion that fenvalerate is associated with the production of spindle cell sarcomas was later retracted by EPA. The study is supplementary and does not satisfy the requirement for a guideline series 83–5 combined chronic/ carcinogenicity study in rats. When taken together with chronic/ carcinogenicity feeding study (MRID's 00082244, 00111888) the guideline requirement for a 83–2a, cancer study in the rat is satisfied.

4. In a 2-year feeding study mice were administered 0, 0, 1.5, 7.5, 38.0 or 187.5 mg/kg/day fenvalerate in the diet. The LOEL was 7.5 mg/kg/day based on granulomatous changes (related to fenvalerate only, not esfenvalerate). The NOEL was 1.5 mg/kg/day. This study satisfies the requirement for combined chronic feeding carcinogenicity study in mice.

In an 18–month feeding study, mice 0, 15.0, 45.0, 150.0 or 450.0 mg/kg/day of fenvalerate in the diet. The LOEL is 45.0 mg/kg/day based on granulomatous changes in the liver and spleen. The NOEL is 15.0 mg/kg/day. No oncogenicity was observed. The study is supplementary and does not satisfy the requirement for a guideline series 83–2b carcinogenicity study in mice.

In a life span feeding study, mice were administered 0, 1.5, 4.5, 15.0 or 45.0 mg/kg/day of fenvalerate in the diet. The LOEL was determined to be 15 mg/kg/day based on the granulomatous lesions observed and on the change in hematological parameters. Fenvalerate was determined not to be carcinogenic in the ddy strain of the mouse. The NOEL was determined to be 3.48 mg/kg/day. The study is supplementary and does not satisfy the requirement for a

guideline series 83–2b carcinogenicity study in mice.

5. In a 21–day probe for a 1 year feeding study 2 male and 2 female beagles were administered 0, 2.80, 6.40 or 9.38 mg/kg/day in males and 0, 2.25, 7.37 or 8.50 mg/kg/day of esfenvalerate. The LOEL was determined to be 6.40 mg/kg/day based on nervous system involvement and decreases in body weight and food consumption. The NOEL is 2.25 mg/kg/day.

In a 1-year feeding study, 6 male and 6 female beagles/group were administered 0, 0.68, 1.36 or 5.29 mg/kg/day esfenvalerate. The LOEL was determined to be 6.40 mg/kg/day based on nervous system involvement and decreases in body weight and food consumption. The NOEL was determined to be 5.29 mg/kg/day. These studies are acceptable and satisfies the requirement for a guideline series 83–1b chronic feeding study in dogs.

6. Esfenvalerate was administered to female rats at doses of 0, 2.5, 5.0, 10.0 or 20.0 mg/kg/day from gestation days 6 through 15 (pilot study doses were 1.0, 2.0, 3.0, 4.0, 5.0 and 20 mg/kg/day). The LOEL is 2.5 mg/kg/day based on behavioral/Central Nervous System clinical signs. The NOEL for maternal toxicity is 2.0 mg/kg/day (from the pilot study). There was no evidence of developmental toxicity at any dose. The NOEL is 20 mg/kg/day, the highest dose tested.

Esfenvalerate was administered to rabbits at doses of 0, 3.0, 10.0 or 20.0 mg/kg/day from gestation days 7 through 19 (pilot study doses were 0, 2.0, 3.0, 4.0, 4.5, 5.0 or 20.0 mg/kg/day). The LOEL is 3.0 mg/kg/day based on behavioral/CNs clinical signs. The NOEL is 2.0 mg/kg/day (from the pilot study). There was no evidence of developmental toxicity at any dose. The LOEL is greater than 20.0 mg/kg/day. The NOEL is equal to or greater than 20.0 mg/kg/day, the highest dose tested.

7. In a 2-generation reproduction toxicity study in rats esfenvalerate was administered to rats at dose levels of 0, 3.75, 5.0, 17.5 and 35.0/17.5 mg/kg/day. The LOEL for parental toxicity is 3.75 mg/kg/day based on decreases in mean body weights of F_1 females and an increased incidence of skin lesions. The NOEL could not be determined. The LOEL for reproductive toxicity is 5.0 mg/kg/day based on decreases in F_1 pup weights on day 21 of lactation; decreases in litter size and F_2 pup weights and an increased incidence of subcutaneous hemorrhage. The NOEL is 3.75 mg/kg/day.

8. In a reverse gene mutation assay in bacteria, *S. typhimurium* and *Escherichia coli* were exposed to fenvalerate in DMSO at concentrations of 15, 50, 150, 500, 1,500, or 5,000 µg/plate in the presence and absence of mammalian metabolic activation (S9-mix). There was no evidence of induced mutant colonies over background.

In a mammalian cell gene mutation assay at the HGPRT locus, Chinese hamster V79 cells cultured *in vitro* were exposed to fenvalerate in DMSO at concentrations of 12.6, 42, 126, 420 µg/ml in the presence of mammalian metabolic activation (S9-mix) and at concentrations of 4.2, 12.6, 42, 126 µg/ml in the absence of S9-mix. There was no evidence of induced mutant colonies over background. In Chinese hamster lung fibroblasts (V79 cells) forward gene mutation assay the test was negative up to cytotoxic and/or precipitating levels (126 µg/ml in the absence of metabolic activation − S9; 420 µg/ml in the presence of metabolic activation +S9).

In a mammalian cell cytogenetics chromosomal aberration assay CHO-K1 cell cultures were exposed to fenvalerate in DMSO at concentrations of 4.2 µg/ml, 8.4 µg/ml, 21 µg/ml, 42 µg/ml respectively without exogenous metabolic activation (S9-mix) and at concentrations of 21 µg/ml, 42 µg/ml, 84 µg/ml, 210 µg/ml respectively with S9-mix. There was no evidence of a significant induction of chromosomal aberrations or polyploid cells over background.

A mouse micronucleus assay was negative in male ICR mice up to the HDT (150 mg/kg) administered by intraperitoneal injection. Since there appears to be no sex specific difference in the toxicity of Esfenvalerate, the use of males only is justifiable. No overt toxicity was observed, but suggestive evidence of bone marrow cytotoxicity was seen 48 hours post-administration at the highest dose level tested.

Other genetic toxicology studies submitted on racemic Fenvalerate indicate that the mixture containing equal parts of the four stereoisomers is not mutagenic in bacteria. The racemic mixture was also negative in a mouse host mediated assay and in a mouse dominant lethal assay.

9. The following studies are considered data gaps in the toxicology data base: general metabolism, 21 day dermal, dermal penetration and acute, subchronic and developmental mammalian neurotoxicity. These studies will be required under a special data call in letter pursuant to Section 3 (c)(2)(B) of FIFRA. Although these data are lacking EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity.* EPA has established an NOEL of 2.0 mg/kg/day through the dietary route in rat and rabbit developmental studies. This NOEL is based on behavioral and central nervous system clinical signs. A MOE of 100 is required.

2. *Short - and intermediate - term toxicity.* To assess risk from (nonfood) short and intermediate term dermal exposure, EPA has established a NOEL of 2.0 mg/kg/day from the rat and rabbit developmental studies. No dermal penetration/absorption study is available and the NOEL incorporates a 25% dermal absorption based on the weight-of-evidence available for structurally related pyrethroids. This NOEL is based on behavioral and central nervous system clinical signs. For exposure via inhalation the Agency used an oral NOEL of 2.0 mg/kg/day and assumed 100% absorption (based on the 2 mg/kg/day used for the dermal risk assessment since no appropriate inhalation toxicity studies are available).

3. *Chronic toxicity*. EPA has established the RfD for esvenvalerate at 0.02 mg/kg/day. This RfD is based on a NOEL of 2.0 mg/kg/day through the dietary exposure route in developmental study in rat. The NOEL is based on behavioral changes and clinical signs of neurotoxicity. This RfD is based on an uncertainty factor of 100.

4. *Carcinogenicity*. Esfenvalerate is classified as a Group E. There is no evidence of carcinogenicity in either rats or mice.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.379) for the residues of fenvalerate, in or on a variety of raw agricultural commodities.

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent of crop treated refinements. Field trial data and FDA monitoring data were used to generate anticipated residues or residue distribution for Monte Carlo analyses. Chronic dietary risk assessments used anticipated residues and percent crop treated refinements. Risk assessments were conducted by EPA to assess dietary exposures and risks from esfenvalerate as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological

study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The NOEL used for the acute dietary exposure was 2.0 mg/kg/day. Potential acute exposures from food commodities were estimated using a Tier 3 acute dietary risk assessment (Monte Carlo Analysis). The MOE's (99.9th percentile) for the US population based on an acute dietary exposure of 0.011717 mg/kg/day are 171. For children 1–6 years old (most highly exposed population) the MOE's based on an acute dietary exposure of 0.019445 mg/kg/day are 103. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields an MOE of 100 or larger.

ii. *Chronic exposure and risk.* Potential chronic exposures were estimated using NOVIGEN's DEEM (Dietary Exposure Evaluation Model). The RfD used for the chronic dietary analysis is 0.02 mg/kg/day. Using tolerance values and anticipated residues discussed above the risk assessment resulted in use of 1.9% of the RfD for the general US population and 4.6% of the RfD for children 1–6 years.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided five years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. Section 408(b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for esfenvalerate were derived from federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonable certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water.* Esfenvalerate is immobile in soil and will not leach into groundwater. Additionally, due to their insolubility and lipophilic nature, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment. A screening evaluation of leaching potential of a typical potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM1). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at depths of 1 and 2 meters are essentially zero (much less than 0.001 parts per billion). Therefore, EPA concludes that residues are not expected to occur in drinking water.

i. *Acute exposure and risk.* Acute drinking water exposure is estimated for the US population to be 0.000039 mg/kg/day with an MOE of 51,743. For Non-nursing infants less than 1 year old the exposure is 0.000074 with and MOE of 27,042.

ii. *Chronic exposure and risk.* Chronic drinking water exposure is estimated for the US population to be 0.000001 mg/kg/day and for the non-nursing infants 0.000005 mg/kg/day. Zero percent of the RfD is occupied by both population groups.

3. *From non-dietary exposure.* Esfenvalerate is registered for non-crop uses including spray treatments in and around commercial and residential areas, treatments for control of ectoparasites on pets, home care products including foggers, pressurized sprays, crack and crevice treatments, lawn and garden sprays, and pet and pet bedding sprays. For the non-agricultural products, the very low amounts of active ingredient they contain, combined with the low vapor pressure (1.5×10^{-9} mm Mercury at 25° C.) and low dermal penetration, would result in minimal inhalation and dermal exposure.

Individual non-dietary risk exposure analyses were conducted using a flea infestation scenario that included pet spray, carpet and room treatment, and lawn care, respectively.

Short- and intermediate-term exposure and risk. The total aggregate non-dietary exposure including lawn, carpet, and pet uses (mg/kg/day) are: 0.000023 for adults; 0.00129 for children aged 1–6 years; and 0.00138 for infants less than one year old.

It can be concluded that the potential non-dietary exposure for esfenvalerate are associated with substantial margins of safety.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk

assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Although esfenvalerate is similar to other members of the synthetic pyrethroid class of insecticides, EPA does not have, at this time, available data to determine whether esfenvalerate has a common method of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, esfenvalerate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that esfenvalerate has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and drinking water. The potential acute exposure from food and drinking water to the overall US population provides an acute dietary exposure of 0.011756 mg/kg/day with an MOE of 170. This acute dietary exposure estimate is considered conservative, using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to esfenvalerate from food and drinking water will utilize 1.9% of the RfD for the U.S. population based on a dietary exposure of 0.000377 mg/kg/day. The major identifiable subgroup with the highest aggregate exposure are children 1 - 6 years old (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the Rfd represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. The potential short- and intermediate-term aggregate risk for the U.S. population is an exposure of 0.0082 mg/kg/day with an MOE of 244.

EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to esfenvalerate residues.

E. Aggregate Cancer Risk for U.S. Population

Esfenvalerate is classified as a Group E carcinogen - no evidence of carcinogenicity in rats or mice. Therefore, a carcinogenicity risk analysis is not required.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children.*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of esfenvalerate, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In both prenatal developmental toxicity studies in rats and rabbits, there is no evidence of developmental toxicity at a dose up to 20 mg/kg/day. Maternal clinical neurotoxicity (based on behavioral and central nervous system clinical signs) was observed at a dose as low as 2.5 or 3.0 mg/kg/day for rats and rabbits respectively. The maternal NOEL was 2.0 mg/kg/day.

iii. *Reproductive toxicity study.* In the two-generation reproduction study in rats, offspring toxicity was observed only at dietary levels which were also found to be toxic to parental animals. The LOEL was 5.1 mg/kg/day based on decrease in mean body weights of females and increased incidence of dermal lesions. The NOEL for parental systemic toxicity was not determined. Effects on the offspring, including decreased pup weights in both generations during early and/or late lactation, decreased litter size, and increased incidence of subcutaneous hemorrhage, were observed at dietary levels of 6.70 mg/kg/day and above, with a NOEL of 5.1 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* There is no evidence of additional sensitivity to young rats or rabbits following pre- or postnatal exposure to esfenvalerate.

v. *Conclusion.* Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* The potential acute exposure from food and drinking water to the most sensitive population subgroup, children 1–6 years old is 0.019477 mg/kg/day with an MOE of 103. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to esfenvalerate from food and drinking water will utilize 4.6% of the RfD for children 1–6 years old, the most sensitive population subgroup based on a dietary exposure of 0.000912 mg/kg/day. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

4. Short- or intermediate-term risk. EPA has concluded that potential short- or intermediate -term aggregate exposure of esfenvalerate from chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure to children (1–6 years old) is 0.0113 mg/kg/day with an MOE of 177. For infants

(less than 1 year old) the exposure is 0.0098 mg/kg/day with an MOE of 204.

EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to esfenvalerate residues.

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants and animals is adequately defined. EPA has concluded that the qualitative nature of the residue is the same for both fenvalerate and esfenvalerate. The residue to be regulated is fenvalerate: the S,S; R,S; S,R; and R,R isomers.

B. Analytical Enforcement Methodology

There is a practical analytical method utilizing electron-capture gas chromatography with nitrogen phosphorous detection available for enforcement with a limit of detection that allows monitoring food with residues at or above tolerance levels. The limit of detection for updated method is the same as that of the current PAM II, which is 0.01 ppm.

C. Magnitude of Residues

Tolerances are based on the sum of all isomers of fenvalerate. Fenvalerate is a racemic mixture of four isomers (about 25% each). This product was registered as Pydrin . However since 1992, an S,S-isomer enriched formulation, Asana® (esfenvalerate), has been the only fenvalerate formulation sold in the U.S. for agricultural use. since the S,S-isomer is the insecticidally active isomer, the use rate for Asana®is four times lower than that for Pydrin®. A petition is pending (PP 4F4329), to convert tolerances (still to be expressed as the sum of all isomers) based on the use rates for Asana®. Bridging residue studies have shown Asana®residues to be 3–4 times lower than Pydrin® residues.

EPA has established a tolerance of 0.2 ppm for fenvalerate on cottonseed. Magnitude of residue and processing studies support this tolerance.

D. International Residue Limits

Codex maximum residue levels (MRL's) have been established for residues of fenvalerate on a number of crops that also have U.S. tolerances. The Codex MRL for fenvalerate on cottonseed is in harmony with the U.S. tolerance.

As indicated in the Notice of Filing, there are small differences between the section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods to establish tolerances, calculate animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, the tolerances are established for residues of fenvalerate in cottonseed at 0.2 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 4– . However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300575] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch,

Information Resources and Services division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule removes time limitations for a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance/exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

40 CFR Part 185

Environmental protection, Food and additives, Pesticides and pest.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pest.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Divisision, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180 — [AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority : 21 U.S.C. 346a and 371.

b. Section 180.379 is amended as follows:

i. By adding a heading to paragraph (a), designating the text following the heading as paragraph (a)(1) and by revising the entry for cottonseed in the table to newly designated paragraph (a)(1).

ii. By redesignating paragraph (b) as paragraph (c).

iii. By adding a paragraph heading to newly designated paragraph (c).

iv. By adding and reserving new paragraph (b) and (d) with paragraph headings.

The additions and amendments to § 180.379 read as follows:

§ 180.379 Cyano-(3-phenoxyphenyl)methyl-4-chloro-α-(1-methylethyl) benzeneacetate; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide Cyano-(3-phenoxyphenyl)methyl-4-chloro-α-(1-methylethyl) benzeneacetate in or on the following raw agricultural commodities:

Commodity	Parts per million
* * *	* *
cottonseed	0.2
* * *	* *

* * * * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* * * *

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185 — [AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority : 21 U.S.C. 346a and 348.

§ 185.1300 [Removed]

b. Section 185.1300 is amended by transferring paragraph (a) introductory text, (a)(1), (a)(2), (a)(3), and (a)(4) to § 180.379 and redesignating them as paragraphs (a)(2), (a)(2)(i), (a)(2)(ii), (a)(2)(iii) and (a)(2)(iv); the remainder of § 185.1300 is removed.

PART 186 — [AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority : 21 U.S.C. 342, 348 and 701.

§ 186.1300 [Removed]

b. Section 186.1300 is amended by transferring the text to § 180.379 and redesignating it as paragraph (a)(3) and § 186.1300 is removed.

[FR Doc. 97–31099 Filed 11–25–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300580; FRL–5755–1]

RIN 2070–AB78

Fenpropathrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpropathrin in or on cottonseed at 1.0 parts per million (ppm), peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by products and eggs at 0.05 ppm, and in the processed products cottonseed oil at 3.0 ppm. It also removes time limitations for tolerances for residues of fenpropathrin on the same commodities that expire on November 15, 1997. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

In addition, this regulation removes a feed additive tolerance for cottonseed hulls at 2.0 ppm. Originally, a feed additive tolerance existed for cottonseed soapstock at 2.0 ppm. In the November 14, 1994 **Federal Register** (59 FR 56454), which extended the time-limitation for these tolerances, the Agency inadvertently changed the expression from cottonseed soapstock to cottonseed hulls. Because a tolerance for cottonseed hulls was never intended, the Agency is removing the tolerance with this regulation. Also, the Agency no longer considers cottonseed soapstock to be a significant feed commodity. Under present residue chemistry guidelines, a tolerance for cottonseed soapstock is no longer required. Therefore, with this regulation, the tolerance for cottonseed soapstock is also removed.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before Jnauary 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300580], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300580], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300580]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Beth Edwards, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5400, e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On April 14, 1993, EPA established time-limited tolerances under section 408 and 409 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of fenpropathrin on cottonseed; meat, meat byproducts, and fat of cattle, goats, hogs, horses, poultry, and sheep; milk fat; eggs; a food additive tolerance in or on cottonseed oil; and a feed additive tolerance in or on cottonseed soapstock (58 FR 19357). On September 27, 1995, EPA established time-limited tolerances for residues of fenpropathrin on strawberries and tomatoes (60 FR 49793)(FRL–4979–1). On July 31, 1996, EPA established time-limited tolerances for residues of fenpropathrin on peanut hay and nutmeat (61 FR 39887)(FRL–5385–1). These tolerances expire on November 15, 1997. Valent U.S.A., on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide fenpropathrin in the commodities mentioned above be removed based on environmental effects data that they had submitted as a condition of the registration. Valent U.S.A. also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of September 25, 1997 (62 FR 50337)(FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 2F4144, 3F4186, and 4F4327) for tolerances by Valent U.S.A. Corporation, 1333 North California Blvd., Walnut Creek, CA 94596–8025. This notice included a summary of the petitions prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.466 be amended by removing the time limitation for tolerances for residues of the insecticide and pyrethroid fenpropathrin, in or on cottonseed at 1.0 parts per million (ppm), peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by-products and eggs at 0.05 ppm, and in the processed products cottonseed oil at 3.0 ppm and cottonseed soapstock at 2.0 ppm.

The basis for time-limited tolerances that expire November 15, 1997 was given in the October 20, 1993 issue of the **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage

pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity database, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources, (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated

considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of fenpropathrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for residues of fenpropathrin on cottonseed at 1.0 parts per million (ppm), peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by-products and eggs at 0.05 ppm, and in the processed product cottonseed oil at 3.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fenpropathrin are discussed below.

1. Acute toxicity studies with technical fenpropathrin: Oral LD_{50} in the rat is 54.0 milligram/kilogram (mg/kg) for males and 48.5 (mg/kg) for females - Toxicity Category I; dermal LD_{50} is 1,600 mg/kg for males and 870 mg/kg for females - Category II; acute inhalation (impossible to generate sufficient test article vapor or aerosol to elicit toxicity) - Category IV; primary eye irritation (no corneal involvement, mild iris and conjunctival irritation) - Category III; and primary dermal irritation (no irritation) - Category IV. Fenpropathrin is not a sensitizer.

2. In a subchronic oral toxicity study, rats were dosed at concentrations of 0, 3, 30, 100, 300, or 600 ppm in the diet. The lowest effect level (LEL) is 600 ppm (30 mg/kg/day) based on body weight reduction (female), body tremors, and increased brain (female) and kidney (male) weights. The NOEL is 300 ppm (15 mg/kg/day).

3. In a subchronic oral toxicity study, dogs were dosed at concentrations of 0, 250, 500, or 1,000 ppm in the diet. A 1,000 ppm dog was sacrificed moribund during the third week after having tremors and showing other signs of poisoning caused by the test article. Because of this death, the dose for this group was reduced to 750 ppm for the remainder of the study. The LOEL is 750 ppm (18.8 mg/kg/day) based on tremors. The NOEL is 500 ppm (12.5 mg/kg/day).

4. In a 21–day dermal toxicity study, rabbits were dosed 5 days/week for 3 weeks on abraded or unabraded skin at doses of 0, 500, 1,200, or 3,000 mg/kg/day. There were no dose-related effects on body weight, food consumption, clinical pathology, gross pathology, or organ weights. Trace or mild inflammatory cell infiltration was seen in the intact and abraded skin in all groups, including controls, and was attributed to the test article. The systemic NOEL is > 3,000 mg/kg/day. Local irritation only.

Although a 21–day dermal toxicity study in rabbits is available the Agency has determined that rats are the most sensitive species to ascertain the dermal toxicity potential of fenpropathrin. Therefore, the lack of a 21–day dermal study in rats is data gap. This study will be required under a special Data-Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data to support these tolerances and these additional studies are not expected to significantly change the risk assessment.

5. In a 1–year feeding study, dogs were dosed at 0, 100, 250, or 750 ppm in the diet. The systemic LEL is 250 ppm (6.25 mg/kg/day) based on tremors in all dogs. The neurologic NOEL is 100 ppm (2.5 mg/kg/day); the systemic NOEL is 100 ppm (2.5 mg/kg/day).

6. In a chronic feeding/carcinogenicity study, rats were dosed at 0, 50, 150, 450, or 600 ppm in the diet (0, 1.93, 5.71, 17.06, or 22.80 mg/kg/day in males, and 0, 2.43, 7.23, 19.45, or 23.98 mg/kg/day in females). There was no evidence of carcinogenicity at any dose up to and including 600 ppm (22.80 and 23.98 mg/kg/day in males and females, respectively). The systemic NOEL (male) is 450 ppm (17.06 mg/kg/day). The systemic NOEL (female) is 150 ppm (7.23 mg/kg/day); systemic LEL (male) is 600 ppm highest dose tested (HDT); 22.80 mg/kg/day) based on increased mortality, body tremors, increased pituitary, kidney, and adrenal weights. The systemic LEL (female) is 450 ppm (19.45 mg/kg/day) based on increased mortality and body tremors.

7. In a chronic feeding/carcinogenicity study, mice were dosed at 0, 40, 150, or 600 ppm in the feed (0, 3.9, 13.7, or 56.0 mg/kg/day in males, and 0, 4.2, 16.2, or 65.2 mg/kg/day in females). As expected, mortality was highest during the final quarter of the study, but the incidence was similar in all dosed and control groups. No other indications of toxicity or carcinogenicity were seen. The systemic NOEL is > 600 ppm (HDT; male/female, 56.0/65.2 mg/kg/day).

8. In a developmental toxicity study in rats, pregnant female rats were dosed by gavage on gestation days 6–15 at 0 (corn oil control) 0.4, 1.5, 2.0, 3.0, 6.0, or 10.0 mg/kg/day. The maternal no observed adverse effect level (NOAEL) is 6 mg/kg/day; maternal LEL is 10 mg/kg/day based on death, moribundity, ataxia, sensitivity to external stimuli, spastic jumping, tremors, prostration, convulsions, hunched posture, squinted eyes, chromodacryorrhea, and

lacrimation; developmental NOAEL is > 10 mg/kg/day.

9. In a developmental toxicity study in rabbits, pregnant female New Zealand rabbits were dosed by gavage on gestation days 7 through 19 at 0, 4, 12, or 36 mg/kg/day. Maternal NOEL is 4 mg/kg/day; maternal LEL is 12 mg/kg/day based on grooming, anorexia, flicking of the forepaws; developmental NOEL is > 36 mg/kg/day (HDT).

10. A 3-generation reproduction study was performed in rats. Rats were dosed with fenpropathrin at concentrations of 0, 40, 120, or 360 ppm (0, 3.0, 8.9, or 26.9 mg/kg/day in males; 0, 3.4, 10.1, or 32.0 mg/kg/day in females, respectively). Parents (male/female): systemic NOEL = 40 ppm (3.0/3.4 mg/kg/day); systemic LEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors with spasmodic muscle twitches, increased sensitivity and maternal lethality; reproductive NOEL = 120 ppm (8.9/10.1 mg/kg/day); reproductive LEL = 360 ppm (26.9/32.0 mg/kg/day) based on decreased mean F_{1B} pup weight, increased F_{2B} loss. Pups (male/female): developmental NOEL = 40 ppm (3.0/3.4 mg/kg/day); developmental LEL = 120 ppm (8.9/10.1 mg/kg/day) based on body tremors, increased mortality.

11. Studies on gene mutation and other genotoxic effects: An Ames Assay was negative for *Salmonella* TA98, TA100, TA1535, TA1537, and TA1538; and *E. coli* WP2uvrA (trp-) with or without metabolic activation; Sister Chromosome Exchange in CHO-K1 Cells - there were no increases in sister chromatid exchanges seen in the CHO-K1 cells treated with S–33206 or the DMSO vehicle; Cytogenetics *in vitro* (CHO/CA) - negative for chromosome aberrations (CA) in Chinese hamster ovary (CHO) cells exposed *in vitro* to toxic doses (≧ 30 µg/ml) without activation; and to limit of solubility (1,000 µg/ml) with activation; *In Vitro* Assay in Mammalian Cells - equivocal results - of no concern; DNA Damage/Repair in *Bacillus subtilis* - not mutagenic or showing evidence of DNA damage at ≤ 5,000 µg/paper disk.

12. In a metabolism study in rats, animals were dosed with radiolabelled S–3206 fenpropathrin by three protocols. They were dosed with S–3206 radiolabelled on either the alcohol or acid portion of the molecule (i.e. [alcohol-^{14}C]–S–3206 or [acid-^{14}C]–S–3206). In Experiment I, rats received 14 daily oral low-doses of 2.5 mg/kg/day of unlabelled S–3206 followed by a 15th dose of either the alcohol or acid radiolabelled S–3206. In Experiments II and III, groups of rats received a single dose of either of the two radiolabelled test articles at 2.5 mg/kg (II) or 25 mg/kg (III). No clinical signs were seen in any rats.

The major biotransformations included oxidation at the methyl group of the acid moiety, hydroxylation at the 4′-position of the alcohol moiety, cleavage of the ester linkage, and conjugation with sulfuric acid or glucuronic acid.

Four metabolites were found and characterized in the urine of rats dosed with alcohol-radiolabel. The major metabolites were the sulfate conjugate of 3-(4′-hydroxyphenoxy)benzoic acid and 3-phenoxybenzoic acid (22–44% and 3–9% of the administered dose, respectively). Eight metabolites were found in the urine of rats dosed with acid-radiolabel, but only four were characterized. The major urinary metabolites of the acid-labeled fenpropathrin were TMPA-glucuronic acid and TMPA-CH_2OH (11–26% and 6–10% of the administered dose, respectively). None of the parent chemical was found in urine.

The major elimination products in the feces included the parent chemical (13–34% of the administered dose) and four metabolites. The fecal metabolites (and the percentage of administered dose) included CH_2OH-fenpropathrin (9–20%), 4′-OH-fenpropathrin (4–11%), COOH-fenpropathrin (2–7%), and 4′-OH-CH_2OH-fenpropathrin (2–7%).

13. No neurological studies are available. These studies will be required under a special Data Call-In letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change this risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of a NOEL of 6.0 mg/kg/day based on clinical signs of neurotoxicity on day one of dosing in dams from developmental toxicity study in rats.

2. *Short - and intermediate - term toxicity.* toxicity. A short- and intermediate-term risk assessment is not required for fenpropathrin. There was no systemic toxicity at 3,000 mg/kg/day in a 21–day study in rabbits.

3. *Chronic toxicity*. EPA has established the RfD for fenpropathrin at 0.025 mg/kg/day. This RfD is based on the 1–year toxicity study in dogs with a NOEL of 2.5 mg/kg/day (tremors) with an uncertainty factor of 100 to account for both interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in any of the chronic studies. Fenpropathrin has not yet been classified.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.466) for the residues of fenpropathrin, in or on a variety of raw agricultural commodities. These are cottonseed (1.0 ppm), strawberries (2.0 ppm), and tomatoes (0.6 ppm); in the fat of cattle, goats, hogs, horses, and sheep at 1.0 ppm; in the meat of cattle, goats, hogs, horses and sheep at 0.1 ppm; in the meat byproducts of cattle, goats, hogs, horses and sheep at 0.1 ppm; milkfat at 2.0 ppm (reflecting 0.08 ppm in whole milk); and poultry fat, meat, meat byproducts, and eggs at 0.05 ppm. A food additive tolerance for residues of fenpropathrin on cottonseed oil at 3.0 ppm has been established under 40 CFR 185.3225. A feed additive tolerance for residues of fenpropathrin on cottonseed soapstock at 2.0 ppm has been established under 40 CFR 186.3225. Risk assessments were conducted by EPA to assess dietary exposures and risks from fenpropathrin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The acute dietary exposure assessment used Monte Carlo modeling incorporating anticipated residues and percent crop treated refinements. The acute dietary Margin of Exposure (MOE) calculated at the 99.9th percentile for the most highly exposed population subgroup (children 1–6 years old) is 803. The MOE calculated at the 99.9th percentile for the general U.S. population is 2,108. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater. Therefore, the acute dietary risk assessment for fenpropathrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk*. The RfD used for the chronic dietary analysis is 0.025 mg/kg/day. The chronic dietary exposure assessment used anticipated residues and percent crop treated information. The risk assessment resulted in use of 0.1% of the RfD for the U.S. population and 0.2% of the most highly exposed population subgroup (non-Hispanic other than black or white).

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA is June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent of crop treated refinements. The chronic dietary risk assessment used

percent crop treated information and anticipated residues.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a timeframe it deems appropriate. Section 408(b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for fenpropathrin were derived from Federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water.* Since fenpropathrin is applied outdoors to growing agricultural crops, the potential exists for fenpropathrin or its metabolites to reach ground or surface water that may be used for drinking water. Fenpropathrin is extremely insoluble in water (14 ppb), with a high octanol/water partitioning coefficient (K_{OW} 1.19×10^5) and a relatively short soil half-life for parent and environmental metabolites. Estimates of fenpropathrin drinking water concentrations were generated with the PRZM I and EXAMS computer models. Based on these analyses, the contribution of water to the dietary risk estimate is negligible. Therefore, EPA concludes that together these data indicate that residues are not expected to occur in drinking water.

i. *Acute exposure and risk.* The acute drinking water MOEs, calculated at the 99.9th percentile, are 5,756 and 3,007 for the U.S. population and non-nursing infants < 1 year old, respectively.

ii. *Chronic exposure and risk.* The chronic drinking water risk assessment resulted in use of 0.3% and 1.6% of the RfD for the U.S. population and non-nursing infants < 1 year old, respectively.

3. *From non-occupational non-dietary exposure.* Fenpropathrin has no other uses, such as indoor pest control, homeowner or turf, that could lead to unique, enhanced exposures.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether fenpropathrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fenpropathrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fenpropathrin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and water. The acute aggregate MOE calculated at the 99.9th percentile for the U.S. population is 1,543. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency concludes that there is a reasonable certainty that no harm will result from acute aggregate exposure to fenpropathrin residues in food and drinking water.

2. *Chronic risk.* Using the Anticipated Residue Contribution (ARC) exposure assumptions described above, EPA has concluded that aggregate exposure to fenpropathrin from food and water will utilize 0.4% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants < 1 year old. EPA generally has no concern for exposures below 100% of the RfD

because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fenpropathrin residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Based on fenpropathrin not being registered for residential uses, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern (MOE less than 100), and that there is a reasonable certainty that no harm will result from aggregate exposure to fenpropathrin residues.

E. Aggregate Cancer Risk for U.S. Population

This chemical has not yet been classified; however, there is no evidence of carcinogenicity in any of the chronic studies. EPA believes that this pesticide does not pose a significant cancer risk.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of fenpropathrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 3-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* See Toxicological Profile in Unit II. A. of this preamble.

iii. *Reproductive toxicity studies.* See Toxicological Profile in Unit II. A. of this preamble.

iv. *Pre- and post-natal sensitivity.* There is no evidence of additional sensitivity to young rats or rabbits following pre- or postnatal exposure to fenpropathrin.

v. *Conclusion.*The data base related to pre- and post-natal sensitivity is complete. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* The aggregate acute MOE calculated at the 99.9th percentile for children age 1–6 is 719. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to fenpropathrin through food and drinking water.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to fenpropathrin from food and water will utilize 1.6% of the RfD for non-nursing infants. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fenpropathrin residues.

4. *Short- or intermediate-term risk.* Based on fenpropathrin not being registered for residential uses, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is a reasonable certainty that no harm will result.

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism In Plants and Animals

Metabolism studies have been conducted on pinto beans, tomatoes, apples, cotton and tomato. In the earlier studies, the parent compound was found to be the major residue; remaining residues were characterized but not identified. The apple metabolism study was deemed fully adequate because the majority of the residue was the parent compound. The cotton temporary tolerances were established with an expiration date because the petitioner had indicated that a new cotton metabolism study would be conducted to further elucidate the nature of radioactive residues in cotton commodities. In both recent plant metabolism studies, on cotton and tomatoes, it has been concluded that the residue of concern is the parent compound fenpropathrin per se.

Metabolism studies with goats and poultry dosed with radiolabeled fenpropathrin were submitted with PP7F03485/FAP7H05527. The majority of the residue in muscle, fat, and milk and eggs was found to be the parent compound, fenpropathrin. The residue in kidney and liver consisted mainly of various metabolites. Livestock metabolites, with the possible exception of TMPA lactone, have also been

identified in rat metabolism studies and their contributions to the overall toxicity of fenpropathrin have been considered. For the apple and pear tolerances, the levels of the metabolites in livestock were low enough not to be included in the tolerance expression.

B. Analytical Enforcement Methodology

Residues of fenpropathrin in peanut raw agricultural and processed commodities were determined using analytical method RM–22–4 Gas Chromatography with Electron Capture Detection (GC/ECD). An EPA trial of method RM–22–4 for fenpropathrin residues in/on apples and method RM–22A–1 for residues of fenpropathrin in meat and milk has been successfully conducted. In addition, recovery of fenpropathrin was tested through FDA multiresidue methods and fenpropathrin was found to be completely recovered by the PAM I Section 302 method (Luke method); thus a confirmatory method is available.

C. Magnitude of Residues

1. *Plant commodities—field trial studies*. For the purposes of dietary risk assessment, residue data generated from residue field trials conducted at maximum application rates and minimum pre-harvest intervals were used to estimate chronic and acute dietary exposure to potential residues of fenpropathrin. For chronic dietary exposure analyses, mean anticipated residue values were calculated, substituting one-half the limit of detection for those samples for which residues were reported as non-detectable. For acute dietary exposure analyses, the entire range of field trial residue data which reflected the current labeled maximum rate and minimum PHI for single serving commodities were used (Tier 3 modeling, as outlined in ''Final Office Policy for Performing Acute Dietary Exposure Assessment,'' D. Edwards, June 13, 1996.) For those foods considered to be blended, mean field trial residues were calculated, substituting the full limit of detection for those samples for which residues were reported as non-detectable (Tier 2 modeling) used residue distributions from field trial studies.

2. *Animal commodities*. For chronic dietary analyses, dietary burdens were calculated using mean field trial residues, adjusted for percent of crop treated and applying appropriate processing factors, for all feed items. For acute dietary analyses, mean field trial residues (with no adjustment for percent of crop treated) were used for those feed items that are processed or blended, while the highest field trial residue values were used for the remaining feed items.

The secondary residue levels in animal tissues were then calculated by multiplying the total dietary burden by the tissue-to-feed ratio calculated from the lactating ruminant or laying hen feeding studies.

D. International Residue Limits

Codex Maximum Residue Limits (MRLs) for fenpropathrin have been established which are in harmony with the U.S. tolerances for cottonseed (1.0 ppm). Codex MRLs have been established which exceed the U.S. tolerances for cattle meat byproducts (0.05 vs. 0.02 ppm), cattle meat (0.5 vs. 0.02 ppm), whole milk (0.1 vs 0.02 ppm), and tomatoes (1.0 vs. 0.6 ppm). Codex MRLs have been established which are below their U.S. counterparts for eggs (0.01 vs 0.02 ppm) and poultry meat byproducts (0.01 vs. 0.02 ppm).

There are differences between the section 408 tolerances and the Codex MRL values for secondary residues in animal products. These differences are mainly caused by differences in the methods used to calculate animal feed dietary exposure. The only substantial difference between the U.S. tolerance and the Codex MRL value is for tomatoes. The JMPR (Joint Meeting on Pesticide Residues) reviewer required that the MRL exceed the highest field residue, and rounded to unity. The EPA reviewer agreed with Valent that one set of field residue samples was possibly comprised by the presence of a high rate processing treatment nearby. High outliers were ignored, and the tolerance was set at 0.6 ppm.

No Canadian MRLs have been established for residues of fenpropathrin. Mexico has established a tolerance for residues of fenpropathrin on cottonseed (1.0 ppm) which is in harmony with the U.S. tolerance.

IV. Conclusion

Therefore, these tolerances are established for residues of fenpropathrin in cottonseed at 1.0 ppm, peanut nutmeat at 0.01 ppm, peanut vine hay at 20 ppm, strawberry at 2.0 ppm, tomato at 0.6 ppm, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, fat of cattle, goats, hogs, horses and sheep at 1.0 ppm, milk fat (reflecting 0.08 ppm in whole milk) at 2.0 ppm, and poultry meat, fat, meat by-products and eggs at 0.05 ppm, and in the processed products cottonseed oil at 3.0 ppm.

In addition to the tolerances being amended, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerances that now appear in § 185.3225 with the tolerances in § 180.466 and is removing the tolerances under § 185.3225 and § 186.3225.

Originally, the tolerance under § 186.3225 was for cottonseed soapstock at 2.0 ppm. In the **Federal Register** of November 14, 1994 (59 FR 56454)(FRL–4919–3) which extended the time-limitation for these tolerances, the Agency inadvertently changed the expression from cottonseed soapstock to cottonseed hulls. Because a tolerance for cottonseed hulls was never intended, the Agency is removing the tolerance by this regulation. Also, the Agency no longer considers cottonseed soapstock as a significant feed commodity. Under present residue chemistry guidelines, a tolerance for cottonseed soapstock is no longer required. Therefore, with this regulation, the tolerance for cottonseed soapstock is also removed.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the

material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Records and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300580] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* , or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Feed additives, Pesticides and pests.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.466, is revised to read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the pesticide chemical fenpropathrin (alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetramethylcyclopropanecarboxylate) in or on the following agricultural commodities:

Commodity	Parts per million
Cattle, fat	1.0
Cattle, mbyp	0.1
Cattle, meat	0.1
Cottonseed	1.0
Cottonseed, oil	3.0
Eggs	0.05
Goats, fat	1.0
Goats, mbyp	0.1
Goats, meat	0.1
Hogs, fat	1.0
Hogs, mbyp	0.1
Hogs, meat	0.1
Horses, fat	1.0
Horses, mbyp	0.1
Horses, meat	0.1
Milkfat (reflecting 0.08 ppm in whole milk).	2.0
Peanut, hay	20.0
Peanut, nutmeat	0.01
Poultry, fat	0.05

Commodity	Parts per million
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	1.0
Sheep, mbyp	0.1
Sheep, meat	0.1
Strawberry	2.0
Tomato	0.6

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.3225 [Removed]

b. By removing § 185.3225 *Fenpropathrin*.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348 and 701.

§ 186.3225 [Removed]

b. By removing § 186.3225 *Fenpropathrin*.

[FR Doc. 97–31102 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPTS–50621C; FRL–5757–6]

RIN 2070–AB27

Dipropylene Glycol Dimethyl Ether; Final Significant New Use Rule; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: EPA issued a document (FR Doc. 97–29153) in the **Federal Register** of November 4, 1997, adding a significant new use rule (SNUR) for the chemical substance described as dipropylene glycol dimethyl ether (DGDE), which was the subject of premanufacture notice (PMN) P–93–507. The CAS No. listed for DGDE in the rule was incorrect. This document corrects that CAS No.

DATES: Effective on November 26, 1997.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a document (FR Doc. 97–29153) in the **Federal Register** of November 4, 1997 (62 FR 59579) (FRL–5745–1), stating that the CAS No. for DGDE was 11109–77–4. This document correctly changes the CAS No. from 11109–77–4 to 111109–77–4.

On page 59583, in the first column, in § 721.3550, in paragraph (a), in the fifth line, ''CAS No. 11109–77–4'' should read ''CAS No. 111109–77–4''.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 19, 1997.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 97–31130 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF DEFENSE

48 CFR Part 231

[DFARS Case 97–D312]

Defense Federal Acquisition Regulation Supplement; Allowability of Costs for Restructuring Bonuses

AGENCY: Department of Defense (DoD).

ACTION: Interim rule with request for comments.

SUMMARY: The Director of Defense Procurement has issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to prohibit use of DoD funds to reimburse a contractor for costs paid by the contractor to an employee for a bonus or other payment in excess of the normal salary paid to the employee, when such payment is part of restructuring costs associated with a business combination. This rule implements Section 8083 of the Fiscal Year 1998 Defense Appropriations Act.

DATES: Effective date: November 26, 1997.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before January 26, 1998, to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments to: Defense Acquisition Regulations Council, Attn: Ms. Sandra G. Haberlin, PDUSD (A&T) DP (DAR), IMB 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telefax number (703) 602–0350.

E-mail comments submitted over the Internet should be addressed to: dfars@acq.osd.mil

Please cite DFARS Case 97–D312 in all correspondence related to this issue. E-mail comments should cite DFARS Case 97–D312 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra G. Haberlin, (703) 602–0131.

SUPPLEMENTARY INFORMATION:

A. Background

This interim rule amends paragraph (f) (1) of DFARS 231.205–6, Compensation for personal services, to implement Section 8083 of the Fiscal Year 1998 Defense Appropriations Act (Pub. L. 105–56). Section 8083 prohibits DoD from using fiscal year 1998 funds to reimburse a contractor for costs paid by the contractor to an employee for a bonus or other payments in excess of the normal salary paid by the contractor to the employee, when such payment is part of restructuring costs associated with a business combination. Similar provisions were contained in the Fiscal Year 1996 and Fiscal Year 1997 Defense Appropriations Acts (Pub. L. 104–61 and Pub. L. 104–208, respectively).

B. Regulatory Flexibility Act

The interim rule is not expected to have a significant economic impact on a substantial umber of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because most contracts awarded to small entities use simplified acquisition procedures or are awarded on a competitive, fixed-price basis, and do not require application of the cost principle contained in this rule. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subpart also will be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite 5 U.S.C. 601, *et seq.* (DFARS Case 97–D312), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the interim rule does not impose any information collection requirements that require Office of Management and Budget approval under 44 U.S.C. 3501, *et seq.*

D. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense that urgent and compelling reasons exist to publish an interim rule prior to affording the public an opportunity to comment. This action is necessary to implement Section 8083 of the Fiscal Year 1998 Defense Appropriations Act (Pub. L. 105–56), which was effective upon enactment on October 8, 1997. However, comments received in response to the publication of this interim rule will be considered in formulating the final rule.

List of Subjects in 48 CFR Part 231

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR part 231 is amended as follows:

1. The authority citation for 48 CFR Part 231 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 231—CONTRACT COST PRINCIPLES AND PROCEDURES

2. Section 231.205–6 is amended by revising paragraph (f)(1) to read as follows:

§ 231.205–6 Compensation for personal services.

(f)(1) In accordance with Section 8122 of Pub. L. 104–61, and similar sections in subsequent Defense appropriations acts, costs for bonuses or other payments in excess of the normal salary paid by the contractor to an employee, that are part of restructuring costs associated with a business combination, are unallowable under DoD contracts funded by fiscal year 1996 or subsequent appropriations. This limitation does not apply to severance payments or early retirement incentive payments. (See 231.205–70(b) for the definitions of ''business combination'' and ''restructuring costs.'')

[FR Doc. 97–31113 Filed 11–25–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE47

Endangered and Threatened Wildlife and Plants; Emergency Rule To Establish an Additional Manatee Sanctuary in Kings Bay, Crystal River, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Emergency rule.

SUMMARY: This emergency rule establishes an additional West Indian manatee (*Trichecus manatus*) sanctuary in Citrus County, Florida, adjacent to Kings Bay/Crystal River at the confluence of the Three Sisters Spring run with a residential canal, and prohibits all waterborne activities in the sanctuary for a period of 120 days. This emergency action will help prevent the taking of manatees by harassment resulting from waterborne activities during upcoming winter months. This increases the number of sanctuaries in Kings Bay to seven and has been initiated to prevent harassment from increasing public use at this site. A proposed rule to establish this sanctuary is published elsewhere in today's **Federal Register**. The proposed rule provides for public comment and a hearing (if requested). The emergency action is effective for 120 days and is taken under the authority of the Endangered Species Act of 1973, as amended, and the Marine Mammal Protection Act of 1972, as amended.

DATES: Effective November 24, 1997, through March 23, 1998, unless terminated sooner by publication in the **Federal Register**. In accordance with 50 CFR 17.106, the effective date for this action was established through a legal notice published in the St. Petersburg Times, Citrus County Edition and the Citrus County Chronicle on November 24, 1997.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours at the Jacksonville Field Office, U.S. Fish and Wildlife Service, 6620 Southpoint Drive South, Suite 310, Jacksonville, Florida 32216–0912.

FOR FURTHER INFORMATION CONTACT: Robert O. Turner at the above address, (904/232–2580 ext. 117); or Vance Eaddy, Senior Resident Agent, U.S. Fish and Wildlife Service, 9721 Executive Center Drive, Suite 206, St. Petersburg, Florida 33702, (813/570–5398).

SUPPLEMENTARY INFORMATION:

Background

Crystal River is a tidal river on the west coast of Florida. Forming the headwaters of Crystal River is Kings Bay, a lake-like body of water fed by numerous freshwater springs. The Kings Bay springs constitute one of the most important natural warm-water refuges for manatees, a federally listed endangered species. More than 250 animals may seek refuge in the bay's warm waters during winter cold periods. With the winter presence of manatees and its sheltered, warm and clear waters, Kings Bay also attracts large numbers of waterborne users (boaters, recreational divers, snorkelers, and swimmers) most of whom seek out manatees for a close viewing experience. The influx of visitors, primarily there to see and interact with manatees, provides a major economic impact to the Crystal River community.

Large aggregations of manatees apparently did not exist in Kings Bay until recent times (Beeler and O'Shea 1988). The first careful counts were made in the late 1960's. Since then manatee numbers have increased significantly. In 1967–1968 Hartman (1979) counted 38 animals. By 1981–1982, the maximum winter count increased to 114 animals (Powell and Rathbun 1984), and in December 1994 the count was 271 (U.S. Fish and Wildlife Service, unpublished data). Both births and immigration of animals from other areas have contributed to the increases in manatee numbers at Crystal River.

The Second Revision of the Florida Manatee Recovery Plan (U.S. Fish and Wildlife Service 1995) identifies the need to minimize disturbance and harassment of manatees in the wild. This concern for the welfare of manatees in Kings Bay has resulted in the establishment of a series of sanctuary areas to protect manatees from any potential negative impacts of human activities. The first three sanctuaries were created in 1980, encompassing a total of about 10 acres in Kings Bay. These were closed to all human access each winter from November 15 to March 31 and provided manatees with areas where they could retreat from waterborne users. To better administer and protect the bay's manatee habitat, the Service purchased several islands associated with the sanctuaries in 1983 and established the Crystal River National Wildlife Refuge. During the 1980's, the number of manatees and divers increased steadily, resulting in the need for additional manatee sanctuaries. In 1994, the Service

established three additional sanctuaries and expanded an existing sanctuary. The six sanctuaries now encompass approximately 39 acres within Kings Bay.

The Kings Bay manatee sanctuary system provides significant protection to the more than 250 manatees that use this area as a winter warm-water refuge. With the increasing number of manatees using Kings Bay and an increasing number of recreational divers and snorkelers coming to Crystal River to seek close encounters with manatees, another problem area outside the existing sanctuary system has been identified.

Since the establishment of the three most recent sanctuaries, reports of waterborne users harassing manatees and causing manatees to leave the Three Sisters Spring run area has been documented by researchers, refuge staff and concerned citizens. The Save the Manatee Club and the Marine Mammal Commission have urged the Service to act to protect manatees utilizing the Three Sisters Spring run area. Dive shop operators have acknowledged that there is a manatee harassment problem in the area of the proposed sanctuary.

Prior to last winter, the Service and local interest groups met separately with local dive shop owners to discuss the harassment issue and the feasibility of establishing a new sanctuary. There was a consensus that a sanctuary was needed and that it would be more effective if it was developed through a local city or county ordinance. Representatives of each of the local dive shops wrote letters recognizing the need for a small sanctuary near Three Sisters Spring and recommended that the regulations be promulgated locally. Local efforts have been made to address the problem and the Service will continue to encourage local officials to create a permanent refuge. However, the Service is taking this interim measure to protect manatees, already beginning to seek the warmer waters of Kings Bay springs, from harassment.

The Service funded a manatee and human interaction study at Three Sisters Spring (January 23–February 17, 1997) which confirmed that harassment was occurring and documented instances in which manatees left the warm waters at the confluence of the spring run and the residential canal when divers, snorkelers and/or swimmers arrived (Wooding, 1997). The Service is concerned that these animals may be leaving earlier than if they were left undisturbed.

Reasons for Emergency Determination

In deciding to implement this rule, the Service has carefully assessed the best available information, and conducted a study to evaluate manatee and human interactions at Three Sisters Spring. The study clearly documented a manatee harassment problem at the site. With more than 250 manatees utilizing the sanctuary system along with an increasing number of visitors who seek close encounters with manatees, manatees are experiencing more frequent disturbance at Three Sisters Spring. Without sufficient space to rest, free from harassment, a significant proportion of the manatees depending upon the Kings Bay springs could be at considerable risk should they be driven away from essential warm-water areas. Based on this evaluation, the preferred appropriate action is to establish an additional sanctuary at the confluence of the Three Sisters Spring run and a residential canal in Kings Bay, Crystal River, Citrus County, Florida. At present, there is currently insufficient time to complete preparations for implementing a permanent sanctuary before cold weather arrives. Therefore, the Service is establishing a seventh manatee sanctuary on an emergency basis to provide maximum protection for manatees until a permanent sanctuary is put in place, either by a local ordinance or by final rule by the Service.

The authority to establish emergency manatee protection areas is provided by the Endangered Species Act and the Marine Mammal Protection Act, and is codified in 50 CFR, part 17, subpart J. Under subpart J, the Director may establish, by regulation, manatee protection areas whenever she determines there is substantial evidence that there is imminent danger of a taking (including harassment) of one or more manatees, and that such establishment is necessary to prevent such a taking.

The emergency sanctuary is located on the west side of the confluence of Three Sisters Spring run and the residential canal, Kings Bay, Crystal River, Citrus County, Florida. The sanctuary will be less than one quarter acre in size.

References Cited

Beeler, E.I. and T.J. O'Shea. 1988. Distribution and mortality of the West Indian manatee (*Trichechus manatus*) in southeastern United States: a compilation and review of recent information. Prepared by the Fish and Wildlife Service for the U.S. Army Corps of Engineers. U.S. Natl. Tech. Info. Serv., Springfield, Virginia PB 88–207 980/AS. 613.

Hartman, D.S. 1979. Ecology and behavior of the manatee (*Trichechus manatus*) in Florida. Am. Soc. Mamm. Spec. Pub. No. 5. 153 pp.

Powell, J.A. and G.B. Rathbun. 1984. Distribution and abundance of manatees along the northern coast of the Gulf of Mexico. Northeast Gulf Sci. 7:1–2.

Wooding, J. 1997. An assessment of manatee behavior relative to interactions with humans at Three Sisters Spring, Crystal River, Florida. A report submitted to the U.S. Fish and Wildlife Service, Jacksonville, Florida. 65 pp.

U.S. Fish and Wildlife Service. 1995. Florida Manatee Recovery Plan Second Revision. U.S. Fish and Wildlife Service, Atlanta, Georgia. 160 pp.

Author. The primary author of this emergency rule is Robert O. Turner, Manatee Coordinator (see **ADDRESSES** section).

Authority

The authority to establish manatee protection areas is provided by the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), as amended.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, the Service amends part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend section 17.108 by adding paragraph (a)(7) to read as follows:

§ 17.108 List of designated manatee protection areas.

(a) * * *

(7) A tract of submerged land on the west side of the confluence of Three Sisters Spring run and the residential canal off the eastern

shore of Kings Bay, Crystal River, lying in the northeast corner of Section 28, Township 18, South Range 17 East in Citrus County, Florida; containing less than one quarter acre.

* * * * *

Dated: November 20, 1997.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 97–31107 Filed 11–21–97; 3:41 pm]

BILLING CODE 4310–55–P

Proposed Rules

Federal Register
Vol. 62, No. 228
Wednesday, November 26, 1997

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–230–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300, A310, and A300–600 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Airbus Model A300, A310, and A300–600 series airplanes. This proposal would require inspections to detect cracking of the aft door frame area, and repair, if necessary. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to detect and correct cracks in the aft door frame area, which could result in reduced structural integrity and rapid decompression of the airplane.

DATES: Comments must be received by December 26, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–230–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–230–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–230–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Airbus Model A300, A310, and A300–600 series airplanes. The DGAC advises that, during scheduled inspections of in-service airplanes, 18 cases of stress corrosion cracks have been found at and between rivet holes on the inner and outer door frame flanges of frames 73A and 75A, and on the inner and outer flanges of the longeron at stringer 11. Such stress corrosion cracking, if not detected and corrected in a timely manner, could result in reduced structural integrity and possible rapid decompression of the airplane.

Explanation of Relevant Service Information

Airbus has issued Service Bulletins A300–53–303 (for Model A300 series airplanes); A310–53–2079 (for Model A310 series airplanes); and A300–53–6056 (for Model A300–600 series airplanes), all dated February 23, 1996. These service bulletins describe procedures for inspections to detect cracking of the aft door frame area, and repair, if necessary. In each of the referenced service bulletins, inspection procedures are provided for multiple locations around the aft door frame area. There are 7 locations specified for Model A300 and A310 series airplanes, and 3 locations specified for Model A300–600 series airplanes. Accomplishment of a permanent repair, as specified in these service bulletins, eliminates the need for the repetitive eddy current inspections for the area in which the permanent repair is accomplished.

The DGAC classified these service bulletins as mandatory and issued French airworthiness directive (CN) 96–135–199(B), dated July 17, 1996, in order to assure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are

certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletins described previously, except as discussed below.

Differences Between the Proposal and the related Service Bulletin

The proposed rule would differ from the Airbus service bulletins described previously in that, unlike certain repair times specified in the referenced service bulletins, this proposed AD would not permit further flight with cracks detected in the aft door frame area. Depending on the extent and location of the cracking, the service bulletins, in certain circumstances, provide for continued flight without immediate repair of the damaged area. The FAA has determined that, due to the safety implications and consequences associated with such cracking, all locations in the aft door frame area that are found to be cracked must be repaired prior to further flight.

Additionally, for cracks found in certain locations, the service bulletins specify that operators should contact Airbus for possible repair solutions. Unlike the procedures described in the service bulletins, this proposed AD would require that any repairs other than those specifically identified in the service bulletins be accomplished in accordance with a method approved by the FAA.

Cost Impact

The FAA estimates that 49 Airbus Model A300 and A310 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 25 work hours per airplane to accomplish the proposed inspections, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed inspections on U.S. operators of Model A300 and A310 series airplanes is estimated to be $73,500, or $1,500 per airplane.

The FAA estimates that 51 Airbus Model A300–600 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 18 work hours per airplane to accomplish the proposed inspections, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed inspections on U.S. operators of Model A300–600 series airplanes is estimated to be $55,080, or $1,080 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus Industrie: Docket 97–NM–230–AD.

Applicability: Model A300, A310, and A300–600 airplanes on which Airbus Modification 6924 has not been installed; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct cracks in the aft door frame area, which could result in reduced structural integrity and possible rapid decompression of the aircraft, accomplish the following:

(a) Prior to the accumulation of 10 years since date of manufacture, or within 12 months after the effective date of this AD, whichever occurs later: Except as provided by paragraphs (b) and (c) of this AD, accomplish a high frequency eddy current inspection to detect stress corrosion cracks in the aft door frame area, and perform the applicable corrective actions, in accordance with Airbus Service Bulletin A300–53–303, dated February 23, 1996 (for Model A300 series airplanes); A310–53–2079, dated February 23, 1996 (for Model A310 series airplanes); or A300–53–6056, dated February 23, 1996 (for Model A300–600 series airplanes); subsequently referred to as the applicable service bulletin. Thereafter, repeat the inspection at intervals not to exceed 5 years, in all areas not repaired permanently in accordance with the applicable service bulletin.

(b) If any crack is found during an inspection required by paragraph (a) of this AD, and the applicable service bulletin specifies to contact Airbus for an appropriate action: Prior to further flight, repair in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate.

(c) If any crack is found during an inspection required by paragraph (a) of this AD, and the applicable service bulletin specifies a compliance time other than ''prior to further flight'' for accomplishment of the repair: Accomplish the repair prior to further flight in accordance with the procedures specified in the applicable service bulletin.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in French airworthiness directive (CN) 96–135–199(B), dated July 17, 1996.

Issued in Renton, Washington, on November 19, 1997.

Stewart R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–31022 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–189–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Mystere Falcon 200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Dassault Model Mystere Falcon 200 series airplanes. This proposal would require reducing the life limit of the polyurethane foam used in the fuselage fuel tanks. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to ensure replacement of the polyurethane foam in the fuselage fuel tanks when it has reached its maximum life limit; polyurethane foam that is not replaced in a timely manner could result in fuel contamination or increased risk of explosion in the fuselage fuel tank.

DATES: Comments must be received by December 26, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–189–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Dassault Falcon Jet, Teterboro Airport, P.O. Box 2000, South Hackensack, New Jersey 07606. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–189–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–189–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on all Dassault Model Mystere Falcon 200 series airplanes. The DGAC advises that studies of aging airplanes conducted by Dassault have shown that, after 8 years, the characteristics of the polyurethane foam material used in the fuselage fuel tanks are no longer acceptable. The airplane maintenance manual originally called for replacement of the polyurethane foam within 10 years. However, based on the Dassault study, the life limit of the foam should be reduced to 8 years. If not replaced in a timely manner, the polyurethane foam could degrade and result in fuel contamination or increased risk of explosion in the fuselage fuel tank.

Explanation of Related French Airworthiness Directive

The DGAC issued French airworthiness directive (CN) 96–078–021(B), dated April 10, 1996, in order to assure the continued airworthiness of these airplanes in France. The French airworthiness directive requires replacement of the polyurethane foam of the fuselage tanks at intervals not to exceed 8 years.

FAA's Conclusions

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require reducing the life limit of the polyurethane foam used in the fuselage fuel tanks. The action would be required to be accomplished in accordance with procedures specified in the airplane maintenance manual.

Cost Impact

The FAA estimates that 20 Dassault Model Mystere Falcon 200 series airplanes of U.S. registry would be

affected by this proposed AD, that it would take approximately 8 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $4,000 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $89,600, or $4,480 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Dassault Aviation: Docket 97–NM–189–AD.

Applicability: All Model Mystere Falcon 200 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fuel contamination or increased risk of explosion in the fuselage fuel tank as a result of degradation of the polyurethane foam used in the fuselage fuel tanks, accomplish the following:

(a) Replace the polyurethane foam in the fuselage fuel tanks with new foam, in accordance with procedures specified in Chapter 5 of the Dassault Falcon 200 Maintenance Manual, at the later of the times specified in paragraph (a)(1) or (a)(2) of this AD. Thereafter, replace the foam with new foam at intervals not to exceed 8 years.

(1) Within 8 years after the last replacement of the foam; or

(2) Within 7 months or 350 flight hours after the effective date of this AD, whichever occurs first.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in French airworthiness directive (CN) 96–078–021(B), dated April 10, 1996.

Issued in Renton, Washington, on November 19, 1997.

Stewart R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–31024 Filed 11–25–97; 8:45 am]

BILLING CODE 4010–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–200–AD]

RIN 2120–AA64

Airworthiness Directives; British Aerospace BAe Model ATP Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain British Aerospace BAe Model ATP airplanes. This proposal would require repetitive inspections to detect uneven wear of the heat pack of the main landing gear (MLG) brake unit; measurement and setting of the wear remaining length (WRL) of the wear indicator pin (WIP); and replacement of the brake heat pack unit with a serviceable unit, if necessary. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to detect uneven wear of the brake heat pack unit and prevent failure of the pressure stator of the MLG brake unit, which could result in reduced braking efficiency and consequent longer stopping distances upon landing.

DATES: Comments must be received by December 26, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–200–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from AI(R) American Support, Inc., 13850 McLearen Road, Herndon, Virginia 20171. This information may be examined at the FAA, Transport

Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–200–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–200–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, notified the FAA that an unsafe condition may exist on certain British Aerospace BAe Model ATP airplanes. The CAA advises it received reports indicating that the heat pack unit of the main landing gear (MLG) brake unit has exhibited uneven wear at the pressure stator/first rotor interface in some instances, which has resulted in a small number of failures of the pressure stator. The pressure stator failures have been attributed to incorrect wear remaining length (WRL) indicated by the wear indicator pin (WIP). Such uneven wear and/or failure of the pressure stator/first rotor interface of the brake units, if not corrected, could result in reduced braking efficiency and consequent longer stopping distances upon landing.

Explanation of Relevant Service Information

Jetstream has issued Service Bulletin ATP/J61–32–71, dated May 23, 1996, and Revision 1, dated June 18, 1996, which describe procedures for repetitive inspections to detect uneven wear of the heat pack of the MLG brake unit at the pressure stator/first rotor interface; measurement and setting of the WRL of the WIP to indicate the correct amount of allowable remaining wear of the brake heat pack unit; and replacement of the brake heat pack unit with a serviceable unit, if necessary. (The Jetstream service bulletin references Dunlop service Bulletin AHA1612/AHA2004–32–1122, dated April 16, 1996, as an additional source of service information for inspecting the brakes, measuring the WRL of the WIP, and setting the corrected length of the pin.

The CAA classified the Jetstream service bulletin as mandatory and issued British airworthiness directive 002–05–96 in order to assure the continued airworthiness of these airplanes in the United Kingdom.

FAA's Conclusions

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Differences Between Proposed AD and Service Information

Operators should note that certain procedures described in the referenced Dunlop Service Bulletin are not included in this AD. Those procedures address the possible delay in the accomplishment of some of the work tasks due to the lack of qualified persons to set the WRL of the WIP. However, this AD permits no delay in setting the corrected length of the pin.

Cost Impact

The FAA estimates that 10 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 5 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $3,000, or $300 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

British Aerospace Regional Aircraft [Formerly Jetstream Aircraft Limited; British Aerospace (Commercial Aircraft) Limited]: Docket 96–NM–200–AD.

Applicability: BAe Model ATP airplanes having constructors numbers 2002 through 2067 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect uneven wear of the brake heat pack unit and prevent failure of the pressure stator of the main landing gear (MLG) brake unit, which could result in reduced braking efficiency and consequent longer stopping distances upon landing, accomplish the following:

(a) Within 300 hours time-in-service (TIS) after the effective date of this AD: Perform an inspection of the brake units of the left and right MLG to detect uneven wear at the pressure stator/first rotor interface, measure the wear remaining length (WRL) of the wear indicator pin (WIP), and accomplish the action specified in paragraph (a)(1) or (a)(2) of this AD, as applicable; in accordance with Jetstream Service Bulletin ATP/J61–32–71, dated May 23, 1996, or Revision 1, dated June 18, 1996.

Note 2: Jetstream Service Bulletin ATP/J61–32–71, dated May 23, 1996, and Revision 1, dated June 18, 1996, reference Dunlop Service Bulletin AHA1612/AHA2004–32–1122, dated April 16, 1996, as an additional source of service information for procedures to inspect the brakes, measure the wear remaining length (WRL) of the wear indicator pin (WIP), and set the corrected length of the pin.

(1) If the WRL of the WIP is greater than or equal to 0.5 inches: Repeat the action required in paragraph (a) of this AD thereafter at intervals not to exceed 300 hours TIS.

(2) If the WRL of the WIP is less than 0.5 inches: Prior to further flight, measure the thickness of the pressure stator and accomplish the action specified in paragraph (a)(2)(i) or (a)(2)(ii) of this AD, as applicable; and repeat the action required in paragraph (a) of this AD thereafter at intervals not to exceed 300 hours TIS.

(i) If the pressure stator is less than or equal to 0.31 inches thick: Replace the heat pack of the MLG brake unit with a serviceable unit and set the WRL of the WIP to indicate the corrected WRL measurement.

(ii) If the pressure stator exceeds 0.31 inches thick: Set the WRL of the WIP to indicate the corrected WRL measurement.

(b) If, during any inspection required by this AD, the WRL of the WIP on any brake unit shows that the wear status of the brake heat pack is outside the acceptable limits specified in Jetstream Service Bulletin ATP/J61–32–71, dated May 23, 1996, or Revision 1, dated June 18, 1996: Prior to further flight, replace the brake heat pack unit with a serviceable unit in accordance with the referenced service bulletin; and repeat the action required in paragraph (a) of this AD thereafter at intervals not to exceed 300 hours TIS.

(c) An alternative method of compliance or adjustment of the initial compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add additional comments, and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in British airworthiness directive 002–05–96.

Issued in Renton, Washington, on November 19, 1997.

Stewart R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–31023 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 773, 778, and 843

RIN 1029–AB94

Ownership and Control; Redesign

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Advance notice of proposed rulemaking; extension of public comment period and notice of public meetings.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM), United States Department of the Interior (DOI) published a notice that it would hold public meetings in order to solicit comments, concerns, and new ideas regarding the drafting of new ownership or control, permit information, and improvidently issued permit regulations to implement certain provisions of the Surface Mining Control and Reclamation Act of 1977. The notice invited written comments regarding the drafting of these regulations and advised that a concept/issue paper has been prepared to assist those interested in commenting or preparing for the meetings. The notice also stated that OSM would meet with interested persons and accept written comments through December 15, 1997. OSM is now extending the time during which written comments may be submitted and announcing the dates and locations for public meetings.

DATES: *Written comments:* The date for submitting written comments is extended until 5:00 p.m., Eastern Time on January 16, 1998.

Public Meetings: The period in which to request a meeting is unchanged. Requests for meetings should be made prior to December 1, 1997. Public meetings have already been scheduled for seven locations. See **SUPPLEMENTARY INFORMATION** for the dates, times and locations.

ADDRESSES: *Written comments and requests for concept/issue paper:* Hand deliver or mail to Earl Bandy, Office of Surface Mining Reclamation and Enforcement, AVS Office, 2679 Regency Road, Lexington, Kentucky 40503. Telephone: (800) 643–9748. E-mail: ebandy@osmre.gov.

Telefax: Copies of the concept/issue paper may be obtained from FAX ON DEMAND by calling 202–219–1703 and following the instructions on the recorded announcement. The concept/issue paper document code is 3009.

Public meetings: Upon request OSM staff will be available to meet with interested persons, individually or in groups, during the comment period. In addition to public meetings scheduled by request, OSM has scheduled meetings at seven locations. See **SUPPLEMENTARY INFORMATION** for the dates, times and locations.

For planning purposes, participants must call 1–800–643–9748 to confirm their attendance. If no confirmations are received for any location where a meeting has been scheduled, that meeting will not be held. Any individual who requires special accommodation to attend a meeting should contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Earl D. Bandy, Jr., Office of Surface Mining Reclamation and Enforcement, 2679 Regency Road, Lexington, Kentucky 40503. Telephone: (606) 233–2796 or (800) 643–9748. E-mail: ebandy@osmre.gov.

SUPPLEMENTARY INFORMATION: On October 29, 1997 (62 FR 56139), OSM published a notice that it would hold public meetings in order to solicit comments, concerns, and new ideas regarding the drafting of new ownership or control, permit information, and improvidently issued permit regulations to implement certain provisions of the Surface Mining Control and Reclamation Act of 1977. The notice also invited written comments regarding the drafting of these regulations and advised that a concept/issue paper has been prepared to assist those interested in commenting or preparing for the meetings. The re-design of these regulations is underway in order to fulfill the commitment made in the publication of the interim final rules on April 21, 1997 (62 FR 19450). The commitment was to seek public comment on proposed regulatory changes that would precede final rules adopted to reflect the January 31, 1997, decision of the U.S. Court of Appeals for the District of Columbia Circuit that invalidated previous ownership or control and related rules.

Public meetings have been scheduled at the following locations on the dates specified.

Date	Time	Location
12/2/97	9 a.m.–12 noon	Holiday Inn South, 5332 Athens-Boonesboro Road, Lexington, KY.
12/3/97	9 a.m.–12 noon	Heart O Town Hotel, 1000 Washington Street, East, Charleston, WV.
12/4/97	10 a.m.–12 noon	OSM Conference Room, 10 Parkway Center, Building #3, Pittsburgh, PA.
12/5/97	10 a.m.–12 noon	OSM Conference Room 220, 1951 Constitution Ave., NW., Washington, DC.
12/8/97	10 a.m.–12 noon	OSM Conference Room, 2nd Floor, 530 Gay Street, Knoxville, TN.
12/9/97	10 a.m.–12 noon	OSM Conference Room, 1st Floor, 501 Belle Street, Alton, IL.
12/10/97	10 a.m.–12 noon	OSM Conference Room, 34th Floor, 1999 Broadway, Denver, CO.

Dated: November 21, 1997.

Mary Josie Blanchard,

Assistant Director, Program Support.

[FR Doc. 97–31096 Filed 11–25–97; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SPATS No. IL–098–FOR]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Illinois regulatory program (hereinafter the ''Illinois program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of a revision to the Illinois regulations pertaining to administrative review. The amendment is intended to revise the Illinois program to be consistent with the corresponding Federal regulations.

This document sets forth the times and locations that the Illinois program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4:00 p.m., c.s.t., December 26, 1997. If requested, a public hearing on the proposed amendment will be held on December 22, 1997. Requests to speak at the hearing must be received by 4:00 p.m., c.s.t. on December 11, 1997.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Andrew R. Gilmore, Director, Indianapolis Field Office, at the address listed below.

Copies of the Illinois program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM'S Indianapolis Field Office.

Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building 575 North Pennsylvania Street, Room 301, Indianapolis, IN 46204, Telephone: (317) 226–6700.

Illinois Department of Natural Resources, Office of Mines and Minerals, 524 South Second Street, Springfield, IL 62701–1787, Telephone (217) 782–4970.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Telephone: (317) 226–6700.

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program

On June 1, 1982, the Secretary of the Interior conditionally approved the Illinois program. Background information on the Illinois program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the June 1, 1982, **Federal Register** (47 FR 23883). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 913.15, 913,16, and 913.17.

II. Description of the Proposed Amendment

By letter dated November 3, 1997 (Administrative Record No. IL–5000), Illinois submitted a proposed amendment to its program pursuant to SMCRA. Illinois submitted the proposed amendment at its own initiative. In its submission letter, Illinois stated the amendment was necessitated by a permit review case wherein the hearing officer found that the Department's burden of proof standard was improper. The hearing officer ruled that a preponderence of the evidence standard was the appropriate standard to apply in a permit review proceeding. On a subsequent appeal of the administrative case, the circuit court agreed that the clearly erroneous standard was invalid, and that the preponderance of the evidence standard was the correct standard to apply (Citizens Organizing Project v. IDNR, 96–MR–126, Sangamon County Circuit Court). The provision of Title 62, Illinois Administrative Code (IAC) that Illinois proposes to amend is at 62 IAC 1847.3(g), permit hearings. Specifically, Illinois proposes to delete the existing language at 62 IAC 1847.3(g) and replace it with the following language.

The standard of proof in a hearing conducted under this Section shall be the preponderence of the evidence.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 731.15. If the amendment is deemed adequate, it will become part of the Illinois program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Indianapolis Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to speak at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.s.t. on December 11, 1997. The location and time of the hearing will be arranged with those persons requesting the hearing. Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

Public Meeting

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the location listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM, Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

OSM has determined and certifies pursuant to the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of $100 million or more in any given year on local, state, or tribal governments or private entities.

List of Subjects in 30 CFR Part 913

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 20, 1997.

Charles E. Sandberg,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 97–31095 Filed 11–25–97; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL162–1b; FRL–5926–7]

Approval and Promulgation of State Implementation Plan; Illinois

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a September 8, 1997, State Implementation Plan (SIP) revision request submitted by the State of Illinois to tighten Volatile Organic Material regulations for cold cleaning degreasing operations in the Chicago and Metro-East ozone nonattainment areas. In the final rules section of this **Federal Register**, the EPA is approving this action as a direct final rule without prior proposal because EPA views this as a noncontroversial action and anticipates no adverse written comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse written comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse written comments, the direct final rule will be withdrawn and all written public comments received will be addressed in a subsequent final rule based on the proposed rule. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments on this proposed rule must be received on or before December 26, 1997.

ADDRESSES: Written comments should be mailed to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the State submittal are available for inspection at: Regulation Development Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Mark J. Palermo, Environmental Protection Specialist, Regulation Development Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6082.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the rules section of this **Federal Register**.

Dated: November 7, 1997.

David A. Ullrich,

Acting Regional Administrator.

[FR Doc. 97–31140 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF DEFENSE

48 CFR Parts 214 and 215

[DFARS Case 97–D011]

Defense Federal Acquisition Regulation Supplement; Distribution of Contract Financing Payments

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: The Director of Defense Procurement is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to specify that, when a contract contains multiple accounting classification reference numbers and a clause for progress payments, the contracting officer shall provide instructions to enable the paying office to distribute the progress payments in proportions that reasonably reflect the performance of work under the contract. This policy was originally scheduled for implementation on October 1, 1997; implementation has been delayed pending a more complete review of the resource implications of the Department's planned manner of distributing progress payments. This regulatory action was subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993. The Administrator of the Office of Information and Regulatory Affairs has determined that this is a major rule under 5 U.S.C. 804.

DATES: Comments on the proposed rule and the associated information collection requirements should be submitted in writing to the addresses specified below on or before January 26, 1998, to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments on the proposed rule to: Defense Acquisition Regulations Council, Attn: Ms. Sandra G. Haberlin, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telefax number (703) 602–0350. E-mail comments submitted over the Internet should be addressed to: dfars@acq.osd.mil. Please cite DFARS Case 97–D011 in all correspondence related to this issue. E-mail correspondence should cite DFARS Case 97–D011 in the subject line.

Interested parties should submit written comments on the associated information collection requirements to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Mr. Peter N. Weiss, Desk Officer, Room 10236, New Executive Office Building, Washington, DC 20503, with a copy to the Defense Acquisition Regulations Council at the address specified above.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra G. Haberlin, (703) 602–0131.

SUPPLEMENTARY INFORMATION:

A. Background

A proposed DFARS rule was published in the **Federal Register** on June 5, 1997 (62 FR 30829). The rule required a contracting officer to provide payment instructions to enable the paying office to distribute financing payments to the contract line item number (CLIN)/subline item number (SLIN) that reflects the work performed during the period covered by the contractor's financing request. Public comments were received from seven sources. All comments were considered.

This DFARS rule differs significantly from the proposed DFARS rule published in the **Federal Register** on June 5, 1997. Therefore, this second proposed rule is being published to obtain further public comments, prior to promulgation of a final rule. One of the main differences is that this revised rule raises the level to which actual funds usage must be identified. The previously published proposed rule required contracting officers to provide distribution instructions at the contract line item or subline item level. DoD has concluded that instructions by CLIN or SLIN are not necessary, in particular, in cases where several CLINs/SLINs are funded with the same accounting classification reference number (ACRN). Consequently, this DFARS rule requires distribution instructions by ACRN, rather than by CLIN/SLIN. Each appropriation or subdivision thereof is reflected in the contract by a distinct ACRN.

A second difference between the two proposed rules is that this revised rule no longer requires the contracting officer to use one of four alternative approaches for developing the payment instructions. However, for research and development contracts, the rule does retain the approach of using oldest funds first, absent conflicting information.

This proposed rule also differs from the June 5, 1997, proposed rule by

clarifying that the rule applies to the progress payments type of financing; and that contractors, when asked by contracting officers to provide information, need to provide best estimates of funding distribution by ACRN, based on existing accounting systems.

B. Regulatory Flexibility Act

The proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meeting of the Regulatory Flexibity Act, 5 U.S.C. 601, *et seq.*, because most contracts awarded to small entities have a dollar value less than the simplified acquisition threshold, and, therefore, do not use the progress payments method of financing. An initial regulatory flexibility analysis has therefore not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subparts will also be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite 5 U.S.C. 601, *et seq.* (DFARS Case 97–D011), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, applies because the proposed rule contains information collection requirements. A new information collection requirement has been submitted to the Office of Management and Budget (OMB) for review under 44 U.S.C. 3507(d)(1)(A).

1. Title, Associated Form, and OMB Number: A new information collection requirement, ''Distribution of Contract Financing Payments,'' has been submitted to OMB for review. An OMB Number has not yet been assigned.

2. Needs and Uses: 31 U.S.C. 1301(a) provides that ''Appropriations shall be applied only to the objects for which the appropriations were made except as otherwise provided by law.'' To facilitate compliance, the Under Secretary of Defense (Comptroller) (USD(C)) has directed paying offices to begin charging progress payments to the obligations that correspond to the deliverables for which costs were incurred during the period covered by the progress payment request. In order to implement this direction, contracting officers must provide progress payment distribution instructions to paying offices. One possible source of information for devising distribution instructions is the contractor, by means of a contract requirement for estimates of distributions by ACRN.

Affected Public: Businesses or other for profit.

Annual Burden Hours: 1,440,000.

Number of Respondents: 2,000.

Average Burden Per Response: 60 hours.

Frequency: On occasion.

3. Supplementary Information: Summary of Information Collection. The collection of information from contractors will be required only to the extent deemed necessary by contracting officers if they are unable to devise payment distribution instructions using other available information. Compliance with 31 U.S.C. 1301(a) does not require submission of information by contractors. However, in order to better meet the requirements of the law, contracting officers may need to obtain certain information from contractors in the form of contractor estimates of payment distribution by ACRN, based on actual or anticipated contract performance. When obtained from contractors, the frequency of submittal of distribution information will be determined by the frequency of the contractor's submission of progress payment requests, but may not be more frequent than monthly.

4. Comments: Particular comments are solicited on:

a. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

b. The accuracy of the agency's estimate of the burden of the information collection;

c. Ways to enhance the quality, utility, and clarity of the information to be collected; and

d. Ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

List of Subjects in 48 CFR Parts 214 and 215

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR Parts 214 and 215 are proposed to be amended as follows:

1. The authority citation for 48 CFR parts 214 and 215 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 214—SEALED BIDDING

2. Sections 214.201, 214.201–2, and 214.201–9 are added to read as follows:

214.201 Preparation of invitations for bids.

214.201–2 Part I—the Schedule.

(g) *Section G, Contract administration data.*

(i) When a contract contains multiple accounting classification reference numbers (ACRNs) (see 204.7101) and includes a clause for progress payments, the contracting officer shall provide instructions to enable the paying office to distribute progress payments to the ACRNs in proportions that reasonably reflect the performance of the work on the contract. Payment instructions shall represent a best estimate based on available information, and shall be updated as necessary.

(ii) The contracting officer may provide payment distribution instructions to the paying office with each progress payment request, or as an extended schedule for application to multiple requests on one contract. If provided as an extended schedule, the instructions must be furnished before the first progress payment is to be paid.

(iii) For incrementally funded research and development (R&D) contracts, or contract line items funded with R&D appropriations, the contracting officer may assume contractor work will be performed for the benefit of ACRNs with the earliest fiscal year's funding (*i.e.*, using oldest funds first), unless there is information to the contrary available.

(iv) For non-R&D contracts, the contracting officer should provide distribution instructions using the best information available, including information based upon—

(A) Contract funds status reports provided under a contract requirement for contractor cost reporting;

(B) The contract delivery schedule; or

(C) A profile of anticipated contractor expenditures based on historical spending patterns, or other knowledge of contractor performance of similar efforts.

(v) If the type of information set forth in paragraph (g)(iv) of this subsection is not available, or the contracting officer is not able to develop distribution instructions based on available information, the contracting officer may develop a best estimate of the contractor's anticipated work progress based on a general knowledge of the contractor or industry practices. Alternatively, the contracting officer may require the contractor to furnish distribution instructions in accordance with a contract requirement. However, if such a requirement is included in a contract, the contracting officer shall—

(A) Require the contractor to provide its best estimate of work performed by

ACRN, in accordance with the guidance provided in DFARS 214.201–2(g), and inform the contractor that this information is not considered to be an attachment to the Standard Form 1443, Contractor's Request for Progress Payment.

(B) Provide information to the contractor on total obligations by ACRN, including their relationship with each contract line item/subline item, and maintain that information as required by contract changes. A matrix such as the following may be used for this purpose:

	AA	AB	AC
0001	$500	.....	.....
0002	1,000	.....	.....
0003AA	.....	$600	.....
0003AB	.....	800	.....
0004	.....	.....	$400
Total	1,500	1,400	400

(C) Not require the contractor to revise its accounting system to account for or accumulate costs by ACRN.

(vi) The overall limit on progress payments on a contract, established through application of the contract progress payment rate and, if applicable, a loss ratio, shall continue to govern the total amount of progress payments that may be paid on a contract. These limits should continue to be applied on a total contract basis. Progress payments will be liquidated at the ACRN level.

214.201–9 Simplified contract format.

(b) *Contract schedule.*

(8) See 214.210–2(g) for contracts that contain multiple accounting classification reference numbers and include a clause for progress payments.

PART 215—CONTRACTING BY NEGOTIATION

3. Section 215.406–2 is revised to read as follows:

215.406–2 Part I—The Schedule.

(g) *Section G, Contract administration data.*

(i) When a contract contains both fixed-price and cost-reimbursement line items or subline items, the contracting officer shall provide, in Section B, Supplies or Services and Prices/Costs, an identification of contract type specified for each contract line item or subline item to facilitate appropriate payment.

(ii) Contracts with multiple accounting classification reference numbers (ACRNs) and a clause for progress payments.

(A) When a contract contains multiple accounting classification reference numbers (ACRNs) (see 204.7101) and includes a clause for progress payments, the contracting officer shall provide instructions to enable the paying office to distribute progress payments to the ACRNs in proportions that reasonably reflect the performance of the work on the contract. Payment instructions shall represent a best estimate based on available information, and shall be updated as necessary.

(B) The contracting officer may provide payment distribution instructions to the paying office with each progress payment request, or as an extended schedule for application to multiple requests on one contract. If provided as an extended schedule, the instructions must be furnished before the first progress payment is to be paid.

(C) For incrementally funded research and development (R&D) contracts, or contract line items funded with R&D appropriations, the contracting officer may assume contractor work will be performed for the benefit of ACRNs with the earliest fiscal year's funding (i.e., using oldest fund first), unless there is information to the contrary available.

(D) For non-R&D contracts, the contracting officer should provide distribution instructions using the best information available, including information based upon—

(*1*) Contract funds status reports provided under a contract requirement for contractor cost reporting;

(*2*) The contract delivery schedule; or

(*3*) A profile of anticipated contractor expenditures based on historical spending patterns, or other knowledge of contractor performance of similar efforts.

(E) If the type of information set forth in paragraph (g)(ii)(D) of this subsection is not available, or the contracting officer is not able to develop distribution instructions based on available information, the contracting officer may develop a best estimate of the contractor's anticipated work progress based on a general knowledge of the contractor or industry practices. Alternatively, the contracting officer may require the contractor to furnish distribution instructions in accordance with a contract requirement. However, if such a requirement is included in a contract, the contracting officer shall—

(*1*) Require the contractor to provide its best estimate of work performed by ACRN, in accordance with the guidance provided in DFARS 215.406–2(g), and inform the contactor that this information is not considered to be an attachment to the Standard Form 1443, Contractor's Request for Progress Payment.

(*2*) Provide information to the contractor on total obligations by ACRN, including their relationship with each contract line item/subline item, and maintain that information as required by contract changes. A matrix such as the following may be used for this purposes:

	AA	AB	AC
0001	$500	.....	.....
0002	1,000	.....	.....
0003AA	.....	$600	.....
0003AB	.....	800	.....
0004	.....	.....	$400
Total	1,500	1,400	400

(3) Not require the contractor to revise its accounting system to account for or accumulate costs by ACRN.

(F) The overall limit on progress payments on a contract, established through application of the contract progress payment rate and, if applicable, a loss ratio, shall continue to govern the total amount of progress payments that may be paid on a contract. These limits should continue to be applied on a total contract basis. Progress payments will be liquidated at the ACRN level.

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DEPARTMENT OF DEFENSE

48 CFR Parts 215 and 252

[DFARS Case 97–D018]

Defense Federal Acquisition Regulation Supplement: Contracting by Negotiation; Part 215 Rewrite

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: The Director of Defense Procurement is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to revise procedures pertaining to contracting by negotiation. These amendments conform with amendments made to the Federal Acquisition Regulation (FAR) in Federal Acquisition Circular 97–02, which was published in the **Federal Register** on September 30, 1997.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before January 26, 1998 to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments to: Defense Acquisition Regulations Council, *Attn:* Ms. Melissa Rider, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington DC 20301–3062. Telefax number (703) 602–0350.

E-mail comments submitted over the Internet should be addressed to: dfars@acq.osd.mil

Please cite DFARS Case 97–D018 in all correspondence related to this issue. E-mail comments should cite DFARS Case 97–D018 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Melissa Rider, (703) 602–0131.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed rule revises DFARS part 215 to align it with the reorganized format of FAR part 15 (FAR Case 95–029, FAR part 15 Rewrite) that was published as a final rule in the **Federal Register** on September 30, 1997 (62 FR 51224). In addition to changes related to format, the following changes have been made:

- DFARS guidance on the four-step source selection process and the alternate source selection process have been removed, as the new guidance at FAR 15.101, best value continuum, clearly allows such source selection processes.
- DFARS requirements for obtaining approvals before requesting second or subsequent best and final offers have been removed in view of the new guidance on proposal revisions at FAR 15.307.
- DFARS guidance on cost realism analysis has been revised to reflect the new guidance on cost realism analysis at FAR 15.404–1(d).
- Thresholds for requesting field pricing assistance have been added at DFARS 215.404–2. Similar guidance was removed from the FAR, but is still considered to be appropriate for DoD activities.
- DFARS guidance on field pricing support has been revised to conform with the FAR revisions that eliminated standard content requirements for field pricing reports.

B. Regulatory Flexibility Act

The proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule primarily consists of conforming DFARS amendments to reflect existing FAR guidance on contracting by negotiation. Therefore, an Initial Regulatory Flexibility Analysis has not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subparts also will be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 97–D018 in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed rule does not impose any information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 215 and 252

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR Parts 215 and 252 are proposed to be amended as follows:

1. The authority citation for 48 CFR parts 215 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 215—CONTRACTING BY NEGOTIATION

2. Part 215 is revised to read as follows:

PART 215—CONTRACTING BY NEGOTIATION

Sec.

215.000 Scope of part.

See 225.872 for additional guidance on procedures for purchasing from qualifying countries.

Subpart 215.2—Solicitation and Receipt of Proposals and Information

215.204–2 Part I—The Schedule.

(g) When a contract contains both fixed-priced and cost-reimbursement line items or subline items, the contracting officer shall provide, in Section B, Supplies or Services and Prices/Costs, an identification of contract type specified for each contract line item or subline item to facilitate appropriate payment.

Subpart 215.3—Source Selection

215.304 Evaluation factors and significant subfactors.

(d)(i) In acquititions that require use of the clause at FAR 52.219–9, Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan, the extent of participation of small and small disadvantaged businesses in performance of the contract shall be addressed in source selection.

(A) For acquititions other than those based only on cost or price competition, the contracting officer shall evaluate the extent which offerors identify and commit to small business and to small disadvantaged business, historically black college and university, or minority institution performance of the contract, whether as a joint venture, teaming arrangements, or subcontractors.

(B) Evaluation factory may include—

(*1*) The extent of which such firms are specifically identified in proposals;

(*2*) The extent to commitment to use such firms (for example, enforceable commitments are to be weighted more heavily than non-enforceable ones);

(*3*) The complexity and variety of the work small firms are to perform;

(*4*) The realism of the proposal;

(*5*) When not otherwise required by 215.305(a)(2), past performance of the offerors in complying with requirements of the clauses at FAR 52.219–8, Utilization of Small, Small Disadvantaged and Women-Owned Small Business Concerns, and 52.219–9, Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan; and

(*6*) The extent of participation of such firms in terms of the value of the total acquisition.

(C) Proposals addressing the extent of small and small disadvantaged business performance may be separate from subcontracting plans submitted pursuant to the clause at FAR 52.219–9 and should be structured to allow for consideration of offers from small businesses.

(D) When an evaluation includes the factors in paragraph (d)(i)(B)(1) of this section, the small, small disadvantaged, or women-owned small businesses considered in the evaluation shall be listed in any subcontracting plan submitted pursuant to FAR 52.219–9 to facilitate compliance with 252.219–7003(g).

(ii) The costs or savings related to contract administration and audit may be considered when the offeror's past performance or performance risk is likely to result in significant costs or savings.

(iii) In competitive acquisition of services—

(A) Evaluation and award should be based, to the maximum extent practicable, on best overall value to the Government in terms of quality and other factors.

(B) The weighting of costs must be commensurate with the nature of the services being acquired.

(*1*) It may be appropriate to award to an offeror, based on technical and quality considerations, at other than the lowest price when—

(*i*) The effort being contracted for departs from clearly defined efforts; or

(*ii*) Highly skilled personnel are required.

(*2*) It may be appropriate to award to the technically acceptable offeror with the lowest price when—

(*i*) Services being acquired are of a routine or simple nature;

(*ii*) Highly skilled personnel are not required; or

(*iii*) The product to be delivered is clearly defined at the outset of the acquisition.

215.305 Proposal evaluation.

(a)(1) Contracting officers shall ensure that the use of uncompensated overtime in contracts to acquire services on the basis of the number of hours provided (see 237.170) will not degrade the level of technical expertise required to fulfill the Government's requirements. When acquiring such services, contracting officers shall conduct a risk assessment, and evaluate for award on that basis, any proposals received that reflect factors such as—

(A) Unrealistically low labor rates or other costs that may result in quality or service shortfalls; and

(B) Unbalanced distribution of uncompensated overtime among skill levels and its use in key technical positions.

(2) When a past performance evaluation is required by FAR 15.304, and the solicitation includes the clause at FAR 52.219–8, Utilization of Small, Small Disadvantaged and Women-Owned Small Business Concerns, the evaluation factors shall include the past performance of offerors in complying with requirements of that clause. When a past performance evaluation is required by FAR 15.304, and the solicitation includes the clause at FAR 52.219–9, Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan, the evaluation factors shall include the past performance of offerors in complying with requirements of that clause.

(b) Any determination to reject a proposal based on a violation or possible violation of Section 27 of the OFPP Act shall be made as specified in FAR 3.104.

Subpart 215.4—Contract Pricing

215.403 Obtaining cost or pricing data.

215.403–1 Prohibition on obtaining cost or pricing data.

(c) *Standards for exceptions from cost or pricing data requirements.*

(1) *Adequate price competition.*

(A) An example of a price ''based on'' adequate price competition is a priced option in a contract where adequate price competition existed, if the contracting officer has determined that the option price is reasonable in accordance with FAR 17.207(d);

(B) Dual or multiple source programs.

(*1*) In dual or multiple source programs, the determination of adequate price competition must be made on a case-by-case basis. Even when adequate price competition exists, in certain cases it may be appropriate to obtain additional information to assist in price analysis.

(*2*) Adequate price competition normally exists when—

(i) Prices are solicited across a full range of step quantities, normally including a 0–100 percent split, from at least two offerors that are individually capable of producing the full quantity; and

(ii) The reasonableness of all prices awarded is clearly established on the basis of price analysis (see FAR 15.404–1(b)).

215.403–1–70 Waivers and exemptions.

(a) The DoD has exempted the Canadian Commercial Corporation and its subcontractors from submission and certification of cost or pricing data on all acquisitions.

(b) The DoD has waived certain cost or pricing data requirements for nonprofit organizations (including educational institutions) on cost-reimbursement-no-fee contracts. The contracting officer shall require—

(1) Submission of information other than cost or pricing data to the extent necessary to determine price reasonableness and cost realism; and

(2) Cost or pricing data from subcontractors that are not nonprofit organizations.

215.403–5 Instructions for submission of cost or pricing data or information other than cost or pricing data.

(b)(1)(A) Contracting officers may develop contract pricing proposal supporting schedules for use by offerors in providing supporting data for their pricing proposals. Schedules should only request data that are necessary and reasonable based on industry, company, or commodity practices.

(B) When the solicitation requires contractor compliance with the Contractor Cost Data Reporting (CCDR) System (Army—AMCP 715–8, Navy—NAV PUB P–5241, and Air Force—AFMCP 800–15), require the contractor to submit DD Form 1921 or 1921–1 with its pricing proposal.

215.404 Proposal analysis.

215.404–1 Proposal analysis techniques.

(d) *Cost realism analysis.*

The contracting officer should determine what information other than cost or pricing data is necessary for the cost realism analysis during acquisition planning and development of the solicitation. Unless such information is available from sources other than the offerors (see FAR 15.402(a)(2)), the contracting officer will need to request data from the offerors. The contracting officer—

(i) Should request only necessary data; and

(ii) May not request submission of cost or pricing data.

(f) *Unit prices.*

For spare parts or support equipment, perform an analysis of—

(i) Those line items where the proposed price exceeds by 25 percent or more the lowest price the Government has paid within the most recent 12-month period;

(ii) Those line items where a comparison of the item description and the proposed price indicates a potential for overpricing;

(iii) Significant high-dollar-value items. If there are no obvious high-dollar-value items, include an analysis of a random sample of items; and

(iv) A random sample of the remaining low-dollar value items. Sample size may be determined by subjective judgment, e.g., experience with the offeror and the reliability of its estimating and accounting systems.

215.404–2 Information to support proposal analysis.

(a) *Field pricing assistance.*

(i) The contracting officer should consider requesting field pricing assistance for—

(A) Fixed-price proposals exceeding the cost or pricing data threshold;

(B) Cost-type proposals exceeding the cost or pricing data threshold from offerors with significant estimating system deficiencies (see 215.407–5–70 (a)(4) and (c)(2)(i)); or

(C) Cost-type proposals exceeding $10 million from offerors without significant estimating system deficiencies.

(ii) The contracting officer should not request field pricing support for proposed contracts or modifications in an amount less than that specified in paragraph (a)(i) of this subsection. An exception may be made when a reasonable pricing result cannot be established, because of—

(A) A lack of knowledge of the particular offeror;

(B) Sensitive conditions (e.g., a change in, or unusual problems with, an offeror's internal systems); or

(C) An inability to evaluate the price reasonableness through price analysis or cost analysis of existing data.

(c) *Audit assistance for prime contracts or subcontracts.*

(i) If, in the opinion of the contracting officer or auditor, the review of a prime contractor's proposal requires further review of subcontractors' cost estimates at the subcontractors' plants (after due consideration of reviews performed by the prime contractor), the contracting officer should inform the administrative contracting officer (ACO) having cognizance of the prime contractor before the review is initiated.

(ii) Notify the appropriate contract administration activities when extensive, special, or expedited field pricing assistance will be needed to review and evaluate subcontractors' proposal under a major weapon system acquisition. Where audit reports are received on contracting actions that are subsequently cancelled, notify the cognizant auditor in writing.

215.404–3 Subcontract pricing considerations.

(a)(i) When obtaining field pricing assistance on a prime contractor's proposal, the contracting officer should request audit or field pricing assistance to analyze and evaluate the proposal of a subcontractor at any tier (notwithstanding availability of data or analyses performed by the prime contractor) if the contracting officer believes that such assistance is necessary to ensure the reasonableness of the total proposed price. Such assistance may be appropriate when, for example—

(A) There is a business relationship between the contractor and subcontractor not conducive to independence and objectivity;

(B) The contractor is a sole source supplier and the subcontract costs represent a substantial part of the contract cost;

(C) The contractor has been denied access to the subcontractor's records;

(D) The contracting officer determines that, because of factors such as the size of the proposed subcontract price, audit or field pricing assistance for a subcontract at any tier is critical to a fully detailed analysis of the prime contractor's proposal;

(E) The contractor or higher-tier subcontractor has been cited for having significant estimating system deficiencies in the area of subcontract pricing, especially the failure to perform adequate cost analyses of proposed subcontract costs or to perform subcontract analyses prior to negotiation of the Government; or

(F) A lower-tier subcontractor has been cited as having significant estimating system deficiencies.

(ii) It may be appropriate for the contracting officer or the ACO to provide assistance to a contractor at any tier where the contractor has been denied access to a subcontractor's records in carrying out the contractor's responsibilities under FAR 15.404–3 to conduct price or cost analysis to determine subcontractor price reasonableness. Under these circumstances, the contracting officer or the ACO should consider whether providing audit or field pricing assistance will serve a valid Government interest.

(iii) When DoD performs the subcontract analysis, DoD shall furnish to the prime contractor or higher-tier subcontractor, with the consent of the subcontractor reviewed, a summary of the analysis performed in determing any unacceptable costs included in the subcontract proposal. If the subcontractor withholds consent, DoD shall furnish a range of unacceptable costs for each element in such a way as to prevent disclosure of subcontractor proprietary data.

(iv) When possible, the contracting officer should notify the appropriate

contract administration activities in advance when extensive, special, or expedited field pricing assistance will be needed to review and evaluate subcontractor proposals under a major weapon system acquisition.

(v) Price redeterminable or fixed-price incentive contracts may include subcontracts placed on the same basis. When the contracting officer wants to reprice the prime contract even though the contractor has not yet established final prices for the subcontracts, the contracting officer may negotiate a firm contract price—

(A) If cost or pricing data on the subcontracts show the amounts to be reasonable and realistic; or

(B) If cost or pricing data on the subcontracts are too indefinite to determine whether the amounts are reasonable and realistic, but—

(*1*) Circumstances require prompt negotiation; and

(*2*) A statement substantially as follows is included in the repricing modification of the prime contract:

As soon as the Contractor establishes firm prices for each subcontract listed below, the Contractor shall submit (in the format and with the level of detail specified by the Contracting Officer) to the Contracting Officer the subcontractor's cost incurred in performing the subcontract and the final subcontract price. The Contractor and Contracting Officer shall negotiate an equitable adjustment in the total amount paid or to be paid under this contract to reflect the final subcontract price.

(vi) If the selection of the subcontractor is based on a trade-off among cost or price and other non-cost factors rather than lowest price, the analysis supporting subcontractor selection should include a discussion of the factors considered in the selection (see also FAR 15.101 and 15.304 and 215.304). If the contractor's analysis is not adequate, return it for correction of deficiencies.

(vii) The contracting officer shall make every effort to ensure that fees negotiated by contractors for cost-plus-fixed-fee subcontracts do not exceed the fee limitations in FAR 15.404–4(c)(4)(i).

215.404–4 Profit.

(b) *Policy.*

(1) Departments and agencies shall use a structured approach for developing a prenegotiation profit or fee objective (profit objective) on any negotiated contract action that requires cost analysis, except on cost-plus-award-fee contracts (but see 215.404–74). There are three approaches—

(A) The weighted guidelines method;

(B) The modified weighted guidelines method; and

(C) An alternate structured approach.

(c) *Contracting officer responsibilities.*

(1) Also, do not perform a profit analysis when assessing cost realism in competitive acquisitions.

(2) The contracting officer—

(A) Shall use the weighted guidelines method (see 215.404–71), unless—

(*1*) The modified weighted guidelines method applies; or

(*2*) An alternate approach is justified.

(B) Shall use the modified weighted guidelines method (see 215.404–72) on contract actions with nonprofit organizations.

(C) May use an alternate structured approach (see 215.404–73) when—

(*1*) The contract action is—

(i) Under $500,000;

(ii) For architect-engineer or construction work;

(iii) Primarily for delivery of material from subcontractors; or

(iv) A termination settlement; or

(2) The weighted guidelines method does not produce a reasonable overall profit objective and the head of the contracting activity approves use of the alternate approach in writing.

(D) Shall use the weighted guidelines method to establish a basic profit rate under a formula-type pricing agreement, and may then use the basic rate on all actions under the agreement, provided that conditions affecting profit do not change.

(E) Shall document the profit analysis in the price negotiation memorandum.

(5) Although specific agreement on the applied weights or values for individual profit factors shall not be attempted, the contracting officer may encourage the contractor to—

(A) Present the details of its proposed profit amounts in the weighted guidelines format or similar structured approach; and

(B) Use the weighted guidelines method in developing profit objectives for negotiated subcontracts.

(6) The contracting officer must also verify that relevant variables have not materially changed (e.g., performance risk, interest rates, progress payment rates, distribution of facilities capital).

(d) *Profit-analysis factors.*

(1) *Common factors.* The common factors are embodied in the DoD structured approaches and need not be further considered by the contracting officer.

215.404–70 DD Form 1547, Record of Weighted Guidelines Method Application.

(a) The DD Form 1547—

(1) Provides a vehicle for performing the analysis necessary to develop a profit objective;

(2) Provides a format for summarizing profit amounts subsequently negotiated as part of the contract price; and

(3) Serves as the principal source document for reporting profit statistics to DoD's management information system.

(b) The military departments are responsibilities for establishing policies and procedures for feeding the DoD-wide management information system on profit and fee statistics (see 215.404–75).

(c) The contracting officer shall—

(1) Use and prepare a DD Form 1547 whenever a structured approach to profit analysis is required by 215.404–4(b) (see 215.404–71, 215.404–72, and 215.404–73 for guidance on using the structured approaches). Administrative instructions for completing the form are in 253.215–70.

(2) Ensure that the DD Form 1547 is accurately completed. The contracting officer is responsible for the correction of any errors detected by the management system auditing process.

215.404–71 Weighted guidelines method.

215.404–71–1 General.

(a) The weighted guidelines method focuses on three profit factors—

(1) Performance risk;

(2) Contract type risk; and

(3) Facilities capital employed.

(b) The contracting officer assigns values to each profit factor; the value multiplied by the base results in the profit objective for that factor. Each profit factor has a normal value and a designated range of values. The normal value is representative of average conditions on the prospective contract when compared to all goods and services acquired by DoD. The designated range provides values based on above normal or below normal conditions. In the price negotiation memorandum, the contracting officer need not explain assignment of the normal value, but should address conditions that justify assignment of other than the normal value.

215.404–71–2 Performance risk.

(a) *Description.*

This profit factor addresses the contractor's degree of risk in fulfilling the contract requirements. The factor consists of three parts—

(1) Technical—the technical uncertainties of performance.

(2) Management—the degree of management effort necessary to ensure that contract requirements are met.

(3) Cost control—the contractor's efforts to reduce and control costs.

(b) *Determination.*

The following extract from the DD Form 1547 is annotated to describe the process.

Item	Contractor risk factors	Assigned weighting	Assigned value	Base (item 18)	Profit objective
21	Technical	(1)	(2)	N/A	N/A
22	Management	(1)	(2)	N/A	N/A
23	Cost Control	(1)	(2)	N/A	N/A
24	Performance Risk Composite	N/A	(3)	(4)	(5)

(1) Assign a weight (percentage) to each element according to its input to the total performance risk. The total of the three weights equals 100%.

(2) Select a value for each element from the list in paragraph (c) of this subsection using the evaluation criteria in paragraphs (d), (e), and (f) of this subsection.

(3) Compute the composite as shown in the following example—

	Assigned weighting (percent)	Assigned value (percent)	Weighted value (percent)
Technical	30	5.0	1.5
Management	30	4.0	1.2
Cost Control	40	4.5	1.8
Composite Value	100		4.5

(4) Insert the amount from Block 18 of the DD Form 1547. Block 18 is total contract costs, excluding general and administrative expenses, contractor independent research and development/bid and proposal expenses, and facilities capital cost of money.

(5) Multiply (3) by (4).

(c) *Values: Normal and designated ranges.*

	Normal value (percent)	Designated range (percent)
Standard	4	2 to 6.
Alternate	6	4 to 8.

(1) Standard.

The standard designated range should apply to most contracts.

(2) Alternate.

Contracting officers may use the alternate designated range for research and development and service contractors when these contractors require relatively low capital investment in buildings and equipment when compared to the defense industry overall. If the alternate designated range is used, do not give any profit for facilities capital employed (see 215.404–71–4(c)(3)).

(d) *Evaluation criteria for technical.*

(1) Review the contract requirements and focus on the critical performance elements in the statement of work or specifications. Factors to consider include—

(i) Technology being applied or developed by the contractor;

(ii) Technical complexity;

(iii) Program maturity;

(iv) Performance specifications and tolerances;

(v) Delivery schedule; and

(vi) Extent of a warranty or guarantee.

(2) *Above normal conditions.*

(i) The contracting officer may assign a higher than normal value in those cases where there is a substantial technical risk. Indicators are—

(A) The contractor is either developing or applying advanced technologies;

(B) Items are being manufactured using specifications with stringent tolerance limits;

(C) The efforts require highly skilled personnel or require the use of state-of-the-art machinery;

(D) The services and analytical efforts are extremely important to the Government and must be performed to exacting standards;

(E) The contractor's independent development and investment has reduced the Government's risk or cost;

(F) The contractor has accepted an accelerated delivery schedule to need DoD requirements; or

(G) The contractor has assumed additional risk through warranty provisions.

(ii) Extremely complex, vital efforts to overcome difficult technical obstacles that require personnel with exceptional abilities, experience, and professional credentials may justify a value significantly above normal.

(iii) The following may justify a maximum value—

(A) Development or initial production of a new item, particularly if performance or quality specifications are tight; or

(B) A high degree of development or production concurrency.

(3) *Below normal conditions.*

(i) The contracting officer may assign a lower than normal value in those cases where the technical risk is low. Indicators are—

(A) Acquisition is for off-the-shelf items;

(B) Requirements are relatively simple;

(C) Technology is not complex;

(D) Efforts do not require highly skilled personnel;

(E) Efforts are routine;

(F) Programs are mature; or

(G) Acquisition is a follow-on effort or a repetitive type acquisition.

(ii) The contracting officer may assign a value significantly below normal for—

(A) Route services;

(B) Production of simple items;

(C) Rote entry or routine integration of Government-furnished information; or

(D) Simple operations with Government-furnished property.

(e) *Evaluation criteria for management.*

(1) The contracting officer should—

(i) Assess the contractor's management and internal control systems using contracting office information and reviews made by field contract administration offices or other DoD field offices;

(ii) Assess the management involvement expected on the prospective contract action;

(iii) Consider the degree of cost mix as an indication of the types of resources applied and value added by the contractor; and

(iv) Consider the contractor's support of Federal socioeconomic programs.

(2) *Above normal conditions.*

(i) The contracting officer may assign a higher than normal value when the

management effort is intense. Indicators of this are—

(A) The contractor's value added is both considerable and reasonably difficult;

(B) The effort involves a high degree of integration or coordination; or

(C) The contractor has a substantial record of active participation in Federal socioeconomic programs.

(ii) The contracting officer may justify a maximum value when the effort—

(A) Requires large scale integration of the most complex nature;

(B) Involves major international activities with significant management coordination (e.g., offsets with foreign vendors); or

(C) Has critically important milestones.

(3) *Below normal conditions.*

(i) The contracting officer may assign a lower than normal value when the management effort is minimal. Indicators of this are—

(A) The program is mature and many end item deliveries have been made;

(B) The contractor adds minimum value to an item;

(C) The efforts are routine and require minimal supervision;

(D) The contractor provides poor quality, untimely proposals;

(E) The contractor fails to provide an adequate analysis of subcontractor costs; or

(F) The contractor does not cooperate in the evaluation and negotiation of the proposal.

(ii) The following may justify a value significantly below normal—

(A) Reviews performed by the field contract administration offices disclose unsatisfactory management and internal control systems (e.g., quality assurance, property control, safety, security); or

(B) The effort requires an unusually low degree of management involvement.

(f) *Evaluation criteria for cost control.*

(1) The contracting officer should evaluate—

(i) The expected reliability of the contractor's cost estimates (including the contractor's cost estimating system);

(ii) The contractor's cost reduction initiatives (e.g., competition advocacy programs, dual sourcing, spare parts pricing reform, value engineering);

(iii) The adequacy of the contractor's management approach to controlling cost and schedule; and

(iv) Any other factors that affect the contractor's ability to meet the cost targets, e.g., foreign currency exchange rates and inflation rates.

(2) *Above normal conditions.*

The contracting officer may assign a higher than normal value if the contractor can demonstrate a highly effective cost control program. Indicators of this are—

(i) The contractor provides fully documented and reliable cost estimates;

(ii) The contractor has an aggressive cost reduction program that has demonstrable benefits;

(iii) The contractor uses a high degree of subcontract competition (e.g., aggressive dual sourcing); or

(iv) The contractor has a proven record of cost tracking and control.

(3) *Below normal conditions.*

The contracting officer may assign a lower than normal value if the contractor demonstrates minimal concern for cost control. Indicators are—

(i) The contractor's cost estimating system is marginal;

(ii) The contractor has made minimal effort to initiate cost reduction programs;

(iii) The contractor's cost proposal is inadequate;

(iv) The contractor has a record of cost overruns or other indication of unreliable cost estimates and lack of cost control.

215.404–71–3 Contract type risk and working capital adjustment.

(a) *Description.* The contract type risk factor focuses on the degree of cost risk accepted by the contractor under varying contract types. The working capital adjustment is an adjustment added to the profit objective for contract type risk. It only applies to fixed-price contracts that provide for progress payments. Though it uses a formula approach, it is not intended to be an exact calculation of the cost of working capital. Its purpose is to give general recognition to the contractor's cost of working capital under varying contract circumstances, financing policies, and the economic environment.

(b) *Determination.*

The following extract from the DD 1547 is annotated to explain the process.

Item	Contractor risk factors		Assigned value	Base (item 18)	Profit objective
25.	Contract Type Risk		(1)	(2)	(3)
		Cost Financed	Length Factor	Interest Rate	
26.	Working Capital (4)	(5)	(6)	(7)	(8)

(1) Select a value from the list of contract types in paragraph (c) of this subsection using the evaluation criteria in paragraph (d) of this subsection.

(2) Insert the amount from Block 18, i.e., the total allowable costs excluding general and administrative expenses, independent research and development and bid and proposal expenses, and facilities capital cost of money.

(3) Multiply (1) by (2).

(4) Only complete this block when the prospective contract is a fixed-price contract containing provisions for progress payments.

(5) Insert the amount computed per paragraph (e) of this subsection.

(6) Insert the appropriate figure from paragraph (f) of this subsection.

(7) Use the interest rate established by the Secretary of the Treasury (230.7101–1(a)). Do not use any other interest rate.

(8) Multiply (5) by (6) by (7). This is the working capital adjustment. It shall not exceed 4 percent of the contract costs in Block 20.

(c) *Values: Normal and designated ranges.*

Contract type	Notes	Normal value (percent)	Designated range (percent)
Firm fixed-price, no financing	(1)	5	4 to 6.
Firm fixed-price, with financing	(2)	3	2 to 4.
Fixed-price-incentive, no financing	(1)	3	2 to 4.
Fixed-price with redeterminable provision	(3)	.....	
Fixed-price-incentive, with financing	(2)	1	0 to 2.

Contract type	Notes	Normal value (percent)	Designated range (percent)
Cost-plus-incentive-fee	(4)	1	0 to 2.
Cost-plus-fixed-fee	(4)	.5	0 to 1.
Time and material contracts (including overhaul contracts priced on time and material basis)	(5)	.5	0 to 1.
Labor-hour contracts	(5)	.5	0 to 1.
Firm fixed-price-level-of-effort-term	(5)	.5	0 to 1.

(1) ''No financing'' means that the contract either does not provide progress payments, or provides them only on a limited basis, such as financing of first articles. Do not compute a working capital adjustment.

(2) ''With financing'' means progress payments. When progress payments are present, compute a working capital adjustment (Block 26).

(3) For the purposes of assigning profit values, treat a fixed-price contract with redeterminable provisions as if it were a fixed-price-incentive contract with below normal conditions.

(4) Cost-plus contracts shall not receive the working capital adjustment.

(5) These types of contracts are considered cost-plus-fixed-fee contracts for the purposes of assigning profit values. They shall not receive the working capital adjustment in Block 26. However, they may receive higher than normal values within the designated range to the extent that portions of cost are fixed.

(d) *Evaluation criteria*—(1) *General.* The contracting officer should consider elements that affect contract type risk such as—

(i) Length of contract;

(ii) Adequacy of cost data for projections;

(iii) Economic environment;

(iv) Nature and extent of subcontracted activity;

(v) Protection provided to the contractor under contract provisions (e.g., economic price adjustment clauses);

(vi) The ceilings and share lines contained in incentive provisions; and

(vii) Risks associated with contracts for foreign military sales (FMS) that are not funded by U.S. appropriations.

(2) *Mandatory.* The contracting officer shall assess the extent to which costs have been incurred prior to definitization of the contract action (see also 217.7404–6(a)). The assessment shall include any reduced contractor risk on both the contract before definitization and the remaining portion of the contract. When costs have been incurred prior to definitization, generally regard the contract type risk to be in the low end of the designated range. If a substantial portion of the costs have been incurred prior to definitization, the contracting officer may assign a value as low as 0%, regardless of contract type.

(3) *Above normal conditions.* The contracting officer may assign a higher than normal value when there is substantial contract type risk. Indicators of this are—

(i) Efforts where there is minimal cost history;

(ii) Long-term contracts without provisions protecting the contractor, particularly when there is considerable economic uncertainty;

(iii) Incentive provisions (e.g., cost and performance incentives) that place a high degree of risk on the contractor; or

(iv) FMS sales (other than those under DoD cooperative logistics support arrangements or those made from U.S. Government inventories or stocks) where the contractor can demonstrate that there are substantial risks above those normally present in DoD contracts for similar items.

(4) *Below normal conditions.* The contracting officer may assign a lower than normal value when the contract type risk is low. Indicators of this are—

(i) Very mature product line with extensive cost history;

(ii) Relatively short-term contracts;

(iii) Contractual provisions that substantially reduce the contractor's risk; or

(iv) Incentive provisions that place a low degree of risk on the contractor.

(e) *Costs financed.* (1) Costs financed equal total costs multiplied by the portion (percent) of costs financed by the contractor.

(2) Total costs equal Block 20 (i.e., all allowable costs, including general and administrative and independent research and development and bid and proposal, but excluding facilities capital cost of money), reduced as appropriate when—

(i) The contractor has little cash investment (e.g., subcontractor progress payments liquidated late in period of performance);

(ii) Some costs are covered by special financing provisions, such as advance payments; or

(iii) The contract is multiyear and there are special funding arrangements.

(3) The portion financed by the contractor is generally the portion not covered by progress payments, i.e., 100% minus the customary progress payment rate (FAR 32.501). For example, if a contractor receives progress payments at 75%, the portion financed by the contractor is 25%. On contracts that provide flexible progress payments (252.232–7003) or progress payments to small businesses, use the customary progress payment rate for large businesses.

(f) *Contract length factor.* (1) This is the period of time that the contractor has a working capital investment in the contract. It—

(i) Is based on the time necessary for the contractor to complete the substantive portion of the work;

(ii) Is not necessarily the period of time between contract award and final delivery (or final payment), as periods of minimal effort should be excluded;

(iii) Should not include periods of performance contained in option provisions; and

(iv) Should not, for multiyear contracts, include periods of performance beyond that required to complete the initial program year's requirements.

(2) The contracting officer—

(i) Should use the following table to select the contract length factor;

(ii) Should develop a weighted average contract length when the contract has multiple deliveries; and

(iii) May use sampling techniques, provided they produce a representative result.

TABLE

Peirod to perform substantive portion	Contract length factor
21 or less	.40
22 to 27	.65
28 to 33	.90
34 to 39	1.15
40 to 45	1.40
46 to 51	1.65
52 to 57	1.90
58 to 63	2.15
64 to 69	2.40
70 to 75	2.65

TABLE—Continued

Peirod to perform substantive portion	Contract length factor
76 or more	2.90

(3) Example: A prospective contract has a performance period of 40 months with end items being delivered in the 34th, 36th, 38th, and 40th months of the contract. The average period is 37 months and the contract length factor is 1.15.

215.404–71.4 Facilities capital employed.

(a) *Description.* This factor focuses on encouraging and rewarding aggressive capital investment in facilities that benefit DoD. It recognizes both the facilities capital that the contractor will employ in contract performance and the contractor's commitment to improving productivity.

(b) *Determination.*

The following extract from the DD Form 1547 has been annotated to explain the process.

Item	Contractor facilities capital employed	Assigned	Amount employed	Profit objective
27.	Land	N/A	(2)	N/A
28.	Buildings	(1)	(2)	(3)
29.	Equipment	(1)	(2)	(3)

(1) Select a value from the list in paragraph (c) of this subsection using the evaluation criteria in paragraph (d) of this subsection.

(2) Use the allocated facilities capital attributable to land, buildings, and equipment, as derived in DD Form 1861, ''Contract Facilities Capital Cost of Money'' (see 230.7001).

(i) In addition to the net book value of facilities capital employed, consider facilities capital that is part of a formal investment plan if the contractor submits reasonable evidence that—

(A) Achievable benefits to DoD will result from the investment; and

(B) The benefits of the investment are included in the forward pricing structure.

(ii) If the value of intracompany transfers has been included in Block 18 at cost (i.e., excluding general and administrative (G&A) expenses and profit), add to the contractor's allocated facilities capital, the allocated facilities capital attributable to the buildings and equipment of those corporate divisions supplying the intracompany transfers. Do not make this addition if the value of intracompany transfers has been included in Block 18 at price (i.e., including G&A expenses and profit).

(3) Multiply (1) by (2).

(c) *Values: Normal and designated ranges.*

Notes	Asset type	Normal value (percent)	Designated range (percent)
(1)	Land	0	N/A
(1)	Buildings	15	10 to 20
(1)	Equipment	35	20 to 50
(2)	Land	0	N/A
(2)	Buildings	5	0 to 10
(2)	Equipment	20	15 to 25
(3)	Land	0	N/A
(3)	Buildings	0	0
(3)	Equipment	0	0

(1) These are the normal values and ranges. They apply to all situations except those noted in (2) and (3).

(2) These alternate values and ranges apply to situations where a highly facilitized manufacturing firm will be performing a research and development or services contract. They balance the method used to allocate facilities capital cost of money, which may produce disproportionate allocation of assets to these types of efforts.

(3) When using a value from the alternate designated range for the performance risk factor (215.404–71–2(c)(2)), do not allow profit on facilities capital employed.

(d) *Evaluation criteria.*

(1) In evaluating facilities capital employed, the contracting officer—

(i) Should relate the usefulness of the facilities capital to the goods or services being acquired under the prospective contract;

(ii) Should analyze the productivity improvements and other anticipated industrial base enhancing benefits resulting from the facilities capital investment, including—

(A) The economic value of the facilities capital, such as physical age, undepreciated value, idleness, and expected contribution to future defense needs; and

(B) The contractor's level of investment in defense related facilities as compared with the portion of the contractor's total business that is derived from DoD;

(iii) Should consider any contractual provisions that reduce the contractor's risk of investment recovery, such as termination protection clause, capital investment indemnification, and productivity saving rewards; and

(iv) Shall ensure that increases in facilities capital investments are not merely asset revaluations attributable to mergers, stock transfers, take-overs, sales of corporate entities, or similar actions.

(2) *Above normal conditions.* (i) The contracting officer may assign a higher than normal value if the facilities capital investment has direct, identifiable, and exceptional benefits. Indicators are—

(A) New investments in state-of-the-art technology that reduce acquisition cost or yield other tangible benefits such as improved product quality or accelerated deliveries;

(B) Investments in new equipment for research and development applications; or

(C) Contractor demonstration that the investments are over and above the normal capital investments necessary to

support anticipated requirements of DoD programs.

(ii) The contracting officer may assign a value significantly above normal when there are direct and measurable benefits in efficiency and significantly reduced acquisition costs on the effort being priced. Maximum values apply only to those cases where the benefits of the facilities capital investment are substantially above normal.

(3) *Below normal conditions.* (i) The contracting officer may assign a lower than normal value if the facilities capital investment has little benefit to DoD. Indicators are—

(A) Allocations of capital apply predominantly to commercial item lines;

(B) Investments are for such things as furniture and fixtures, home or group level administrative offices, corporate aircraft and hangars, gymnasiums; or

(C) Facilities are old or extensively idle.

(ii) The contracting officer may assign a value significantly below normal when a significant portion of defense manufacturing is done in an environment characterized by outdated, inefficient, and labor-intensive capital equipment.

215.404–72 Modified weighted guidelines method for nonprofit organizations.

(a) *Definition.* As used in this subpart, a nonprofit organization is a business entity—

(1) That operates exclusively for charitable, scientific, or educational purposes;

(2) Whose earnings do not benefit any private shareholder or individual;

(3) Whose activities do not involve influencing legislation or political campaigning for any candidate for public office; and

(4) That is exempted from Federal income taxation under section 501 of the Internal Revenue Code.

(b) For nonprofit organizations that are Federally Funded Research and Development Centers (FFRDCs), the contracting officer—

(1) Should consider whether any fee is appropriate. Considerations shall include the FFRDC's—

(i) Proportion of retained earnings (as established under generally accepted accounting methods) that relates to DoD contracted effort;

(ii) Facilities capital acquisition plans;

(iii) Working capital funding as assessed on operating cycle cash needs;

(iv) Contingency funding; and

(v) Provision for funding unreimbursed costs deemed ordinary and necessary to the FFRDC.

(2) Shall, when a fee is considered appropriate, compute the fee objective using the weighted guidelines method in 215.404–71, with the following modifications—

(i) *Modifications to performance risk (Blocks 21–24 of the DD Form 1547).*

(A) If the contracting officer assigns a value from the standard designated range (215.404–71–2(c)), reduce the fee objective by an amount equal to 1% of the costs in Block 18 of the DD Form 1547. Show the net (reduced) amount on the DD Form 1547.

(B) If the contracting officer assigns a value from the alternate designated range, reduce the fee objective by an amount equal to 2% of the costs in Block 18 of the DD Form 1547. Show the net (reduced) amount on the DD Form 1547.

(ii) *Modifications to contract type risk (Block 25 of the DD Form 1547).* Use a designated range of −1% to 8% in lieu of the values in 215.404–71–3. There is no normal value.

(c) For nonprofit organizations that are entities that have been identified by the Secretary of Defense or a Secretary of a Department as receiving sustaining support on a cost-plus-fixed-fee basis from a particular DoD department or agency, compute a fee objective for covered actions using the weighted guidelines method in 215.404–71, modified as described in paragraph (b)(2) of this subsection.

(d) For all other nonprofit organizations, compute a fee objective for covered actions using the weighted guidelines method in 215.404–71, modified as described in paragraph (b)(2)(i) of this subsection.

215.404–73 Alternative structured approaches.

(a) The contracting officer may use an alternate structured approach under 215.404–4(c).

(b) The contracting officer may design the structure of the alternate, but it shall include—

(1) Consideration of the three basic components of profit—performance risk, contract type risk (including working capital), and facilities capital employed. However, the contracting officer is not required to complete Blocks 21 through 30 of the DD Form 1547.

(2) Offset for facilities capital cost of money.

(i) The contracting officer shall reduce the overall prenegotiation profit objective by the lesser of 1% of total cost or the amount of facilities capital cost of money. The profit amount in the negotiation summary of the DD Form 1547 must be net of the offset.

(ii) This adjustment is needed for the following reason: The values of the profit factors used in the weighted guidelines method were adjusted to recognize the shift in facilities capital cost of money from an element of profit to an element of contract cost (see FAR 31.205–10) and reductions were made directly to the profit factors for performance risk. In order to ensure that this policy is applied to all DoD contracts that allow facilities capital cost of money, similar adjustments shall be made to contracts that use alternate structured approaches.

215.404–74 Fee requirements for cost-plus-award-fee contracts.

In developing a fee objective for cost-plus-award-fee contracts, the contracting officer shall—

(a) Follow the guidance in FAR 16.404–2 and 216.404–2;

(b) Not use the weighted guidelines method or alternate structured approach;

(c) Apply the offset policy in 215.404–73(b)(2) for facilities capital cost of money, i.e., reduce the base fee by the lesser of 1% of total costs or the amount of facilities capital cost of money; and

(d) Not complete a DD Form 1547.

215.404–75 Reporting profit and fee statistics.

(a) Contracting officers in contracting offices that participate in the management information system for profit and fee statistics shall send completed DD Forms 1547 on actions of $500,000 or more, where the contracting officer used either the weighted guidelines method, an alternate structured approach, or the modified weighted guidelines method, to their designated office within 30 days after contract award.

(b) Participating contracting offices and their designated offices are—

Contracting office	Designated office
Army	
All	Army Procurement Research and Analysis Office, Attn: SFRD–KPR (WGL), Bldg 12500, C Wing, Ft. Lee, VA 23801–6045.
Navy	
*Naval Air Systems Command *Naval Sea Systems Command *Space and Naval Warfare Systems Command *Naval Facilities Engineering Command *Naval Supply Systems Command *Office of Naval Research *Headquarters, United States Marine Corps *Strategic Systems Programs Office *Military Sealift Command *Automatic Data Processing Selection Office *Navy Regional Data Automation Center *Naval Research Laboratory *Navy Commercial Communications Center *Naval Aviation Depot Operations Center *Includes all subordinate field offices	Commander, Fleet and Industrial Supply Center, Norfolk, Washington Detachment, Code 402, Washington Navy Yard, Washington, DC 20374.
Air Force	
Air Force Materiel Command, (all field offices)	Air Force Materiel Command, 645 CCSG/SCOS, Attn: J010 Clerk, 2721 Sacramento Street, Wright-Patterson Air Force Base, OH 45433.

(c) When negotiation of a contract action over $500,000 has been delegated to another contracting agency (e.g., to an administrative contracting officer), that agency shall ensure that a copy of the DD Form 1547 is provided to the delegating office for reporting purposes within 30 days from negotiation of the contract action.

(d) Contracting offices outside the United States, its possessions, and Puerto Rico are exempt from reporting.

(e) Designated offices send a quarterly (non-cumulative) report of DD Form 1547 data to—

Washington Headquarters Service, Directorate for Information Operations and Reports, (WHS/DIOR), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302

(f) In preparing and sending the quarterly report, designated offices—

(1) Perform the necessary audits to ensure information accuracy;

(2) Do not enter classified information;

(3) Transmit the report via computer magnetic tape using the procedures, format, and editing process issued by the Director of Defense Procurement; and

(4) Send the reports not later than the 30th day after the close of the quarterly reporting periods.

(g) These reporting requirements have been assigned report control symbol: P&L(Q)1751.

215.406–1 Prenegotiation objectives.

(a) Also consider—

(i) Data resulting from application of work measurement systems in developing prenegotiation objectives; and

(ii) Field pricing assistance personnel participation in planned prenegotiation and negotiation activities.

(b) Prenegotiation objectives, including objectives related to disposition of findings and recommendations contained in preaward and postaward contract audit and other advisory reports, shall be documented and reviewed in accordance with Departmental procedures.

215.406–3 Documenting the negotiation.

(a)(7) Include the principal factors related to the disposition of findings and recommendations contained in preaward and postaward contract audit and other advisory reports.

(10) The documentation—

(A) Must address significant deviations from the prenegotiation profit objectives;

(B) Should include the DD Form 1547, Record of Weighted Guidelines Application (see 215.404–70), if used, with supporting rationale; and

(C) Must address the rationale for not using the weighted guidelines method when its use would otherwise be required by 215.404–70.

215.407–1 Defective cost or pricing data.

(b)(2) Unless there is clear evidence to the contrary, the contracting officer may presume the defective data were relied on and resulted in a contract price increase equal to the amount of the defect plus related overhead and profit or fee. The contracting officer is not expected to reconstruct the negotiation by speculating as to what would have been considered by the negotiating parties if the nondefective data had been known.

215.407–2 Make-or-buy programs.

(e) *Program requirements.*—(1) *Items and work included.* The minimum dollar amount is $1 million.

215.407–3 Forward pricing rate agreements.

(b)(i) Use forward pricing rate agreement (FPRA) rates when such rates are available, unless waived on a case-by-case basis by the head of the contracting activity.

(ii) Advise the ACO of each case waived.

(iii) Contact the ACO for questions on FPRAs or recommended rates.

215.407–4 Should-cost review.

(b) *Program should-cost review.* (2) DoD contracting activities should consider performing a program should-cost review before award of a definitive major systems contract exceeding $100 million.

(c) *Overhead should-cost review.* (1) Contact the DCMC/DLA Overhead Center, Fort Belvoir, VA 22060–6221, at (703) 767–3387, for questions on overhead should-cost analysis.

(2)(A) The Defense Contract Management Command/Defense Logistics Agency (DCMC/DLA), or the military department responsible for performing contract administration functions (e.g., Navy SUPSHIP), should consider, based on risk assessment, performing an overhead should-cost review of a contractor business unit (as defined in FAR 31.001) when all of the following conditions exist:

(1) Projected annual sales to DoD exceed $1 billion;

(2) Projected DoD versus total business exceeds 30 percent;

(3) Level of sole-source DoD contracts is high;

(4) Significant volume of proposal activity is anticipated;

(5) Production or development of a major weapon system or program is anticipated; and

(6) Contractor cost control/reduction initiatives appear inadequate.

(B) The head of the contracting activity may request an overhead should-cost review for a business unit that does not meet the criteria in paragraph (b)(1) of this subsection.

(C) Overhead should-cost reviews are labor intensive. These reviews generally involve participation by the contracting, contract administration, and contract audit elements. The extent of availability of military department, contract administration, and contract audit resources to support DCMC/DLA-led teams should be considered when determining whether a review will be conducted. Overhead should-cost reviews generally shall not be conducted at a contractor business segment more frequently than every three years.

215.407–5 Estimating systems.

215.407–5–70 Disclosure, maintenance, and review requirements.

(a) *Definitions.*

(1) ''Adequate estimating system'' means an estimating system that—

(i) Is established, maintained, reliable, and consistently applied; and

(ii) Produces verifiable, supportable, and documented cost estimates.

(2) ''Contractor'' means a business unit as defined in FAR 31.001.

(3) ''Estimating system'' is as defined in the clause at 252.215–7002, Cost Estimating System Requirements.

(4) ''Significant estimating system deficiency'' means a shortcoming in the estimating system that is likely to consistently result in proposal estimates for total cost or a major cost element(s) that do not provide an acceptable basis for negotiation of fair and reasonable prices.

(b) *Applicability.*

(1) DoD policy is that all contractors have estimating systems that—

(i) Are adequate;

(ii) Consistently produce well-supported proposals that are acceptable as a basis for negotiation of fair and reasonable prices;

(iii) Are consistent with and integrated with the contractor's related management systems; and

(iv) Are subject to applicable financial control systems.

(2) A large business contractor is subject to estimating system disclosure, maintenance, and review requirements if—

(i) In its preceding fiscal year the contractor received DoD prime contracts or subcontracts totaling $50 million or more for which cost or pricing data were required; or

(ii) In its preceding fiscal year the contractor received DoD prime contracts or subcontracts totaling $10 million or more (but less than $50 million) for which cost or pricing data were required and the contracting officer, with concurrence or at the request of the administrative contracting officer (ACO), determines it to be in the best interest of the Government (e.g., significant estimating problems are believed to exist or the contractor's sales are predominantly Government).

(c) *Responsibilities.*

(1) The contracting officer shall—

(i) Through use of the clause at 252.215–7002, Cost Estimating System Requirements, apply the disclosure, maintenance, and review requirements to large business contractors meeting the criteria in paragraph (b)(2)(i) of this subsection;

(ii) Consider whether to apply the disclosure, maintenance, and review requirements to large business contractors under paragraph (b)(2)(ii) of this subsection; and

(iii) Not apply the disclosure, maintenance, and review requirement to other than large business contractors.

(2) The cognizant ACO, for contractors subject to paragraph (b)(2) of this subsection, shall—

(i) Determine the adequacy of the disclosure and system; and

(ii) Pursue correction of any deficiencies.

(3) The cognizant auditor, on behalf of the ACO, serves as team leader in conducting estimating system reviews.

(4) A contractor subject to estimating system disclosure, maintenance, and review requirements shall—

(i) Maintain an adequate system;

(ii) Describe its system to the ACO;

(iii) Provide timely notice of changes in the system; and

(iv) Correct system deficiencies identified by the ACO.

(d) *Characteristics of an adequate estimating system.*

(1) *General.* An adequate system should provide for the use of appropriate source data, utilize sound estimating techniques and good judgment, maintain a consistent approach, and adhere to estimated policies and procedures.

(2) *Evaluation.* In evaluating the adequacy of a contractor's estimating system, the ACO should consider whether the contractor's estimating system, for example—

(i) Establishes clear responsibility for preparation, review, and approval of cost estimates;

(ii) Provides a written description of the organization and duties of the personnel responsible for preparing, reviewing, and approving cost estimates;

(iii) Assures that relevant personnel have sufficient training, experience, and guidance to perform estimating tasks in accordance with the contractor's established procedures;

(iv) Identifies the sources of data and the estimating methods and rationale used in developing cost estimates;

(v) Provides for appropriate supervision throughout the estimating process;

(vi) Provides for consistent application of estimating techniques;

(vii) Provides for detection and timely correction of errors;

(viii) Protects against cost duplication and omissions;

(ix) Provides for the use of historical experience, including historical vendor pricing information, where appropriate;

(x) Requires use of appropriate analytical methods;

(xi) Integrates information available from other management systems, where appropriate;

(xii) Requires management review including verification that the company's estimating policies, procedures and practices comply with this regulation;

(xiii) Provides for internal review of and accountability for the adequacy of the estimating system, including the comparison of projected results to actual results and an analysis of any differences;

(xiv) Provides procedures to update cost estimates in a timely manner throughout the negotiation process; and

(xv) Addresses responsibility for review and analysis of the reasonableness of subcontract prices.

(3) *Indicators of potentially significant estimating deficiencies.* The following examples indicate conditions that may produce or lead to significant estimating deficiencies—

(i) Failure to ensure that historical experience is available to and utilized by cost estimators, where appropriate;

(ii) Continuing failure to analyze material costs or failure to perform subcontractor cost reviews as required;

(iii) Consistent absence of analytical support for significant proposed cost amounts;

(iv) Excessive reliance on individual personal judgment where historical experience of commonly utilized standards are available;

(v) Recurring significant defective pricing findings within the same cost element(s);

(vi) Failure to integrate relevant parts of other management systems (e.g., production control or cost accounting) with the estimating system so that the ability to generate reliable cost estimates is impaired; and

(vii) Failure to provide established policies, procedures, and practices to persons responsible for preparing and supporting estimates.

(e) *Review procedures.* Cognizant audit and contract administration activities shall—

(1) Establish and manage regular programs for reviewing selected contractors' estimating systems.

(2) Conduct reviews as a team effort.

(i) The contract auditor will be the team leader.

(ii) The team leader will—

(A) Coordinate with the ACO to ensure that team membership includes qualified contract administration technical specialists.

(B) Advise the ACO and contractor of significant findings during the conduct of the review and during the exit conference.

(C) Prepare a team report.

(*1*) The ACO or a representative should—

(*i*) Coordinate the contract administration activity's review;

(*ii*) Consolidate findings and recommendations; and

(iii) When appropriate, prepare a comprehensive written report for submission to the auditor.

(2) The contract auditor will attach the ACO's report to the team report.

(3) Tailor reviews to take full advantage of the day-to-day work done by both organizations.

(4) Conduct a review every three years of contractors subject to the disclosure requirements. The ACO and auditor may lengthen or shorten the three-year period based on their joint risk assessment of the contractor's past experience and current vulnerability.

(f) *Disposition of survey team findings.*

(1) *Reporting of survey team findings.* The auditor will document the findings and recommendations of the survey team in a report to the ACO. If there are significant estimating deficiencies, the auditor will recommend disapproval of all or portions of the estimating system.

(2) *Initial notification to the contractor.* The ACO will provide a copy of the team report to the contractor and, unless there are no deficiencies mentioned in the report, ask the contractor to submit a written response in 30 days, or a reasonable extension.

(i) If the contractor agrees with the report, the contractor has 60 days from the date of initial notification to correct any identified deficiencies or submit a corrective action plan showing milestones and actions to eliminate the deficiencies.

(ii) If the contractor disagrees, the contractor should provide rationale in its written response.

(3) *Evaluation of contractor's response.* The ACO, in consultation with the auditor, will evaluate the contractor's response to determine whether—

(i) The estimating system contains deficiencies that need correction;

(ii) The deficiencies are significant estimating deficiencies that would result in disapproval of all or a portion of the contractor's estimating system; or

(iii) The contractor's proposed corrective actions are adequate to eliminate the deficiency.

(4) *Notification of ACO determination.* The ACO will notify the contractor and the auditor of the determination and, if appropriate, of the Government's intent to disapprove all or selected portions of the system. The notice shall—

(i) List the cost elements covered;

(ii) Identify any deficiencies requiring correction; and

(iii) Require the contractor to correct the deficiencies within 45 days or submit an action plan showing milestones and actions to eliminate the deficiencies.

(5) *Notice of disapproval.* If the contractor has neither submitted an acceptable corrective action plan nor corrected significant deficiencies within 45 days, the ACO shall disapprove all or selected portions of the contractor's estimating system. The notice of disapproval must—

(i) Identify the cost elements covered;

(ii) List the deficiencies that prompted the disapproval; and

(iii) Be sent to the cognizant auditor, and each contracting and contract administration office having substantial business with the contractor.

(6) *Monitoring contractor's corrective action.* The auditor and ACO will monitor the contractor's progress in correcting deficiencies. If the contractor fails to make adequate progress, the ACO shall take whatever action is necessary to ensure that the contractor corrects the deficiencies. Examples of actions the ACO can take are: bringing the issue to the attention of higher-level management, reducing or suspending progress payments (see FAR 32.503–6), and recommending nonaward of potential contracts.

(7) *Withdrawal of estimating system disapproval.* The ACO will withdraw the disapproval when the ACO determines that the contractor has corrected the significant system deficiencies. The ACO will notify the contractor, the auditor, and affected contracting and contract administration activities of the withdrawal.

(g) *Impact of estimating system deficiencies on specific proposals.*

(1) Field pricing teams will discuss identified estimating system deficiencies and their impact in all reports on contractor proposals until the deficiencies are resolved.

(2) The contracting officer responsible for negotiation of a proposal generated by an estimating system with an identified deficiency shall evaluate whether the deficiency impacts the negotiations. If it does not, the contracting officer should proceed with negotiations. If it does, the contracting officer should consider other alternatives, e.g.—

(i) Allowing the contractor additional time to correct the estimating system deficiency and submit a corrected proposal;

(ii) Considering another type of contract, e.g., and FPIF instead of an FFP;

(iii) Using additional cost analysis techniques to determine the reasonableness of the cost elements affected by the system's deficiency;

(iv) Segregating the questionable areas as a cost reimbursable line item;

(v) Reducing the negotiation objective for profit or fee; or

(vi) Including a contract (reopener) clause that provides for adjustment of the contract amount after award.

(3) The contracting officer who incorporates a reopener clause into the contract is responsible for negotiating price adjustments required by the clause. Any reopener clause necessitated by an estimating deficiency should—

(i) Clearly identify the amounts and items that are in question at the time of negotiation;

(ii) Indicate a specific time or subsequent event by which the contractor will submit a supplemental proposal, including cost or pricing data, identifying the cost impact adjustment necessitated by the deficient estimating system;

(iii) Provide for the contracting officer to unilaterally adjust the contract price if the contractor fails to submit the supplemental proposal; and

(iv) Provide that failure of the Government and the contractor to agree to the price adjustment shall be a dispute under the Disputes clause.

215.408 Solicitation provisions and contract clauses.

(1) Use the clause at 252.215–7000, Pricing Adjustments, in solicitations and contracts that contain the clause at—

(i) FAR 52.215–11, Price Reduction for Defective Cost or Pricing Data-Modifications;

(ii) FAR 52.215–12, Subcontractor Cost or Pricing Data; or

(iii) FAR 52.215–13, Subcontractor Cost or Pricing Data—Modifications.

(2) Use the clause at 252.215–7002, Cost Estimating System Requirements, in all solicitations and contracts to be awarded on the basis of cost or pricing data.

215.470 Estimated data prices.

(a) The Department of Defense requires estimates of the prices of data in order to evaluate the cost to the Government of data items in terms of their management, product, or engineering value.

(b) When data are required to be delivered under a contract, the solicitation will include DD Form 1423, Contract Data Requirements List. The form and the provision included in the solicitation request the offeror to state what portion of the total price is estimated to be attributable to the production or development of the listed data for the Government (not to the sale of rights in the data). However, offerors' estimated prices may not reflect all such costs; and different offerors may reflect these costs in a different manner, for the following reasons:

(1) Differences in business practices in competitive situations;

(2) Differences in accounting systems among offerors;

(3) Use of factors or rates on some portions of the data;

(4) Application of common effort to two or more data items; and

(5) Differences in data preparation methods among offerors.

(c) Data price estimates should not be used for contract pricing purposes without further analysis.

(d) The contracting officer shall ensure that the contract does not include a requirement for data that the contractor has delivered or is obligated to deliver to the Government under another contract or subcontract, and that the successful offeror identifies any such data required by the solicitation. However, where duplicate data are desired, the contract price shall include the costs of duplication, but not of preparation, of such data.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

3. Section 252.215–7000 is amended by revising the introductory text to read as follows:

252.215–7000 Pricing Adjustments.

As prescribed in 215.408(1), use the following clause:

* * * * *

4. Section 252.215–7002 is amended by revising the introductory text to read as follows:

252.215–7002 Cost Estimating System Requirements.

As prescribed in 215.408(2), use the following clause:

* * * * *

5. Section 252.243–7000 is amended by revising the clause date and paragraph (c)(1) to read as follows:

252.243–7000 Engineering Change Proposals.

* * * * *

Engineering Change Proposals (XXX 19XX)

* * * * *

(c) * * *

(1) A completed contract pricing proposal; and

* * * * *

[FR Doc. 97–31109 Filed 11–25–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE47

Endangered and Threatened Wildlife and Plants; Proposed Rule To Establish an Additional Manatee Sanctuary in Kings Bay, Crystal River, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes to establish an additional West Indian manatee (*Trichecus manatus*) sanctuary in Citrus County, Florida, adjacent to Kings Bay/Crystal River at the confluence of the Three Sisters Spring run with a residential canal. All waterborne activities in the sanctuary would be prohibited from November 15 through March 31 of each year. The proposed action would help prevent the taking of manatees by harassment resulting from waterborne activities during the winter months. The number of sanctuaries in Kings Bay would be increased to seven to accommodate the increase in the number of manatees using the area each winter and to offset harassment from increasing public use. Due to insufficient time to complete preparations for establishing a permanent sanctuary before cold weather arrives, an emergency rule is published elsewhere in today's **Federal Register** to provide the manatee with immediate protection for a period of 120 days. This action is proposed under the authority of the Endangered Species Act of 1973, as amended, and the Marine Mammal Protection Act of 1972, as amended.

DATES: Comments from all interested parties must be received by January 26, 1998. If requested, a public hearing will be held for the purpose of receiving comments on the permanent establishment of an additional manatee sanctuary at Kings Bay, Crystal River, Florida.

ADDRESSES: Written comments and materials should be sent to Manatee Coordinator, U.S. Fish and Wildlife Service, 6620 Southpoint Drive South, Suite 310, Jacksonville, Florida 32216–0912.

FOR FURTHER INFORMATION CONTACT: Robert O. Turner at the above address, (904/232–2580 ext.117); or Vance Eaddy, Senior Resident Agent, U.S. Fish and Wildlife Service, 9721 Executive Center Drive, Suite 206, St. Petersburg, Florida 33702, (813/570–5398)

SUPPLEMENTARY INFORMATION:

Background

Crystal River is a tidal river on the west coast of Florida. Forming the headwaters of Crystal River is Kings Bay, a lake-like body of water fed by numerous freshwater springs. The Kings Bay springs constitute one of the most important natural warm-water refuges for manatees, a federally listed endangered species. More than 250 animals may seek refuge in the bay's warm waters during winter cold periods. With the winter presence of manatees and its sheltered, warm and clear waters, Kings Bay also attracts large numbers of waterborne users (boaters, recreational divers, snorkelers, and swimmers) most of whom seek out manatees for a close viewing experience. The influx of visitors, primarily there to see and interact with manatees, provides a major economic impact to the Crystal River community.

Large aggregations of manatees apparently did not exist in Kings Bay until recent times (Beeler and O'Shea 1988). The first careful counts were made in the late 1960's. Since then manatee numbers have increased significantly. In 1967–1968 Hartman (1979) counted 38 animals. By 1981–1982, the maximum winter count increased to 114 animals (Powell and Rathbun 1984), and in December 1994 the count was 271 (U.S. Fish and Wildlife Service, unpublished data). Both births and immigration of animals from other areas have contributed to the increases in manatee numbers at Crystal River.

The Second Revision of the Florida Manatee Recovery Plan (U.S. Fish and Wildlife Service 1995) identifies the need to minimize disturbance and harassment of manatees in the wild. This concern for the welfare of manatees in Kings Bay has resulted in the establishment of a series of sanctuary areas to protect manatees from any potential negative impacts of human activities. The first three sanctuaries were created in 1980, encompassing a total of about 10 acres in Kings Bay. These were closed to all human access each winter from November 15 to March 31 and provided manatees with areas where they could retreat from waterborne users. To better administer and protect the bay's manatee habitat, the Service purchased several islands associated with the sanctuaries in 1983 and established the Crystal River National Wildlife Refuge. During the 1980's, the number of manatees and divers increased steadily, resulting in the need for additional manatee sanctuaries. In 1994, the Service established three additional sanctuaries and expanded an existing sanctuary. The six sanctuaries now encompass approximately 39 acres within Kings Bay.

The Kings Bay manatee sanctuary system provides significant protection to the more than 250 manatees that use this area as a winter warm-water refuge. With the increasing number of manatees using Kings Bay and an increasing number of recreational divers and snorkelers coming to Crystal River to seek close encounters with manatees, another problem area outside the existing sanctuary system has been identified.

Since the establishment of the three most recent sanctuaries, reports of waterborne users harassing manatees and causing manatees to leave the Three Sisters Spring run area has been documented by researchers, refuge staff and concerned citizens. The Save the Manatee Club and the Marine Mammal Commission have urged the Service to act to protect manatees utilizing the Three Sisters Spring run area. Dive shop operators have acknowledged that there is a manatee harassment problem in the area of the proposed sanctuary.

Prior to last winter, the Service and local interest groups met separately with local dive shop owners to discuss the harassment issue and the feasibility of establishing a new sanctuary. There was a consensus that a sanctuary was needed and that it would be more effective if it was developed through a local city or county ordinance. Representatives of each of the local dive shops wrote letters recognizing the need for a small sanctuary near Three Sisters Spring and recommended that the regulations be promulgated locally. Local efforts have been made to address the problem and the Service will continue to encourage local officials to create a permanent refuge. However, in conjunction with the emergency rule published elsewhere in today's **Federal Register**, regulations at 50 CFR 17.106(e) require the Service to also commence with the establishment of the sanctuary through publication of a proposed rule.

The Service funded a manatee and human interaction study at Three Sisters Spring (January 23–February 17, 1997) which confirmed that harassment was occurring and documented instances in which manatees left the warm waters at the confluence of the spring run and the residential canal when divers, snorkelers and/or swimmers arrived (Wooding, 1997). The Service is concerned that these animals may be leaving earlier than if they were left undisturbed.

Reasons for Determination

Refer to the emergency rule published elsewhere in today's **Federal Register**.

National Environmental Policy Act

The Service has determined this action qualifies as a categorical exclusion in accordance with 516 DM 2, Appendix 1 and 516 DM 5, Appendix 1. No further National Environmental Policy Act documentation will therefore be made.

Required Determinations

This proposed rule was not subject to Office of Management and Budget review under Executive Order 12866. The rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The previous establishment of sanctuaries in Kings Bay, Crystal River, did not result in a significant economic impact. Thus it is not expected that any significant impacts would result from the establishment of a sanctuary (less than one quarter acre in size) at the Three Sisters Spring. Also, no direct costs, enforcement costs, information collection, or record-keeping requirements are imposed on small entities by this action and the rule contains no information collection requirements under the Paperwork Reduction Act of 1995. This rule does not require a Federalism assessment under Executive Order 12612 because it would not have any significant federalism effects as described in the order.

References Cited

Refer to the emergency rule published elsewhere in today's **Federal Register**.

Author: The primary author of this proposed rule is Robert O. Turner, Manatee Coordinator (see **ADDRESSES** section).

Authority

The authority to establish manatee protection areas is provided by the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), as amended.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, the Service proposes to amend part 17, subchapter B of chapter

I, title 50 of the Code of Federal Regulations, as follows:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend section 17.108 by adding paragraph (a)(7) to read as follows:

§ 17.108 List of designated manatee protection areas.

(a) * * *

(7) A tract of submerged land on the west side of the confluence of Three Sisters Spring run and the residential canal off the eastern shore of Kings Bay, Crystal River, lying in the northeast corner of Section 28, Township 18, South Range 17 East in Citrus County, Florida; containing less than one quarter acre.

* * * * *

Dated: November 20, 1997.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 97–31108 Filed 11–21–97; 3:41 pm]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 971107264–7264–01; I.D. 102297A]

RIN 0648–AK47

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; 1998 Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule and proposed 1998 initial specifications; request for comments.

SUMMARY: NMFS proposes initial specifications for the 1998 fishing year for Atlantic mackerel, *Loligo* and *Illex* squids, and butterfish (MSB). In addition, NMFS proposes to amend the minimum net mesh size requirement for *Loligo* squid to make it applicable only to the cod end of the net. The intent of this change is to reduce the frequency that nets need to be replaced with a resultant cost savings to the fishery. Regulations governing these fisheries require NMFS to publish specifications for the upcoming fishing year and provide an opportunity for the public to comment.

DATES: Public comments must be received on or before December 26, 1997.

ADDRESSES: Copies of the Mid-Atlantic Fishery Management Council's quota paper and recommendations, the Environmental Assessment, and Regulatory Impact Review, including analysis of impacts under the Regulatory Flexibility Act, are available from David R. Keifer, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, DE 19901.

Comments should be sent to Andrew A. Rosenberg, Ph.D., Regional Administrator, Northeast Region, NMFS, 1 Blackburn Drive, Gloucester, MA 01930. Please mark the envelope ''Comments—1998 MSB specifications.''

FOR FURTHER INFORMATION CONTACT: Myles Raizin, (978) 281–9104.

SUPPLEMENTARY INFORMATION: Regulations implementing the Fishery Management Plan for Atlantic Mackerel, Squid, and Butterfish Fisheries (FMP) prepared by the Mid-Atlantic Fishery Management Council (Council) appear at 50 CFR part 648. These regulations require NMFS to publish a proposed rule specifying the initial annual amounts of the initial optimum yield (IOY) as well as the amounts for allowable biological catch (ABC), domestic annual harvest (DAH), domestic annual processing (DAP), joint venture processing (JVP), and total allowable levels of foreign fishing (TALFF) for the species managed under the FMP. No reserves are permitted under the FMP for any of these species. In addition to commercial quotas, the Council, in consultation with its Squid, Mackerel, and Butterfish Technical Monitoring Committee, may recommend revisions to the amount of *Loligo* and *Illex* squids and butterfish that may be retained, possessed, and landed by vessels issued the incidental catch permit; commercial minimum fish sizes; commercial trip limits; commercial seasonal quotas/closures for *Loligo* or *Illex* squid; minimum mesh sizes; commercial gear restrictions; recreational harvest limit; recreational minimum fish size; and recreational possession limits.

The following table contains the proposed initial specifications for the 1998 Atlantic mackerel, *Loligo* and *Illex* squids, and butterfish fisheries as recommended by the Council:

PRELIMINARY INITIAL ANNUAL SPECIFICATIONS FOR ATLANTIC MACKEREL, SQUID, AND BUTTERFISH FOR THE FISHING YEAR JANUARY 1 THROUGH DECEMBER 31, 1998

[Metric ton (mt)]

Specifications	Squid		Atlantic Mackerel	Butterfish
	Loligo	Illex		
Max OY	[1]26,000	[1]24,000	[2] N/A	[3]16,000
ABC	21,000	19,000	382,000	7,200
IOY	21,000	19,000	[4] 80,000	5,900
DAH	21,000	19,000	[5] 80,000	5,900
DAP	21,000	19,000	50,000	5,900
JVP	0	0	15,000	0
TALFF	0	0	0	0

[1] Maximum optimum yield (Max OY) corresponds to a level of fishing beyond which overfishing occurs for *Loligo* and *Illex.*

[2] Max OY is not applicable for Atlantic mackerel.

[3] Max OY is specified as a catch level that would result from F_{msy} for butterfish.

[4] IOY for Atlantic mackerel may be increased during the year, but the total will not exceed 382,000 mt.

[5] Includes 15,000 mt of Atlantic mackerel recreational allocation.

1998 Proposed Specifications

Atlantic Mackerel

The ABC is recommended to be 382,000 mt. This is consistent with the overfishing definition for Atlantic mackerel that restricts ABC in U.S. and Canadian waters to that quantity of mackerel associated with a fishing mortality rate of $F_{0.1,}$ estimated by the most recent stock assessment (1996) at 405,000 mt. In addition, the recommendation must maintain a spawning stock size of at least 900,000 mt in the year following the year for which specifications are being developed (see § 648.21(b)(2)). A harvest of 405,000 mt is estimated by the assessment to result in an estimated spawning stock for 1999 of 1,695,000 mt. Using the projected Canadian catch of 23,000 mt, the proposed measure would cap ABC for Atlantic mackerel at 382,000 mt (405,000—23,000 mt).

IOY is a modification of ABC which reflects social and economic factors (see § 648.21(b)(2)(ii)). IOY is comprised of two components: DAH and TALFF. DAH is the sum of a recreational catch estimate: DAP and JVP. The Council estimates that the 1998 recreational catch will be 15,000 mt, and DAP will be 50,000 mt. The Council also recommends that IOY be set at a level that provides for a JVP of 15,000 mt and TALFF of zero. The resulting IOY recommended is 80,000 mt.

DAP has historically been estimated using the Council's annual process or survey, which this year estimated 11,364 mt necessary for 1998. However, for the 1998 estimates, response was low and did not contain projections from the large, known processors. In addition, inquiries concerning entry of displaced New England groundfish trawlers into the Atlantic mackerel fishery have led the Council to anticipate increases in harvest. Therefore, the Council recommends no change to the DAP for the 1998 fishery from the 1997 level of 50,000 mt.

The 1998 JVP specification of 15,000 mt was reduced by 10,000 mt from 1997 to reflect the concern the Council has about the negative effect that joint ventures (JVs) could have on the further development of the U.S. export market. The potential for future North Sea mackerel total allowable catch (TAC) reductions may provide an opportunity for U.S. producers to sell additional mackerel on the international market. The reduction is consistent with the Council's stated policy to proceed on a course that recognizes the need for JVs in the short term to allow U.S. harvesters to take mackerel at levels in excess of current U.S. processing capacity. However, in the longer term, the Council intends to eliminate JVs as U.S. processing and export capacity increases.

An IOY level that keeps TALFF at zero is recommended for the 1998 Atlantic mackerel fishery. The Fisheries Act of 1995 prohibits a specification of TALFF unless recommended by the Council. In 1992, the Council used testimony from both the domestic fishing and processing industries and analysis of nine economic factors found at § 648.21(b)(2)(iii) to determine that mackerel produced from directed foreign fishing would directly compete with U.S. processed products, thus limiting markets available to U.S. processors. The industry was nearly unanimous in its assessment that a specification of TALFF would impede the growth of the U.S. fishery. The Council sees no evidence that this evaluation has changed. Further, the Council believes that an expanding mackerel market and uncertainty regarding world supply, due to recent declines in the North Sea mackerel stock, have resulted in increased opportunities for U.S. producers to increase sales to new markets abroad. The U.S. industry has made some progress in capturing an increased market share for mackerel in Japan over the past 2 years, though Canada and Jamaica remain the most important export nations. Several factors indicate that market expansion for U.S. Atlantic mackerel is likely to continue. In addition, U.S. Atlantic mackerel stock abundance remains high. The continued low abundance of several important groundfish stocks in the Gulf of Maine, southern New England, and on Georges Bank and restrictions on fishing for those species also increase the likelihood that harvesters will redirect their efforts to Atlantic mackerel. Atlantic mackerel is considered a prime candidate for innovation in harvesting, processing, and marketing.

The Council also recommended that four special conditions imposed in previous years continue to be imposed on the 1998 Atlantic mackerel fishery as follows: (1) Joint ventures be allowed south of 37°30′ N. lat., but river herring bycatch can not exceed 0.25 percent of the over-the-side transfers of Atlantic mackerel; (2) the Administrator, Northeast Region, NMFS (Regional Administrator) must ensure that impacts on marine mammals are reduced in the prosecution of the Atlantic mackerel fishery; (3) the mackerel OY may be increased during the year, but the total must not exceed ABC; and (4) a joint venture with a particular nation shall not be allowed unless the Regional Administrator determines, based on an evaluation of performance, that the nation's purchase obligations from previous years have been fulfilled.

Atlantic Squids

The FMP sets the Maximum Optimum Yield (Max OY) for *Loligo* squid at 26,000 mt. The recommended ABC for the 1998 *Loligo* squid fishery is 21,000 mt, unchanged from the 1997 ABC. This level represents the harvest level associated with a fishing mortality rate of F_{50}, which was adopted in Amendment 6 to the FMP as an appropriate target harvest level for this species. The Council recommended that IOY should equal ABC.

The FMP sets the Max OY for *Illex* squid at 24,000 mt. The Council recommended an ABC of 19,000 mt, which represents the harvest level associated with a fishing mortality rate of F_{50} as required in Amendment 6 to the FMP. As for *Loligo* squid, the Stock Assessment Workshop (SAW) 21 recommended that F_{50} would be an appropriate target harvest level for this species. The Council recommended that the IOY for *Illex* squid be set equal to ABC.

Butterfish

The FMP sets the Max OY for butterfish at 16,000 mt. The most recent stock assessment was done in 1994 (SAW–17) and advised that the stock may not be able to sustain landings in excess of the long-term historical average (1965–92) of 7,200 mt. Based on this advice, the Council recommends maintaining ABC at 7,200 mt (unchanged from 1997). The Council also recommended maintaining IOY and DAH at 1997 levels (5,900 mt) to reflect the uncertainty that exists regarding the level of discards in the directed fishery.

As a result of the approval of Amendment 5, the FMP specifies that there will be no JVP or TALFF specified for *Loligo* squid, *Illex* squid, or butterfish, except that a butterfish bycatch TALFF will be specified if TALFF is specified for Atlantic mackerel. Since the Council recommended no TALFF for Atlantic mackerel, no bycatch TALFF is required for butterfish.

Framework Measure for Loligo Squid Nets

Amendment 5 to the Atlantic Mackerel, Squid, and Butterfish FMP established a minimum mesh requirement of 1⅞ inches (48 mm) throughout the entire net, for vessels possessing *Loligo* squid. Amendment 5 also established a framework procedure whereby the minimum mesh provision

for *Loligo* squid could be reconsidered by the Council on an annual basis. Numerous members of the commercial fishing industry testified before the Council that the minimum mesh requirement for *Loligo* squid established in Amendment 5, applied throughout the entire net, was creating a major compliance problem within the squid industry. Testimony was given that, after continuous use, meshes forward of the codend become distorted and shrink. Because the body of the net forward of the codend lasts significantly longer than the codend, this problem becomes more acute with time. Industry is concerned that nets, which were legal when new, could be in violation of the minimum mesh provision after extended use. Since selection occurs in the codend of the net, they argue that the requirement for minimum mesh throughout the entire net is creating an unnecessary burden on the industry.

In response to these concerns the Council decided to change the minimum mesh requirement for *Loligo* squid such that it applies to the codend of the net only. The actual mesh size requirement of 1⅞ inches (48 mm) remains unchanged. Thus the Council has chosen to modify the mesh requirement for *Loligo* squid for 1998 by requiring that nets have a minimum mesh size of 1⅞ inches (48 mm) diamond, inside stretch measure, applied throughout the codend for at least 150 continuous meshes forward of the terminus of the net, or, if the net is not long enough for such a measurement, the terminal one-third of the net, measured from the terminus of the net to the head rope. This should relieve the industry of major costs associated with replacing the body of the net before its useful service life has been realized. The effects on the fishery should be minimal since the selection process, which occurs in the codend, will be unchanged. The Council concluded that the benefits to the industry in terms of cost savings far outweighed any negative effects of applying the mesh requirement to the codend only. Additional savings in terms of enforcement of the mesh regulations should be realized since enforcement officers will only be required to check mesh sizes in the codend instead of the entire net, which, in most cases, is quite large and can consume a significant amount of time during the boarding process.

Classification

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. It is assumed that all vessels prosecuting these fisheries are small entities. For *Loligo* and *Illex* squid and butterfish, gross revenues are not expected to decrease as a consequence of the proposed actions. In 1996, *Loligo* squid landings were 12,459 mt. The proposed IOY specification for *Loligo* squid in 1998 is 21,000 mt. In 1996, *Illex* squid landings were 16,969 mt. The proposed IOY specification for *Illex* squid in 1998 is 19,000 mt. In 1996, butterfish landings were 3,489 mt. The proposed IOY specification for butterfish in 1998 is 5,900 mt. In the case of Atlantic mackerel, the 1998 IOY was reduced from 90,000 mt in 1997 to the proposed level of 80,000 mt in 1998. Both specifications far exceed recent harvest in the 1996 fishery of 15,712 mt. In addition, the reduction in IOY in 1998 was due to a reduction in the JV specification by 10,000 mt. Since there has been no JV activity in recent years, the reduction in the JV specification should not affect revenues in the fishery.

Based on this information, the 1998 quotas allow for a further expansion of domestic fishing effort. Assuming that prices are constant and 1997 harvest levels are similar to those in 1996, the 1998 quotas represent no constraint on the ability of individual vessels to increase revenues. It was also determined that restricting the minimum mesh size to the codend, for the *Loligo* squid fishery, would decrease operating costs for the industry by reducing the number of times they would be forced to change the mesh in the body of the net.

NMFS, therefore, concludes that the proposed 1998 quota specifications for the squid, mackerel, and butterfish fisheries would not decrease annual gross revenues by more than 5 percent for a substantial number of small entities. Furthermore, it is not expected that any vessels would cease operations if these proposed specifications are implemented, nor should compliance costs increase by 10 percent or more for 20 percent of the vessels or processors in any of these fisheries. As a result, a regulatory flexibility analysis was not prepared.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: November 20, 1997.

David L. Evans,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF NORTHEASTERN UNITED STATES

1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 648.23, paragraph (a) introductory text is revised to read as follows:

§ 648.23 Gear restrictions.

(a) *Mesh restrictions and exemptions.* Owners or operators of otter trawl vessels possessing *Loligo* squid harvested in or from the EEZ may only fish with nets having a minimum mesh size of 1⅞ inches (48 mm) diamond mesh, inside stretch measure, applied throughout the codend for at least 150 continuous meshes forward of the terminus of the net, or for codends with less than 150 meshes, the minimum mesh size codend shall be a minimum of one-third of the net measured from the terminus of the codend to the head rope, unless they are fishing during the months of June, July, August, and September for *Illex* squid seaward of the following coordinates (copies of a map depicting this area are available from the Regional Administrator upon request):

* * * * *

[FR Doc. 97–31065 Filed 11–25–97; 8:45 am]
BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 62, No. 228

Wednesday, November 26, 1997

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 21, 1997.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, D.C. 20503 *and* to Department Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, D.C. 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) May be obtained by calling (202) 720–6746.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

- **Food and Consumer Service**

Title: Food Coupon Deposit Document.
OMB Control Number: 0584–0314.
Summary of Collection: The Food Coupon Deposit Document is used by all financial institutions when remitting food coupons to the Federal Reserve.
Need and Use of the Information: The information allows financial institutions, the Federal Reserve and the Food and Consumer Service to track food coupon deposits.
Description of Respondents: Business or other for-profit.
Number of Respondents: 10,000.
Frequency of Responses: Reporting: On occasion.
Total Burden Hours: 3,675.

- **Rural Utilities Service**

Title: 7 CFR 1794, Environmental Policies and Procedures.
OMB Control Number: 0572–New.
Summary of Collection: Information collected includes a proposal for the project and an environmental analysis.
Need and Use of the Information: The information will be used to evaluate the cost and feasibility of the project and the environmental impact.
Description of Respondents: Not-for-profit institutions; Business or other for-profit.
Number of Respondents: 600.
Frequency of Responses: Reporting: On occasion.
Total Burden Hours: 415,000.

- **Food and Consumer Service**

Title: FSP Store Application.
OMB Control Number: 0584–0008.
Summary of Collection: The Food Stamp Act of 1977, as amended, requires that the Agency determine the eligibility of firms and specified programs to accept and redeem food stamp benefits and to monitor them for compliance and continued eligibility.
Need and Use of the Information: This information is used for determining a firm's eligibility for participation in the program, program administration, compliance monitoring and investigations, and for sanctioning stores found to be violating the program.
Description of Respondents: Business or other for-profit.
Number of Respondents: 80,613.
Frequency of Responses: Reporting: On occasion.
Total Burden Hours: 18,396.

- **Foreign Agricultural Service**

Title: Regulations Covering CCC's Facility Guarantee Program (FGP).
OMB Control Number: 0551–0032.
Summary of Collection: The Commodity Credit Corporation (CCC) requires that an application be submitted to participate in the Facility Guarantee Program (FGP). A request to become an eligible participant in the FGP is included in the application. This information ensures CCC that all participants have a business office in the United States.
Need and Use of the Information: The information is necessary in order to determine eligibility for participation in the Facility Guarantee Program.
Description of Respondents: Business or other for-profit.
Number of Respondents: 25.
Frequency of Responses: Recordkeeping; Reporting: On occasion.
Total Burden Hours: 647.

- **Natural Resources Conservation Service**

Title: Rural Abandoned Mine Program.
OMB Control Number: 0578–0019.
Summary of Collection: Information is collected regarding progress in applying the conservation plan and a contract to receive Federal cost-share assistance is completed.
Need and Use of the Information: The information is used to ensure proper utilization of program funds.
Description of Respondents: Farms; Individuals or households; State, Local or Tribal Government.
Number of Respondents: 400.
Frequency of Responses: Reporting: On occasion.
Total Burden Hours: 223.
Emergency processing of this submission has been requested by December 12, 1997.

- **Rural Business—Cooperative Service**

Title: 7 CFR Part 4284–G, Rural Business Opportunity Grants.
OMB Control Number: 0570–New.
Summary of Collection: Information collected includes a scope of work, organizational documents, a narrative description of the project, financial statements, and an evaluation method of the project's success.
Need and Use of the Information: The information is used to make decisions

regarding eligibility of applicants and selection priority, to ensure compliance with applicable laws and regulations, and to evaluate the program.

Description of Respondents: Not for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 100.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Monthly; Quarterly.

Total Burden Hours: 8704.

Donald Hulcher,

Departmental Clearance Officer.

[FR Doc. 97–31015 Filed 11–25–97; 8:45 am]

BILLING CODE 3410–01–M

DEPARTMENT OF AGRICULTURE

Economic Research Service

Notice of Intent To Seek Approval to Collect Information

AGENCY: Economic Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub.L. No. 104–13) and Office of Management and Budget (OMB) regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the Economic Research Service's (ERS) intention to request approval for a new information collection on the demographic and economic characteristics of participants in USDA's Single Family Direct Loan Rural Housing Program in order to better understand how this program helps provide adequate and affordable housing for rural residents.

DATES: Comments on this notice must be received by January 30, 1998 to be assured of consideration.

ADDITIONAL INFORMATION OR COMMENTS: Contact Linda Ghelfi or Leslie Whitener, Food Assistance, Poverty, and Well-Being Branch, Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture, 1800 M. St., NW, Washington, D.C. 20036–5801, 202–694–5420.

SUPPLEMENTARY INFORMATION:

Title: Application for ERS collection of information on participants in USDA's Single Family Direct Loan Rural Housing Program.

Type of Request: Approval to collect information on participants in USDA's Single Family Direct Loan Rural Housing Program.

Abstract: The Economic Research Service has the responsibility to provide social and economic intelligence on changing rural housing needs in the United States to help assess the relationship between Federal housing assistance policies and rural development. Research activities focus on three major objectives: (1) Identification of trends in rural housing availability, affordability, and adequacy which underlie an understanding of rural housing needs; (2) assessment of the use and effectiveness of Federal housing assistance programs in rural areas; and (3) investigation of the potential effects of Federal policy changes on rural housing programs and the residents they serve. Housing has an enormous influence on the quality of life of rural residents, and rural housing is an important focus of the Department's rural development efforts. Research findings are provided to public and private decision-makers for use in developing and evaluating policies and programs to insure that adequate and affordable housing is available to rural residents.

The USDA, through its Rural Development Single Family Direct Loan Housing Program, has provided billions of dollars to over 600,000 low-income rural borrowers nationwide. The Department has only sporadic and incomplete information on the residents that benefit from these program outlays and what this program means for the stock of available, affordable, and adequate single family housing in rural areas. The data collection effort proposed here will provide a unique and detailed information base on the characteristics of USDA's Section 502 Direct Loan Program participants to help (1) assess the impact of this housing-assistance program on rural residents and their communities and (2) provide a better understanding of the effects of changing Federal policies, such as welfare reform, on rural borrowers's participation in the direct loan program. The survey will collect information from USDA-assisted borrowers to determine their demographic, employment, income, and housing characteristics; reliance on other public assistance programs; and dependence on rural housing program funds. This information will help to fill a serious gap in our understanding of the nature of housing needs in rural areas and will provide USDA and other policy makers with sound information to help evaluate current programs and develop more effective rural housing policies. ERS, working with Washington State University's Social and Economic Sciences Research Center, will conduct a telephone survey of borrowers participating in USDA's Section 502 Single Family Direct Loan Housing Program. Borrowers to be interviewed will be selected from a simple random national sample of recent borrowers who obtained loans during 1995, 1996, or 1997, taken from USDA's Rural Development administrative records. Survey data will be collected using Computer-Assisted Telephone Interviewing (CATI) techniques, which are more efficient and less time consuming than traditional written interview techniques. Responses are voluntary and confidential. Survey data will be used with other data for statistical purposes and reported only in aggregate or statistical form.

Information to be obtained from borrowers includes: characteristics of current and past housing; housing problems; satisfaction with current residence, neighborhood, and the USDA financing experience; demographic characteristics of household members; education and employment characteristics of borrowers; public assistance program participation; and sources and amounts of household income. No existing data sources, including USDA administrative data or the biennial American Housing Survey, are sufficiently detailed to allow an in-depth analysis of the relationships among these variables for participants in the Section 502 program. These data and the research they will support are vital to the Department's ability to assess the impact of its rural housing programs on rural residents and rural community development.

Estimate of Burden: Public reporting burden for this data collection is estimated to average 20 minutes per completed interview, including time for listening to instructions, gathering data needed, and responding to questionnaire items.

Respondents: Homeowners who obtained a loan during 1995, 1996, and 1997 through USDA's Section 502 Single Family Direct Loan Program.

Estimated Number of Respondents: 3,000.

Estimated Total Annual Burden on Respondents: 1,000 hours. Copies of information concerning the data collection can be obtained from Linda Ghelfi or Leslie Whitener, Food Assistance, Poverty and Well-Being Branch, Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture, 1800 M. St., NW, Washington, D.C. 20036–5801, 202–694–5420.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper functions of the agency, including

whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden on those who are to respond, such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques. Comments may be sent to Linda Ghelfi, Food Assistance, Poverty and Well-Being Branch, Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture, 1800 M. St., NW, Washington, D.C. 20036–5801. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Signed at Washington, D.C.

Thomas A. Carlin,

Deputy Director, Food and Rural Economics Division.

[FR Doc. 97–31079 Filed 11–25–97; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of initiation of antidumping and countervailing duty administrative reviews and request for revocation in part.

SUMMARY: The Department of Commerce has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews. The Department also received a request to revoke one countervailing duty order in part.

EFFECTIVE DATE: November 26, 1997.

FOR FURTHER INFORMATION CONTACT: Holly A. Kuga, Office of AD/CVD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone: (202) 482–4737.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b) (1997), for administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates. The Department also received a request to revoke in part the countervailing duty order on certain agricultural tillage tools from Brazil.

Initiation of Reviews

In accordance with section 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than October 31, 1998.

Antidumping duty proceedings	Period to be reviewed
Italy: Pressure Sensitive Tape	
A–475–059	10/1/96–9/30/97
N.A.R.S.p.A.	
Japan: Tapered Roller Bearings, Under 4 Inches	
A–588–054	10/1/96–9/30/97
Koyo Seiko Co., Ltd.	
NSK, Ltd.	
Fuji Heavy Industries, Ltd.	
Japan: Tapered Roller Bearings, Over 4 Inches	
A–588–604	10/1/96–9/30/97
NSK Ltd.	
NTN	
Fuji Heavy Industries, Ltd.	
Malaysia: Extruded Rubber Thread	
A–557–805	10/1/96–9/30/97
Filati Lastex Sdn. Bhd.	
Filmax Sdn. Bhd.	
Heveafil Sdn. Bhd.	
Rubberflex Sdn. Bhd.	
Rubfil Sdn. Bhd.	
The People's Republic of China: Helical Spring Lock Washers*	
A–570–822	10/1/96–9/30/97
Hangzhou Spring Washer Plant	
Zejiang Wanxin Group Co., Ltd.	
*If one of the above named companies does not qualify for a separate rate, all other exporters of helical spring lock washers from the People's Republic of China who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.	
The People's Republic of China: Chrome-Plate Lug Nuts*/**	
A–570–808	9/1/96–8/31/97
China National Automotive Industry I/E Corp.	
China National Machinery & Equipment I/E Corp.	
Shanghai Automobile Import & Export Co.	
Tianjin Automobile Import & Export Co.	
Ningbo Knives & Scissors Factory	
China National Automotive Import & Export Corp./Yangzhou Branch	
Jiangsu Rudong Grease Gun Factory	
China National Automotive Industry I/E Corp./Nantong Branch	

* Inadvertently omitted from previous initiation notice.

** If one of the above named companies does not qualify for a separate rate, all other exporters of chrome-plated lug nuts from the People's Republic of China who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

Countervailing duty proceedings	Period to be reviewed
Brazil: Certain Agricultural Tillage Tools	
C–351–406	1/1/96–12/31/96
Marchesan Implementos e Maquinas Argicolas ''TATU'' S.A.*	
*Marchesan has submitted a request for partial revocation of the order under 19 CFR 351.222(c)(3). The Department will examine the request for revocation to determine whether Marchesan meets the threshold requirements for revocation under 19 CFR 351.222(e)(2)(iii).	
India: Certain Iron-Metal Castings.	
C–533–063	1/1/96–12/31/96
Calcutta Ferrous Ltd.	
Carnation Enterprise Pvt. Ltd.	
Carnation Industries	
Commex Corporation	
Crescent Foundry Co. Pvt. Ltd.	
Delta Enterprises	
Dinesh Brothers (P) Ltd.	
Kajaria Iron Castings Ltd.	
Kejriwal Iron & Steel Works	
Metflow	
Nandikeshwari Iron Foundry Pvt. Ltd.	
Orissa Metal Industries	
Overseas Iron Foundry	
R.B. Agarwalla & Company	
R.B. Agarwalla & Co. Pvt. Ltd.	
RSI Limited	
Serampore Industries Pvt. Ltd.	
Shree Rama Enterprise	
Shree Uma Foundries	
Siko Exports	
SSL Exports	
Super Iron Foundry	
Uma Iron & Steel	
Victory Castings Ltd.	

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under section 351.211 or a determination under section 351.218(d) (sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

For transition orders defined in section 751(c)(6) of the Act, the Secretary will apply paragraph (j)(1) of this section to any administrative review initiated in 1996 or 1998 (19 CFR 351.213(j)(1–2)).

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 353.34(b) and 355.34(b).

These initiations and this notice are in accordance with section 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)), and 19 CFR 351.221(c)(1)(i).

Dated: November 21, 1997.

Louis Apple,

Acting Deputy Assistant Secretary, Group II Import Administration.

[FR Doc. 97–31133 Filed 11–25–97; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–502]

Certain Welded Carbon Standard Steel Pipes and Tubes From India; Amendment of Final Results of New Shippers Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of amendment of final results of new shippers antidumping duty administrative review.

SUMMARY: On September 10, 1997, the Department of Commerce published the final results of its new shippers antidumping duty administrative review on certain welded carbon standard steel pipes and tubes from India. The review covered two manufacturers/exporters of the subject merchandise to the United States and the period May 1, 1995 through April 30, 1996. Because of ministerial errors made with respect to one manufacturer/exporter, we are publishing an amendment to the final results in accordance with 19 CFR 353.28(c).

EFFECTIVE DATE: November 25, 1997.

FOR FURTHER INFORMATION CONTACT: Kristie Strecker or Greg Thompson, AD/CVD Enforcement Group I, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, telephone: (202) 482–3174 or (202) 482–0410, respectively.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Tariff Act) by the Uruguay Round Agreements Act (URAA).

Background

On September 10, 1997 (62 FR 47632), the Department of Commerce (the Department) published the final results of the new shipper review of the antidumping duty order on certain welded carbon standard steel pipes and tubes from India (51 FR 9089, March 17, 1989). On September 23, 1997, we received a timely allegation from Rajinder Pipes Ltd. (Rajinder), pursuant to § 353.28 of the regulations, that we made ministerial errors in the final results.

Rajinder contended that in the margin calculations for the final results we incorrectly deducted inventory carrying costs incurred in India from U.S. price and failed to deduct advertising expenses from normal value. See Memorandum to the File from Kristie Strecker to Robin Gray (October 21, 1997). We agree with Rajinder that these were ministerial errors, and we have corrected these ministerial errors in these amended results in order to reflect our intent and our practice pursuant to § 353.28.

Amended Final Results of Review

As a result of our correction of the ministerial errors, we have determined the margin for the period May 1, 1995 through April 30, 1996 to be:

Company	Margin (percent)
Rajinder	18.25

The Customs Service shall assess antidumping duties on all appropriate entries. Individual differences between U.S. price and normal value may vary from the percentage stated above. The Department will issue appraisement instructions concerning the respondent directly to the U.S. Customs Service. Furthermore, the following deposit requirements will be effective for all shipments of the subject merchandise, entered, or withdrawn from warehouse, for consumption on or after the publication date of these amended final results of administrative review, as provided for by section 751(a)(1) of the Tariff Act: (1) The cash deposit rate for Rajinder will be the rate indicated above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or in the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review conducted by the Department, the cash deposit rate will be 7.08 percent, the all-others rate established in the LTFV investigation.

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice serves as the final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during these review periods. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Timely written notification or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of the APO is a sanctionable violation.

These amended final results of administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.28(c).

Dated: November 19, 1997.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 97–31134 Filed 11–25–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–549–401]

Certain Apparel From Thailand; Final Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of countervailing duty administrative review.

SUMMARY: On September 3, 1997, the Department of Commerce published in the **Federal Register** its preliminary results of administrative review of the countervailing duty order on Certain Apparel from Thailand for 1991. The Department of Commerce has now completed this review in accordance with section 751(a) of the Tariff Act of 1930, as amended. For information on the net bounty or grant, please see the ''Final Results of Review'' section. We will instruct the U.S. Customs Service to assess countervailing duties as indicated in that section.

EFFECTIVE DATE: November 26, 1997.

FOR FURTHER INFORMATION CONTACT: Robert Copyak or Constance Cunningham, Office of CVD/AD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

The Department of Commerce (the Department) is conducting this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994.

Background

On September 3, 1997, the Department published in the **Federal Register** (62 FR 46475) the preliminary results of its administrative review of the countervailing duty order on Certain Apparel from Thailand. Since the publication of the preliminary results, the following events have occurred. We invited interested parties to comment on the preliminary results. On September 23, 1997, we received one comment from UNITE, formerly known as the

Amalgamated Clothing and Textile Workers Union, indicating support for the preliminary results.

This review covers the period January 1, 1991, through December 31, 1991, and involves 19 companies and 4 programs.

Scope of Review

Imports covered by this review are certain apparel from Thailand. Such merchandise is described in detail in the Appendix to this notice.

Calculation Methodology for Assessment Purposes

The country-wide rate we calculated for this administrative review was above *de minimis,* as defined by 19 CFR § 355.7 (1994). We examined the net rate calculated for each company to determine whether individual company rates differed significantly from the weighted-average country-wide rate, pursuant to 19 CFR § 355.22(d)(3). Four companies had significantly different net rates during the review period. These companies are treated separately for assessment purposes. All other companies are assigned the country-wide rate. *See* ''Final Results of Review'' section, below.

Analysis of Programs

I. Programs Conferring Subsidies

In the preliminary results we found that these programs conferred countervailable benefits on the subject merchandise. Our review of the record has not led us to change our findings from the preliminary results. On this basis, the weighted-average bounty or grant for these programs are as follows:

Program name	Program rate (percent)
Export Packaging Credits	0.55
Tax Certificates for Exports	.31
Electricity Discounts for Exporters	.20
Investment Promotion Act (IPA)—Sections 28 and 36(4)	.07

II. Programs Found Not to be used

We determine that the producers and/or exporters of the subject merchandise did not apply for or receive benefits under the following programs:

A. Rediscount of Industrial Bills
B. Assistance for Trading Companies
C. IPA (Sections 29, 30, 31, 33, 36(1–3))
D. Export Processing Zones
E. Financing from the Industrial Finance Corporation of Thailand

Final Results of Review

For the period January 1, 1991 through December 31, 1991, we determine the net bounty or grant to be 1.13 percent *ad valorem* for all companies except Thai Garment Export Co., Ltd., Fairtex Garment Co., Ltd., Fang Brothers Holding (Thailand) Co., Ltd., and East Asia Textile Ind. Co., Ltd., which have *de minimis* rates. In accordance with 19 CFR 355.7, any rate less than 0.5 percent *ad valorem* is *de minimis.*

The Department will instruct the U.S. Customs Service to assess countervailing duties of 1.13 percent *ad valorem* for all shipments of the subject merchandise exported on or after January 1, 1991, and on or before December 31, 1991, for all producers and exporters except Thai Garment Export Co., Ltd., Fairtex Garment Co., Ltd., Fang Brothers Holding (Thailand) Co., Ltd., and East Asia Textile Co., Ltd. For these companies, the Department will instruct the U.S. Customs Service to liquidate all shipments of the subject merchandise without regard to countervailing duties.

As noted above, this countervailing duty order was subject to section 753 of the Act, as amended by the URAA. *See Countervailing Duty Order; Opportunity to Request a Section 753 Injury Investigation* (60 FR 27,693, May 26, 1995). Because no domestic interested parties exercised their right under section 753(a) of the Act to request an injury investigation, the International Trade Commission made a negative injury determination with respect to this order, pursuant to section 753(b)(4) of the Act. As a result, the Department revoked this countervailing duty order, effective January 1, 1995, pursuant to section 753(b)(3)(B) of the Act. *See Revocation of Countervailing Duty Order* (60 FR 40568, August 9, 1995) and *Notice of Determination to Amend Revocation, in Part, of Countervailing Duty Order* (62 FR 392, January 3, 1997). Accordingly the Department will not issue further instructions with respect to cash deposits of estimated countervailing duties.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 355.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: November 19, 1997.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

Appendix

[C–549–401]

Countervailing Duty Order on Certain Apparel From Thailand; Harmonized Tariff Schedule Numbers

HTS No.	Annotation
6101.2000	Coverage excludes garments having embroidery or permanently affixed applique work on the outer surface.
6101.3020	
6102.1000	
6103.1920	Coverage limited to garments that would be covered if separately entered.
6103.2200	Coverage limited to garments that would be covered if separately entered.
6103.2300	Coverage limited to garments that would be covered if separately entered.
6103.2910	Coverage limited to garments that would be covered if separately entered.
6103.4210	Coverage excludes garments having embroidery or permanently affixed applique work on the outer surface.
6103.4315	Coverage excludes garments having embroidery or permanently affixed applique work on the outer surface.
6103.4910	Coverage excludes garments having embroidery or permanently affixed applique work on the outer surface.
6104.1320	
6104.1915	
6104.2100.10	
6104.2100.30	
6104.2100.40	

HTS No.	Annotation
6104.2100.60	
6104.2100.80	
6104.2200.10	
6104.2200.60	
6104.2200.80	
6104.2200.90	
6104.2300.22	
6104.2910.60	
6104.5100	Coverage excludes garments having embroidery or permanently affixed applique work on the outer surface.
6104.5310	Coverage limited to wool skirts.
6104.5910	Coverage limited to wool skirts; coverage excludes girls' skirts or divided skirts not having embroidery or permanently affixed applique work on the outer surface.
6104.6920	Coverage limited to wool trousers.
6105.1000	
6105.2020	
6106.1000	
6109.1000	
6109.9010.07	
6109.9010.09	
6109.9010.13	
6109.9010.25	
6109.9010.47	
6109.9010.49	Coverage excludes garments having embroidery or permanently affixed applique work on the outer surface.
6110.2020	Coverage excludes men's or boys' garments having embroidery or permanently affixed applique work on the outer surface.
6110.3030.05	
6110.3030.10	
6110.3030.15	
6110.3030.20	
6110.3030.25	
6110.3030.40	
6110.3030.50	
6111.3040	Coverage limited to sweaters; coverage excludes garments having embroidery or permanently affixed applique work on the outer surface.
6111.3050	
6111.9040	Coverage limited to sweaters.
6111.9050	
6112.1200.10	
6112.1200.30	
6112.1200.50	
6112.1910.10	Coverage limited to men's and boy's garments that would be covered if separately entered.
6112.1910.30	Coverage excludes men's or boy's garments that would be covered if separately entered.
6112.1910.50	Coverage excludes men's or boy's garments that would be covered if separately entered.
6112.2010.10	Coverage excludes men's or boy's garments that would be covered if separately entered.
6112.2010.30	Coverage limited to men's and boy's garments that would be covered if separately entered.
6112.2010.50	Coverage excludes men's or boy's garments that would be covered if separately entered.
6112.2010.60	Coverage excludes men's or boy's garments that would be covered if separately entered.
6112.2010.80	Coverage limited to men's and boy's garments that would be covered if separately entered.
6114.2000	
6114.3010.10	
6114.3030	
6201.1220	
6201.1340	
6201.9220	
6203.1910	Coverage limited to garments that would be covered if separately entered.
6203.2230	Coverage limited to garments that would be covered if separately entered.
6203.2300	Coverage limited to garments that would be covered if separately entered.
6203.2920	Coverage limited to garments that would be covered if separately entered.
6203.4240	
6203.4340	
6203.4920	
6204.2300	Coverage limited to woolen garments that would be covered if separately entered.
6204.2920.10	
6204.2920.30	
6204.2920.40	
6204.2920.50	Coverage limited to garments that would be covered if separately entered.
6205.2020	
6208.2200	
6208.9200.30	
6208.9200.40	
6209.2050	

[FR Doc. 97–31132 Filed 11–25–97; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Export Trade Certificate of Review

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of initiation of process to revoke export trade certificate of review No. 88–00002.

SUMMARY: The Secretary of Commerce issued an export trade certificate of review to Olde South Traders, Inc. Because this certificate holder has failed to file an annual report as required by law, the Department is initiating proceedings to revoke the certificate. This notice summarizes the notification letter sent to Olde South Traders, Inc.

FOR FURTHER INFORMATION CONTACT: Morton Schnabel, Acting Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (''the Act'') (15 U.S.C. 4011–21) authorizes the Secretary of Commerce to issue export trade certificates of review. The regulations implementing Title III (''the Regulations'') are found at 15 CFR part 325. Pursuant to this authority, a certificate of review was issued on May 23, 1988 to Olde South Traders, Inc.

A certificate holder is required by law (Section 308 of the Act, 15 U.S.C. 4018) to submit to the Department of Commerce annual reports that update financial and other information relating to business activities covered by its certificate. The annual report is due within 45 days after the anniversary date of the issuance of the certificate of review (Sections 325.14 (a) and (b) of the Regulations). Failure to submit a complete annual report may be the basis for revocation. (Sections 325.10(a) and 325.14(c) of the Regulations).

The Department of Commerce sent to Olde South Traders, Inc. on May 13, 1997, a letter containing annual report questions with a reminder that its annual report was due on July 7, 1997. Additional reminders were sent on August 7, 1997, and on September 12, 1997. The Department has received no written response to any of these letters.

On November 20, 1997, and in accordance with Section 325.10(c)(1) of the Regulations, a letter was sent by certified mail to notify Olde South Traders, Inc. that the Department was formally initiating the process to revoke its certificate. The letter stated that this action is being taken because of the certificate holder's failure to file an annual report.

In accordance with Section 325.10(c)(2) of the Regulations, each certificate holder has thirty days from the day after its receipt of the notification letter in which to respond. The certificate holder is deemed to have received this letter as of the date on which this notice is published in the **Federal Register**. For good cause shown, the Department of Commerce can, at its discretion, grant a thirty-day extension for a response.

If the certificate holder decides to respond, it must specifically address the Department's statement in the notification letter that it has failed to file an annual report. It should state in detail why the facts, conduct, or circumstances described in the notification letter are not true, or if they are, why they do not warrant revoking the certificate. If the certificate holder does not respond within the specified period, it will be considered an admission of the statements contained in the notification letter (Section 325.10(c)(2) of the Regulations).

If the answer demonstrates that the material facts are in dispute, the Department of Commerce and the Department of Justice shall, upon request, meet informally with the certificate holder. Either Department may require the certificate holder to provide the documents or information that are necessary to support its contentions (Section 325.10(c)(3) of the Regulations).

The Department shall publish a notice in the **Federal Register** of the revocation or modification or a decision not to revoke or modify (Section 325.10(c)(4) of the Regulations). If there is a determination to revoke a certificate, any person aggrieved by such final decision may appeal to an appropriate U.S. district court within 30 days from the date on which the Department's final determination is published in the **Federal Register** (Sections 325.10(c)(4) and 325.11 of the Regulations).

Dated: November 20, 1997.

Morton Schnabel,

Acting Director, Office of Export Trading Company Affairs.

[FR Doc. 97–30979 Filed 11–25–97; 8:45 am]
BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Export Trade Certificate of Review

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of initiation of process to revoke export trade certificate of review No. 91–00003.

SUMMARY: The Secretary of Commerce issued an export trade certificate of review to Fabiano & Associates, Inc. Because this certificate holder has failed to file an annual report as required by law, the Department is initiating proceedings to revoke the certificate. This notice summarizes the notification letter sent to Fabiano & Associates, Inc.

FOR FURTHER INFORMATION CONTACT: Morton Schnabel, Acting Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (''the Act'') (15 U.S.C. 4011–21) authorizes the Secretary of Commerce to issue export trade certificates of review. The regulations implementing Title III (''the Regulations'') are found at 15 CFR part 325. Pursuant to this authority, a certificate of review was issued on May 29, 1991 to Fabiano & Associates, Inc.

A certificate holder is required by law (Section 308 of the Act, 15 U.S.C. 4018) to submit to the Department of Commerce annual reports that update financial and other information relating to business activities covered by its certificate. The annual report is due within 45 days after the anniversary date of the issuance of the certificate of review (Sections 325.14 (a) and (b) of the Regulations). Failure to submit a complete annual report may be the basis for revocation. (Sections 325.10(a) and 325.14(c) of the Regulations).

The Department of Commerce sent to Fabiano & Associates, Inc. on May 20, 1997, a letter containing annual report questions with a reminder that its annual report was due on July 14, 1997. Additional reminders were sent on August 7, 1997, and on September 12, 1997. The Department has received no written response to any of these letters.

On November 20, 1997, and in accordance with Section 325.10(c)(1) of the Regulations, a letter was sent by certified mail to notify Fabiano & Associates, Inc. that the Department was formally initiating the process to revoke its certificate. The letter stated that this action is being taken because of the

certificate holder's failure to file an annual report.

In accordance with Section 325.10(c)(2) of the Regulations, each certificate holder has thirty days from the day after its receipt of the notification letter in which to respond. The certificate holder is deemed to have received this letter as of the date on which this notice is published in the **Federal Register**. For good cause shown, the Department of Commerce can, at its discretion, grant a thirty-day extension for a response.

If the certificate holder decides to respond, it must specifically address the Department's statement in the notification letter that it has failed to file an annual report. It should state in detail why the facts, conduct, or circumstances described in the notification letter are not true, or if they are, why they do not warrant revoking the certificate. If the certificate holder does not respond within the specified period, it will be considered an admission of the statements contained in the notification letter (Section 325.10(c)(2) of the Regulations).

If the answer demonstrates that the material facts are in dispute, the Department of Commerce and the Department of Justice shall, upon request, meet informally with the certificate holder. Either Department may require the certificate holder to provide the documents or information that are necessary to support its contentions (Section 325.10(c)(3) of the Regulations).

The Department shall publish a notice in the **Federal Register** of the revocation or modification or a decision not to revoke or modify (Section 325.10(c)(4) of the Regulations). If there is a determination to revoke a certificate, any person aggrieved by such final decision may appeal to an appropriate U.S. district court within 30 days from the date on which the Department's final determination is published in the **Federal Register** (Sections 325.10(c)(4) and 325.11 of the Regulations).

Dated: November 20, 1997.

Morton Schnabel,

Acting Director, Office of Export Trading Company Affairs.

[FR Doc. 97–30980 Filed 11–25–97; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Modernization Transition Committee (MTC)

ACTION: Notice of public meeting.

Time and Date: December 10, 1997 beginning at 8:00 a.m.

Place: This meeting will take place at the Silver Spring Holiday Inn, 8777 Georgia Avenue, Silver Spring, Maryland.

Status: The meeting will be open to the public. The time between 11:30 a.m. and noon will be set side for oral comments or questions from the public and approximately 50 seats will be available on a first-come first-served basis.

Matters To Be Considered: This meeting will cover: Consultation on 12 combined Automation and Closure Certifications including the NWS report and consultation on Evansville, 10 combined Consolidation, Automation and Closure Certifications, and 1 Automation Certification; consultation on the FY 1999 National Implementation Plan; and reports on the NWS Modernization status and NWS interactions with the Astoria community.

CONTACT PERSON FOR MORE INFORMATION: Mr. Nicholas Scheller, National Weather Service, Modernization Staff, 1325 East-West Highway, SSMC2, Silver Spring, Maryland 20910. Telephone: (301) 713–0454.

Dated: November 20, 1997.

Nicholas R. Scheller,

Manager, National Implementation Staff.

[FR Doc. 97–30973 Filed 11–25–97; 8:45 am]

BILLING CODE 3510–12–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 111497B]

Marine Mammals; Permit No. 1004 (P595)

AGENCY: National Marine Fisheries Service, (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Scientific research permit amendment.

SUMMARY: Notice is hereby given that a request for amendment of scientific research no. 1004 submitted by the Whale Conservation Institute, 191 Weston Road, Lincoln, MA 01773, has been granted.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment, in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910 (301/713–2289); and

Director, Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298 (508/281–9250).

SUPPLEMENTARY INFORMATION: On September 16, 1997, notice was published in the **Federal Register** (62 FR 48611) that an amendment of permit no. 1004, issued June 21, 1997 (61 FR 33906) had been requested by the above-named organization. The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972 (MMPA) as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973 (ESA) as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing endangered species permits (50 CFR parts 217–227).

Permit No. 1004 has been amended to: (1) extend the expiration date of the permit from June 30, 1998 to November 30, 1998; (2) increase the number of imported southern right whale (*Eubalaena australis*) tissue samples taken at Peninsula Valdez, Argentina from 20 to 340; and (3) redefine these ''tissue samples'' from southern right whales to include baleen, blood and bone, skin/blubber and organ tissues (from dead/stranded whales), and sloughed skin (from live free-ranging whales).

Issuance of this amendment as required by the ESA of 1973 was based on a finding that the permit: (1) was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which is the subject of this permit; and (3) is consistent with the purposes and policies set forth in Section 2 of the ESA.

Dated: November 19, 1997.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 97–30977 Filed 11–25–97; 8:45 am]

BILLING CODE 3510–22–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of Temporary Suspension of Export Visa and Certification Requirements for Certain Cotton, Wool and Man-Made Fiber Textile Products Produced or Manufactured in Haiti

November 21, 1997

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs suspending export visa and certification requirements.

EFFECTIVE DATE: November 24, 1997.

FOR FURTHER INFORMATION CONTACT: Roy Unger, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

Effective on November 24, 1997, and until further notice, textile products which are produced or manufactured in Haiti and exported from Haiti, regardless of the date of export, shall not be denied entry for the lack of a visa or certification. This is a temporary measure which is being taken by the U.S. Government and which only waives the requirements to present a visa or certification with the shipment. It does not waive other documentation requirements.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 21, 1997.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This letter refers to the directive of February 19, 1987 from the Chairman of the Committee for the Implementation of Textile Agreements establishing visa and certification requirements for certain cotton, wool and man-made fiber textile products from Haiti. That letter directed you to prohibit entry into the United States for consumption or withdrawal from warehouse for consumption of cotton, wool and man-made fiber textile products, produced or manufactured in Haiti, which are not visaed or certified in accordance with procedures described in the letter.

Effective on November 24, 1997, and until further notice, you are directed not to deny entry of textile products, produced or manufactured in Haiti and exported from Haiti, regardless of the date of export, for lack of a visa or certification. This is a temporary measure which is being taken by the U.S. Government and which only waives the requirements to present a visa or certification with the shipment. It does not waive other documentation requirements.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 97–31175 Filed 11–24–97; 9:47 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

[OMB Control Number 0704–0229]

Notice of Request for Comments

AGENCY: Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), DoD announces the proposed extension of a public information collection requirement, and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. This information collection requirement is currently approved by the Office of Management and Budget (OMB) for use through June 30, 1998. DoD proposes that OMB extend its approval for use through June 30, 2001.

DATES: Consideration will be given to all comments received by January 26, 1998.

ADDRESSES: Written comments and recommendations on the proposed information collection requirement should be sent to: Defense Acquisition Regulations Council, Attn: Ms. Amy Williams, PDUSD(A&T)DP(DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telefax (703) 602–0350.

E-mail comments submitted over the Internet should be addressed to: dfarsacq.osd.mil.

Please cite OMB Control Number 0704–0229 in all correspondence related to this issue. E-mail comments should cite OMB Control Number 0704–0229 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, at (703) 602–0131. A copy of this information collection requirement is available electronically via the Internet at: http://www.dtic.mil/dfars/

Paper copies may be obtained from Ms. Amy Williams, PDUSD(A&T)DP(DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062.

Title, Associated Form, and OMB Number: Foreign Acquisition—Defense Federal Acquisition Regulation Supplement part 225 and Related Clauses at 252.225, DD Form 2139, OMB Control Number 0704–0229.

Needs and Uses: This information collection requirement pertains to information collection requirements used to ensure contractor compliance with restrictions on the acquisition of foreign products imposed by statute or policy to protect the industrial base. Other information is required for compliance with U.S. trade agreements and Memoranda of Understanding, which promote reciprocal trade with U.S. allies, and for inclusion in reports to the Department of Commerce on the Balance of Payments Program.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Annual Burden Hours: 74,333 hours.

Number of Respondents: 31,347.

Responses per Respondent: Approximately 7.

Number of Responses: 224,262.

Average Burden per Response: .33 hours.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

- *DFARS 252.225–7000,* Buy American Act-Balance of Payments Program Certificate, as prescribed in 225.109(a), requires the offeror to identify in its proposal supplies that do not meet the definition of domestic end product, separately listing qualifying and nonqualifying country end products.
- *DFARS 252.225–7003,* Information for Duty-Free Entry Evaluation, as prescribed in 225.605–70(e), requires a check in paragraph (a) as to whether the

offer is based on furnishing a domestic end product with nonqualifying country components for which the offeror requests duty-free entry, or a foreign end product, other than those that will be accorded duty-free entry as qualifying country end products or components, or eligible products under a trade agreement. If the answer to paragraph (a) is positive, then paragraph (b) requires two checks, as to whether such foreign supplies are now in the United States, whether duty has been paid, and if the duty has not yet been paid, an indication of what amount is included in the offer to cover such duty. Paragraph (c) requires the awardee to identify, at the request of the contracting officer, the foreign supplies which are subject to duty-free entry. Alternate I, as prescribed in 225.605–70(e), is used when the Buy American Act/Balance of Payments Program does not apply, and refers to U.S. made end products rather than domestic products (proposed rule, published September 9, 1997, 62 FR 47407).

- *DFARS 252.225–7005,* Identification of Expenditures in the United States, as prescribed in 225.305–70, requires contractors to identify, on each request for payment under certain contracts subject to the Balance of Payments Program, the part of the requested payment representing expenditures in the United States.
- *DFARS 252.225–7006,* Buy American Act-Trade Agreements—Balance of Payments Program Certificate, as prescribed in 225.408(a)(1), is similar to 225.252–7000, but requires separate listing of end products that are U.S. made but not domestic, or that are from a qualifying country, designated country, Caribbean Basin country, NAFTA country, or other nondesignated country.
- *DFARS 252.225–7009,* Duty-Free Entry-Qualifying Country Supplies (End Products and Components), *DFARS 252.225–7010,* Duty-Free Entry-Additional Provisions, and *DFARS 252.225–7037,* Duty-Free Entry-Eligible End Products, all as prescribed in 225.605–70, require the contractor or an authorized agent to provide information on shipping documents and customs forms regarding those items that are eligible for duty-free entry (proposed rule, published March 11, 1997, 62 FR 11142).
- *DFARS 252.225–7016* Restriction on Acquisition of Ball and Roller Bearings, as prescribed in 225.7019–4, requires contractor retention of records showing compliance with the restriction until 3 years after final payment. The contractor agrees to make the records available to the contracting officer upon request. The Contractor may request a waiver in accordance with 225.7019–3, which also requires the contractor to submit a written plan for transitioning to domestically manufactured bearings, for a waiver under a multiyear contract or a contract exceeding 12 months.
- *DFARS 252.225–7018,* Notice of Prohibition of Certain Contracts with Foreign Entities for the Conduct of Ballistic Missile Defense RDTSE, as prescribed in 225.7011–5, is used in all competitively negotiated Ballistic Missile Defense solicitations for research, development, test, and evaluation, unless foreign participation is otherwise excluded, and requires the offeror to check its status as a U.S. firm.
- *DFARS 252.225–7020,* Trade Agreements Certificate, as prescribed in 225.408(a)(3), requires the offeror to list nondesignated country end products. This is a new provision, used in solicitations for information technology products subject to the Trade Agreements Act, in lieu of 252.225–7006 (proposed rule, published September 9, 1997, 62 FR 47407).
- *DFARS 252.225–7025,* Restriction on Acquisition of Forgings, as prescribed in 225.7102–4, requires contractor retention of records showing compliance with the restriction until 3 years after final payment. The contractor agrees to make the records available to the contracting officer upon request. The contractor may request a waiver in accordance with 225.7102–3.
- *DFARS 252.225–7026,* Reporting of Contract Performance Outside the United States, as prescribed in 225.7203, requires the contractor to submit a Report of Contract Performance Outside the United States when any part of the contract that exceeds a specified dollar threshold will be performed outside the United States. The specified threshold is $500,000 for contracts that exceed $10 million, or the simplified acquisition threshold ($100,000) for contracts that exceed $500,000. The Contractor may submit the report on DD Form 2139, Report of Contract Performance Outside the United States, or may use a computer-generated report that contains all information required by DD Form 2139 (proposed rule, published October 17, 1997, 62 FR 54017).
- *DFARS 252.225–7032,* Waiver of United Kingdom Levies, as prescribed in 225.873–3, requires United Kingdom (U.K.) prime contractors, and prime contractors with subcontracts of a dollar value exceeding $1 million with U.K. firms, to provide certain information necessary for DoD to obtain a waiver of U.K. levies.
- *DFARS 252.225–7035,* Buy American Act—North American Free Trade Agreement Implementation Act—Balance of Payments Program Certificate, as prescribed in 225.408(a)(3), requires the offeror to list qualifying country (except Canada), NAFTA country, or other foreign end products. Alternate I, as prescribed in 225.408(a)(3), requires listing of Canadian end products, rather than NAFTA country end products, in solicitations between $25,000 and $50,000 (proposed rule published March 11, 1997 (62 FR 11142).

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

[FR Doc. 97–31110 Filed 11–25–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Revision of the Department of Defense 6055.9—Standard, Department of Defense Ammunition and Explosives Safety Standards

AGENCY: Department of Defense.

ACTION: Notice of change.

SUMMARY: The Department of Defense Explosives Safety Board (DDESB) is today announcing several changes to Department of Defense 6055.9—Standard, dated October 1992. Because of the length of time since the Standard was last published in full, the DDESB is republishing the Standard with all changes adopted by the Board since 1992 incorporated therein.

The DDESB is taking this action pursuant to its statutory authority as set forth in Title 10, United States Code, Section 172 (10 U.S.C. 172) and DoD Directive 6055.9, ''Explosives Safety Board (DDESB) and DoD Component Explosives Safety Responsibilities,'' July 29, 1996. The Standard is applicable to the Office of the Secretary of Defense, the Military Departments (including the Army and Air Force National Guards), the Defense Nuclear Agency, the Defense Logistics Agency, the Coast Guard (when under DoD control), and other parties who produce or manage ammunition or explosives under contract to the DoD. Through DoD 6055.9–STD, the DDESB establishes minimum explosives safety requirements for storing and handling ammunition and explosives. Copies of this Standard may be obtained from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 27161.

For more detailed information on specific aspects of this Standard, contact Ray Sawyer by calling (703) 325–8625 or by writing to Department of Defense Explosives Safety Board, 2461 Eisenhower Avenue, Room 856–C, Alexandria, VA 22331–0600.

SUPPLEMENTARY INFORMATION: Dating back to 1928 when Congress directed the Secretaries of the military departments to establish a joint board of officers to ''keep informed on stored supplies of ammunition and components thereof * * *, with particular regard to keeping those supplies properly dispersed and stored and to preventing hazardous conditions from arising to endanger life and property inside or outside of storage reservations,'' the DDESB (formerly known as the Ammunition Safety Board) has periodically revised or updated the Standard based on new scientific or technical information and explosives safety experience. The implementation of a change to DoD 6055.9–STD does not depend on formal publication of a change to DoD 6055.9–STD. Changes to the Standard are effective when adopted by the Board, or as the Board may otherwise direct. In order to ensure compliance, the Services and Defense Agencies modify their Service or Agency implementing procedures and standards accordingly.

This revision to the October 1992 version of DoD 6055.9–STD incorporates decisions of the DDESB made at its 307th through 314th meetings held from July 1992 through February 1997. Although the decisions adopted at the 307th meeting of the Board in July 1992 pre-date the October 1992 publication, the Standard was already at the printer and those changes could not be included. This revision also reflects the recent assignment of the DDESB to the Office of the Under Secretary of Defense for Acquisition and Technology.

The changes included herein address the following:

- Expands the Scope of the Standard to include application to any energetic material (U.S. titled or otherwise) on DoD owned or leased facilities.
- Eliminates high explosives limits for training military working dogs for explosives detection and maintains evacuation distances applicable to personnel who are not involved in the training activity.
- Establishes quantity-distance criteria for non-essential personnel and establishes protection level criteria for essential personnel for use at ammunition and explosives burning sites.
- Expands and clarifies quantity-distance criteria for the location of steel tanks used to store hazardous materials or water with respect to ammunition and explosives locations.
- Establishes criteria for sites where explosives loaded containers may be moved from a rail to a road transport mode, and vice versa.
- Modifies lightning protection criteria into performance oriented criteria that are consistent with current National Fire Protection Association (NFPA) standards.
- Establishes criteria that apply to locations where inhabited building quantity-distance arcs are allowed to extend beyond DoD boundary lines.
- Clarifies the application of explosion propagation prevention measures when storing Storage Compatibility Groups B and F ammunition with other compatibility groups ammunition.
- Expands the exemption from quantity-distance requirements for specific combat aircraft weapons loads.
- Establishes quantity-distance criteria for Navy Maritime Pre-positioning Ships based on test results for specific ship explosives load configurations.
- Expands and clarifies the standards applicable to real property containing ammunition, explosives, or chemical agents, including providing for specified depth criteria in the absence of a site-specific assessment.
- Specifies the conditions that would allow limited opening of boxes loaded with ammunition while inside storage facilities.
- Clarifies the quantity-distance criteria applicable to training facilities occupied by military personnel.
- Clarifies the criteria for types of ammunition and inert materials that may be stored in modular storage units and sets explosives limits for modular storage cells.
- Based upon tests results and analysis, reduces the quantity-distance criteria for U.S. 3rd generation harden aircraft shelters.
- Allows commanders to determine the appropriate separation distances between aircraft parking areas, combat aircraft parking areas, the associated ready ammunition storage facilities, and ammunition cargo areas.
- Based upon test results, clarifies the criteria used to satisfy the quantity-distance requirements for underground ammunition and explosives storage facilities.
- Establishes requirement to retain the explosives facility site plan package at the installation.
- Establishes quantity-distance criteria for siting range control points with respect to other potential explosion sites.
- Expands and clarifies quantity-distance criteria to include separation of combat- and explosives-loaded aircraft from taxiways and runways.
- Revises the definitions and quantity-distance requirements, particularly inter-magazine separation requirements, for earth covered magazines.
- Clarifies the requirements for location of overhead electric services lines with respect to ammunition and explosives facilities.
- Expands and clarifies the requirements for transporting materials contaminated with chemical agents.
- Clarifies the criteria for containers that may be used to monitor protective clothing that may be used in chemical agent areas.
- Modifies public traffic route distance criteria by expanding traffic density evaluations to include rail and ship traffic, basing density on passengers per day, and providing guidance for evaluating traffic density to clarify the use of minimum fragment distances.
- Corrects inconsistencies with current Hazard Division 1.6 ammunition criteria, and harmonizes U.S. criteria with NATO criteria.
- Establishes criteria applicable to the use of revetments to separate ammunition stored on pads or hung on aircraft.

In adopting these changes, the DDESB has determined that the Standards, as changed, are at least as protective as the previous Standards.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–30996 Filed 11–25–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–20]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Assistance Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–20, with attached transmittal, policy justification and sensitivity of technology pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

0 9 NOV 1997

In reply refer to:
I-55236/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-20, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance (LOA) to Korea for defense articles and services estimated to cost $109 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-20

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Korea

(ii) Total Estimated Value:

Major Defense Equipment*	$ 88 million
Other	$ 21 million
TOTAL	$ 109 million

(iii) Description of Articles or Services Offered:
Three MK 41 Vertical Launch Systems, 144 MK 13 MOD 0 canisters, U.S. Government and contractor engineering and logistics personnel services, personnel training and training equipment, support and test equipment, spare and repair parts, publications and technical documentation, launch system software development and maintenance and other related elements of logistics support.

(iv) Military Department: Navy (LOW)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:
See Annex attached.

(vii) Date Report Delivered to Congress: 09 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Korea - MK 41 Vertical Launch Systems

The Government of Korea has requested the possible sale of three MK 41 Vertical Launch Systems, 144 MK 13 MOD 0 canisters, U.S. Government and contractor engineering and logistics personnel services, personnel training and training equipment, support and test equipment, spare and repair parts, publications and technical documentation, launch system software development and maintenance and other related elements of logistics support. The estimated cost is $109 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for political stability and economic progress in Northeast Asia.

The missile launchers will be installed on new construction frigates and are intended for use with STANDARD missiles as the principal air defense armament of these new vessels. Korea will have no difficulty absorbing this missile launch systems into its armed forces.

The proposed sale of this shipboard missile launch systems and support will not affect the basic military balance in the region.

The prime contractor will be Lockheed Martin Aero and Naval Systems, Baltimore, Maryland. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this proposed sale will not require the assignment of any contractor representatives in Korea; however, there will be three U.S. Government personnel for approximately 39 months during the preparation, equipment installations, and equipment test and checkout of the MK 41 Vertical Launch Systems on the ships.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 98-20

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The MK-41 Vertical Launch Systems (VLS) contains sensitive technology and is Unclassified. The launch control computer program, which also contains missile launch rates, is classified Confidential. Sections of the MK-41 technical documentation, which disclose launcher vulnerabilities, are classified Confidential.

2. If a technologically advanced adversary were to obtain knowledge of this system, it is possible that countermeasures could be developed to reduce its effectiveness.

3. A determination has been made that Korea can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

[FR Doc. 97–30983 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–13]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Assistance Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense in publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–13, with attached transmittal, policy justification, and sensitivity of technology pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternative OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

0 9 NOV 1997

In reply refer to:
I-55944/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-13, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Portugal for defense articles and services estimated to cost $185 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-13

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act (U)

(i) Prospective Purchaser: Portugal

(ii) Total Estimated Value:

Major Defense Equipment*	$ 0 million
Other	$ 185 million
TOTAL	$ 185 million

(iii) Description of Articles or Services Offered: Twenty Mid-Life Update (MLU) modification kits for Portuguese Air Force F-16A/B aircraft, installation, support equipment, training and training devices, technical assistance, technical orders, system drawings, U.S. Government and contractor engineering, spare parts, and other logistics elements necessary for full program support.

The MLU is an avionics retrofit program for F-16 aircraft consisting of a Central Core Computer, Block 50 cockpit design, Digital Terrain System, Global Positioning System, APG-66(V2) radar upgrade, Integrated Data Modem, microwave landing system and night capabilities provisions, and an Advanced Identification Friend or Foe (AIFF).

(iv) Military Department: Air Force (NMP)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached.

(vii) Date Report Delivered to Congress: 04 NOV 1997

* as defined Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Portugal - F-16A/B Mid-Life Update Modification Kits

The Government of Portugal has requested a possible sale of 20 Mid-Life Update (MLU) modification kits for Portuguese Air Force F-16A/B aircraft, installation, support equipment, training and training devices, technical assistance, technical orders, system drawings, U.S. Government and contractor engineering, spare parts, and other logistics elements necessary for full program support. The estimated cost is $185 million.

The MLU production phase is the continuation of the development program notified to the Congress in August 1990. This multi-national effort has included the governments of the United States, Belgium, Denmark, The Netherlands, and Norway who have participated with the United States Air Force in the full scale MLU engineering development and integration effort. The MLU is an avionics retrofit program for F-16 aircraft consisting of a Central Core Computer, Block 50 cockpit design, Digital Terrain System, Global Positioning System, APG-66(V2) radar upgrade, Integrated Data Modem, microwave landing system and night capabilities provisions, and an Advanced Identification Friend or Foe (AIFF).

This proposed sale will contribute to the foreign policy and national security objectives of the United States by improving the military capabilities of Portugal while enhancing weapon system standardization and interoperability with the U.S. forces in the region.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The prime contractor will be Lockheed Martin Tactical Aircraft systems, Fort Worth, Texas. There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this proposed sale will require the assignment of U.S. Government personnel and contractor representatives to Portugal to provide technical and logistics services prior to delivery of the last MLU kit. The number of personnel and types of skills necessary to support the program will be determined jointly between U.S. and Portuguese representatives upon program implementation.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 98-13

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The F-16A weapon system is unclassified except as mentioned below. The aircraft does contain state-of-the-art technology. Sensitive elements of the F-16A include the F100-PW-200/220 turbofan engine, the FMS version of the AN/ALR-69 radar warning receiver (RWR), the FMS version of the AN/ALQ-131 electronic countermeasures pod, the FMS version of the AN/APG-66 radar, the AIM-7 radar missile capability, the AIM-9 missile capability, the AIM-120 (AMRAAM) missile capability, the ATLIS II laser designator pod capability, and the fly by wire flight control system. The system design notes on software architecture are also critical elements.

2. Classified elements of the F-16A include the F100 engine infrared signature, radar software documentation, the Operational Flight Program (OFP) and the Emitter Identification Data (EID) for the ALR-69, the OFP and EID for the ALQ-131, the OFP for the Fire Control Computer, AIM-9 hardware, AIM-7 hardware, AIM-120 hardware, and 15 operating manuals and maintenance technical orders containing performance information, operating and test procedures, and other information related to support operation and repair at the organizational and intermediate levels. Classified elements of the MLU kit in addition to the above items include: the Advanced IFF (AIFF). The hardware, software, and data identified are classified to protect vulnerabilities, design, and performance parameters, munitions related data, and similar critical information.

3. If a technologically advanced adversary were to obtain knowledge of these specific hardware and software elements, they might be able to develop countermeasures or countertactics which could reduce weapon system effectiveness. Of additional concern, but requiring a much longer exploitation period, is the possibility such information could be used in the development of systems with similar advanced capabilities.

4. A determination has been made that the recipient country can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This proposed sale is necessary in furtherance of

[FR Doc. 97–30984 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–09]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Assistance Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmitted 98–09, with attached transmittal, policy justification, Section 620C(d) of the Foreign Assistance Act of 1961, and sensitivity of technology pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

0 9 NOV 1997

In reply refer to:
I-52383/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-09, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to Turkey for defense articles and services estimated to cost $26 million. Soon after this letter is delivered to your office, we plan to notify the news media.

You will also find attached a certification as required by Section 620C(d) of the Foreign Assistance Act of 1961, as amended, that this action is consistent with Section 620C(b) of that statute.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-09

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Turkey

(ii) Total Estimated Value:

Major Defense Equipment*	$ 22 million
Other	$ 4 million
TOTAL	$ 26 million

(iii) Description of Articles or Services Offered:
Four AN/TPQ-36(V)9 FIREFINDER radar sets with support equipment, a U.S. Government Quality Assurance Team, spare and repair parts, measurement and diagnostic equipment, publications, personnel training and training equipment, technical assistance, U.S. Government and contractor technical and logistics personnel services and other related elements of program support.

(iv) Military Department: Army (JAY)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:
See Annex attached.

(vii) Date Report Delivered to Congress: 09 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Turkey - AN/TPQ-36(V)9 FIREFINDER Radar Sets

The Government of Turkey has requested a possible sale of four AN/TPQ-36(V)9 FIREFINDER radar sets with support equipment, a U.S. Government Quality Assurance Team, spare and repair parts, measurement and diagnostic equipment, publications, personnel training and training equipment, technical assistance, U.S. Government and contractor technical and logistics personnel services and other related elements of program support. The estimated cost is $26 million.

This proposed sale will contribute to the foreign policy and national security objectives of the United States by improving the military capabilities of Turkey a major NATO ally while furthering weapon system standardization and interoperability.

This purchase augments similar radars purchased and delivered under prior FMS cases and provides a modest increase in counter-mortar capability consistent with Turkey's force modernization plans. These radar sets will be provided in accordance with, and subject to the limitation on use and transfer provided for under the Arms Export Control Act, as embodied in the terms of sale. This proposed sale will not adversely affect either the military balance in the region or U.S. efforts to encourage a negotiated settlement of the Cyprus question. Turkey will have no difficulty absorbing these additional radars into its armed forces.

The prime contractor will be the Hughes Aircraft Corporation, Los Angeles, California. There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to Turkey. A Quality Assurance team consisting of four persons will be required in-country for two weeks to assist in deprocessing and inspecting the equipment upon delivery.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

THE SECRETARY OF STATE

WASHINGTON

November 9, 1997

Certification Under Section 620C(d)
Of The Foreign Assistance Act of 1961, As Amended

Pursuant to section 620C(d) of the Foreign Assistance Act of 1961, as amended (the Act), Executive Order 12163 (sec. 1-201(a)(13)) and State Department Delegation of Authority No. 145, (sections 1(a)(1) and 4(d)), I hereby certify that the furnishing to Turkey of four AN/TPQ-36(V)9 FIREFINDER radar sets and program support at an estimated cost of $26 million, is consistent with the principles contained in section 620C(b) of the Act.

This certification will be made part of the notification to the Congress under section 36(b) of the Arms Export Control Act regarding the proposed sale of the above-named articles and services, and is based on the justification accompanying said notification, of which said justification constitutes a full explanation.

Madeleine Albright

Madeleine K. Albright

[FR Doc. 97–30985 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–12]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Assistance Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–12, with attached transmittal, policy justification, Section 620C(d) of the Foreign Assistance Act of 1961, and sensitivity of technology pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

09 NOV 1997

In reply refer to:
I-55446/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-12, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to Greece for defense articles and services estimated to cost $31 million. Soon after this letter is delivered to your office, we plan to notify the news media.

You will also find attached a certification as required by Section 620C(d) of the Foreign Assistance Act of 1961, as amended, that this action is consistent with Section 620C(b) of that statute.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-12

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Greece

(ii) Total Estimated Value:

Major Defense Equipment*	$ 30 million
Other	$ 1 million
TOTAL	$ 31 million

(iii) Description of Articles or Services Offered:
Thirty Army Tactical Missiles and launch assemblies (ATACMS), support equipment, spare and repair parts, personnel training and training equipment, U.S. Government and contractor technical assistance, publications and other related elements of logistics support.

(iv) Military Department: Army (XGS, Amendment 1)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:
See Annex attached.

(vii) Date Report Delivered to Congress: 09 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Greece - Army Tactical Missile System

The Government of Greece has requested a possible sale of 30 Army Tactical Missiles and launch assemblies (ATACMS), support equipment, spare and repair parts, personnel training and training equipment, U.S. Government and contractor technical assistance, publications and other related elements of logistics support. The estimated cost is $31 million.

This proposed sale will contribute to the foreign policy and national security of the United States by improving the military capabilities of Greece and enhancing weapon system standardization and interoperability of this important NATO ally.

The proposed sale complements a previous initial sale of 41 ATACMS that were approved in July 1996. The additional 30 ATACMS under this proposal will provide the Hellenic Army with an area fire system for use against hostile artillery, air defense and maneuver elements. ATACMS mounts on the multiple launch rocket system (MLRS) launcher which Greece has previously purchased and, therefore, will have no difficulty absorbing these additional systems capabilities. The missiles will be provided to Greece in accordance with and subject to the limitations on use and transfer of the Arms Export Control Act, as embodied in the terms of sale. This sale will not adversely affect either the military balance in the region or U.S. efforts to encourage a negotiated settlement of the Cyprus question.

The prime contractor will be Lockheed Martin Loral Vought Systems, Dallas, Texas. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to Greece.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

THE SECRETARY OF STATE

WASHINGTON

November 9, 1997

Certification Under Section 620C(d)
Of The Foreign Assistance Act of 1961, As Amended

Pursuant to section 620C(d) of the Foreign Assistance Act of 1961, as amended (the Act), Executive Order 12163 (sec. 1-201(a)(13)) and State Department Delegation of Authority No. 145, (sec. 1(a)(1) and 4(d)), I hereby certify that the furnishing to Greece of 30 Army Tactical Missiles and launch assemblies (ATACMS) and program support at an estimated cost of $31 million, is consistent with the principles contained in section 620C(b) of the Act.

This certification will be made part of the notification to the Congress under section 36(b) of the Arms Export Control Act regarding the proposed sale of the above-named articles and services, and is based on the justification accompanying said notification, of which said justification constitutes a full explanation.

Madeleine K. Albright

[FR Doc. 97–30986 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–21]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Assistance Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–21, with attached transmittal, policy justification, and sensitivity of technology pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternative OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

0 9 NOV 1997

In reply refer to:
I-56131/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-21, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to Egypt for defense articles and services estimated to cost $197.9 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-21

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Egypt

(ii) Total Estimated Value:

Major Defense Equipment*	$ 137.0 million
Other	$ 60.9 million
TOTAL	$ 197.9 million

(iii) Description of Articles or Services Offered:
Co-production of 50 M88A2 recovery vehicle kits, 53 M2 machine guns, 100 AN/PVS-7B night vision goggles, spare and repair parts, contractor technical support, support and test equipment, ammunition, publications, program management, personnel training and training equipment, U.S. Government and contractor technical and logistics services and other related elements of program support.

(iv) Military Department: Army (JBM)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:
See Annex attached.

(vii) Date Report Delivered to Congress: 09 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Egypt - Co-production of M88A2 Recovery Vehicle Kits

The Government of Egypt has requested the possible sale of co-production of 50 M88A2 recovery vehicle kits, 53 M2 machine guns, 100 AN/PVS-7B night vision goggles, spare and repair parts, contractor technical support, support and test equipment, ammunition, publications, program management, personnel training and training equipment, U.S. Government and contractor technical and logistics services and other related elements of program support. The estimated cost is $197.9 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for political stability and economic progress in the Middle East.

The proposed sale and co-production of these vehicles at their Factory 200, Egyptian Tank Plant, will support the 555 M1A2 tanks in their inventory. The M88A2 recovery vehicles will be used for towing, winching, and hoisting operations supporting recovery operations and evacuation of heavy tanks and other tracked combat vehicles. The proposed sale of this equipment and support will not affect the basic military balance in the region.

The prime contractor will be United Defense, Limited Partnership, York, Pennsylvania. There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any contractor representatives but will require the assignment of approximately 26 U.S. Government personnel in-country for three years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 98-21

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex
Item No. vi

(vi) Sensitivity of Technology:

1. The M88A2 recovery vehicles includes the following classified or sensitive components:

a. AVDS-1790-8CR Engine Propulsion System - an unique modification to the standard piston engine family found in the M60 series and the base M88A1. Manufacturing processes associated with the production of turbochargers, fuel injection system, and cylinders are proprietary, and therefore, commercially competition sensitive.

b. Hydraulic System - use of commercially available hydraulic components is not entirely unique in the armored vehicle world. None of the subcomponents of the system are classified. Manufacturing processes associated with winches, hydraulic motors, control valves, and the like are proprietary and therefore, commercially competition sensitive.

2. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification. Moreover, the benefits to be derived from this sale, as outlined in the Policy Justification, outweigh the potential damage that could result if the sensitive technology were revealed to unauthorized persons.

[FR Doc. 97–30987 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–16]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Assistance Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of P.L. 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–16, with attached transmittal and policy justification pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

0 9 NOV 1997

In reply refer to:
I-56704/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-16, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Taipei Economic and Cultural Representative Office in the United States for defense articles and services estimated to cost $140 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-16

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Taipei Economic and Cultural Representative Office (TECRO) in the United States pursuant to P.L. 96-8

(ii) Total Estimated Value:

Major Defense Equipment*	$ 0 million
Other	$ 140 million
TOTAL	$ 140 million

(iii) Description of Articles or Services Offered: This sale will provide funds for the establishment of a Cooperative Logistics Supply Support Arrangement (CLSSA) for spare parts in support of F-5B/E/F, F-104, F-16, C-130, C-119, C-47, and T-38 aircraft and for U.S. systems and sub-systems of the Indigenous Defense Fighter (IDF) aircraft.

(iv) Military Department: Air Force (KDF)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: none

(vii) Date Report Delivered to Congress: 09 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Taipei Economic and Cultural Representative Office in the United States - Cooperative Logistics Supply Support Arrangement

The Taipei Economic and Cultural Representative Office in the United States (TECRO) has requested the establishment of a Cooperative Logistics Supply Support Arrangement (CLSSA) for spare parts in support of F-5B/E/F, F-104, F-16, C-130, C-119, C-47, and T-38 aircraft and for U.S. systems and sub-systems of the Indigenous Defense Fighter (IDF) aircraft. The estimated cost is $140 million.

This proposed sale is consistent with United States law and policy, as expressed in Public Law 96-8.

These spare parts are required to assure that aircraft and aircraft systems previously procured from the United States are maintained in a mission capable status. The recipient will have no difficulty utilizing these spare parts.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

Procurement of these items will be from the many contractors providing similar items to the U.S. armed forces. There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to Taiwan.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 97–30989 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–15]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Assistance Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT:

Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–15, with attached transmittal and policy justification pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

13 NOV 1997

In reply refer to:
I-56156/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-15, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to the Republic of Korea for defense articles and services estimated to cost $160 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-15

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

(i) Prospective Purchaser: Republic of Korea

(ii) Total Estimated Value:

Major Defense Equipment*	$ 0 million
Other	$ 160 million
TOTAL	$ 160 million

(iii) Description of Articles or Services Offered: This sale will provide fund for the purpose of spare parts under a Cooperative Logistics Supply Support Arrangement (CLSSA) requisition case (FMSO II) for the support of F-4D/E, RF-4C, F-5A/B/E/F, RF-5A, A/T-37, F-16C/D, and C-130H aircraft; AN/FPS-117 and AN/FRN-45 radar systems; and AIM-7 and AIM-9 missile components. These items are of U.S. origin and are being operated by the Republic of Korea.

(iv) Military Department: Air Force (KCH)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: None

(vii) Date Report Delivered to Congress: 13 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Republic of Korea - Cooperative Logistics Supply Support Arrangement

The Republic of Korea has requested a possible sale of spare parts under a Cooperative Logistics Supply Support Arrangement (CLSSA) requisition case (FMSO II) for the support of F-4D/E, RF-4C, F-5A/B/E/F, RF-5A, A/T-37, F-16C/D, and C-130H aircraft; AN/FPS-117 and AN/FRN-45 radar systems; and AIM-7 and AIM-9 missile components. These items are of U.S. origin and are being operated by the Republic of Korea. The estimated cost is $160 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for political stability and economic progress in Northeast Asia.

The Republic of Korea needs these additional spare parts to maintain the aircraft, radar, and missile systems previously procured from the United States in a mission capable status.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

Procurement of these items of support will be from the many contractors providing similar items to the U.S. armed forces. There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to the Republic of Korea.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 97–30990 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–11]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Assistance Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT:

Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–11, which attached transmittal and policy justification pages.

Dated: November 20, 1997.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

09 NOV 1997

In reply refer to:
I-55169/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-11, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to Portugal for defense articles and services estimated to cost $29 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-11

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

(i) Prospective Purchaser: Portugal

(ii) Total Estimated Value:

Major Defense Equipment*	$ 26 million
Other	$ 3 million
TOTAL	$ 29 million

(iii) Description of Articles or Services Offered: Fourteen M109A5 self-propelled howitzers, Quality Assurance Team (QAT), spare and repair parts, support equipment, publications and technical data, personnel training and training equipment and other related elements of logistics support.

(iv) Military Department: Army (UPV)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: None

(vii) Date Report Delivered to Congress 09 NOV 1997

* as defined Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Portugal - M109A5 Self-propelled Howitzers

The Government of Portugal has requested a possible sale of 14 M109A5 self-propelled howitzers, Quality Assurance Team (QAT), spare and repair parts, support equipment, publications and technical data, personnel training and training equipment and other related elements of logistics support. The estimated cost is $29 million.

This proposed sale will contribute to the foreign policy and national security objectives of the United States by improving the military capabilities of Portugal while enhancing weapon system standardization and interoperability.

Portugal currently operates M109A2 self-propelled howitzers and will use this new procurement of howitzers to re-equip existing units and retire older artillery pieces, modernizing the Army's fire support capability. Portugal will have no difficulty absorbing these howitzers.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The prime contractor will be United Defense Limited Partnership (UDLP), York, Pennsylvania. There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this proposed sale will require the assignment of several contractor representatives for three months to provide technical support. This proposed sale will require U.S. Government Quality Assurance Team during initial delivery and fielding of the new howitzers in-country.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 97–30991 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–07]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Assistance Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–07, with attached transmittal, policy justification, and Certification Under Section 620C(d) of the Foreign Assistance Act of 1961.

Dated: October 29, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

10 OCT 1997

In reply refer to:
I-55506/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-07 and under separate cover the classified annex thereto. This Transmittal concerns the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Greece for defense articles and services estimated to cost $42 million. Soon after this letter is delivered to your office, we plan to notify the news media of the unclassified portion of this Transmittal.

You will also find attached a certification as required by Section 620C(d) of the Foreign Assistance Act of 1961, as amended, that this action is consistent with Section 620C(b) of that statute.

Sincerely,

H. Diehl McKalip
Acting Director

Same ltr to: House Committee on International Relations
Senate Committee on Appropriations
Senate Committee on Foreign Relations
House Committee on National Security
Senate Committee on Armed Services
House Committee on Appropriations

Attachments

Separate Cover:
Classified Annex

Transmittal No. 98-07

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act (U)

(i) Prospective Purchaser: Greece

(ii) Total Estimated Value:

Major Defense Equipment*	$ 41 million
Other	$ 1 million
TOTAL	$ 42 million

(iii) Description of Articles or Services Offered:
Ninety AIM-120B Advanced Medium-Range Air-to-Air Missiles (AMRAAM), missile containers, and other related elements of logistics and program support.

(iv) Military Department: Air Force (SBD, Amendment 6)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:
See Annex under separate cover.

(vii) Date Report Delivered to Congress: 10 OCT 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Greece - AIM-120B Advanced Medium-Range Air-to-Air Missiles

The Government of Greece has requested a possible sale of 90 AIM-120B Advanced Medium-Range Air-to-Air Missiles (AMRAAM), missile containers, and other related elements of logistics and program support. The estimated cost is $42 million.

This proposed sale will contribute to the foreign policy and national security objectives of the United States by improving the military capabilities of Greece while enhancing weapon system standardization and interoperability with U.S. forces.

These additional missile systems will augment Greece's previous procurement of 150 AMRAAMs as well as enhance aircraft air-to-air capabilities. These missiles will be provided to Greece in accordance with and subject to the limitations on use and transfer of the Arms Export Control Act, as embodied in the terms of sale. This proposed sale will not adversely affect either the military balance in the region or U.S. efforts to encourage a negotiated settlement of the Cyprus question.

The principal contractors will be Hughes Aircraft International Services Company, Tucson, Arizona and Raytheon Company, Bedford, Massachusetts. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to Greece.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 97–30992 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of Secretary

[Transmittal No. 98–08]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Assistance Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–08, with attached transmittal, policy justification, Section 620C(d) of the Foreign Assistance Act of 1961, and sensitivity of technology pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternative OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

0 9 NOV 1997

In reply refer to:
I-52381/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-08, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance (LOA) to Greece for defense articles and services estimated to cost $376 million. Soon after this letter is delivered to your office, we plan to notify the news media.

You will also find attached a certification as required by Section 620C(d) of the Foreign Assistance Act of 1961, as amended, that this action is consistent with Section 620C(b) of that statute.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-08

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Greece

(ii) Total Estimated Value:

Major Defense Equipment*	$296 million
Other	$ 80 million
TOTAL	$376 million

(iii) Description of Articles or Services Offered:
Seven CH-47D CHINOOK helicopters with 28 M60 and eight M2 machine guns, chaff, radar warning receiver, three spare turbine engines, ammunition, spare and repair parts, support equipment, publications and technical data, communications equipment, maintenance, personnel training and training equipment, U.S. Government Quality Assurance Team, field service representatives, contractor engineering and technical support services, preparation of aircraft for shipment, and other related elements of logistics support.

(iv) Military Department: Army (JBK and XHE)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:
See Annex attached.

(vii) Date Report Delivered to Congress: 0 9 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Greece - CH-47D CHINOOK Helicopters

The Government of Greece has requested a possible sale of seven CH-47D CHINOOK helicopters with 28 M60 and eight M2 machine guns, chaff, radar warning receiver, three spare turbine engines, ammunition, spare and repair parts, support equipment, publications and technical data, communications equipment, maintenance, personnel training and training equipment, U.S. Government Quality Assurance Team, field service representatives, contractor engineering and technical support services, preparation of aircraft for shipment, and other related elements of logistics support. The estimated cost is $376 million.

This proposed sale will contribute to the foreign policy and national security objectives of the United States by improving the military capabilities of Greece and enhancing standardization and interoperability with U.S. forces.

These helicopters will provide the Greek armed forces an improved capability to transport personnel and cargo for both military and humanitarian assistance purposes. They will be provided to Greece in accordance with and subject to the limitations on use and transfer of the Arms Export Control Act, as embodied in the terms of sale. This proposed sale will not adversely affect either the military balance in the region or U.S. efforts to encourage a negotiated settlement of the Cyprus question.

The principal contractors will be Boeing Defense and Space Group, Philadelphia, and Allied Signal Aerospace Incorporated, Torrance, California. One or more proposed offset agreements may be related to this proposed sale.

Implementation of this proposed sale will require the assignment of a Quality Assurance Team for two weeks to support delivery of the helicopters. Two contractor representatives will be required for one year and may remain an additional year.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

THE SECRETARY OF STATE

WASHINGTON

November 9, 1997

Certification Under Section 620C(d)
Of The Foreign Assistance Act of 1961, As Amended

Pursuant to section 620C(d) of the Foreign Assistance Act of 1961, as amended (the Act), Executive Order 12163 (sec. 1-201(a)(13)) and State Department Delegation of Authority No. 145, (sec. 1(a)(1) and 4(d)), I hereby certify that the furnishing to Greece of CHINOOK helicopters and program support at an estimated cost of $376 million, is consistent with the principles contained in section 620C(b) of the Act.

This certification will be made part of the notification to the Congress under section 36(b) of the Arms Export Control Act regarding the proposed sale of the above-named articles and services, and is based on the justification accompanying said notification, of which said justification constitutes a full explanation.

Madeleine K. Albright

[FR Doc. 97–30993 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–14]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Assistance Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT:

Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–14, with attached transmittal and policy justification pages.

Dated: November 20, 1997.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

12 NOV 1997

In reply refer to:
I-56116/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-14, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Singapore for defense articles and services estimated to cost $287 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-14

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

(i) Prospective Purchaser: Singapore

(ii) Total Estimated Value:

Major Defense Equipment*	$ 1 million
Other	$ 286 million
TOTAL	$ 287 million

(iii) Description of Articles or Services Offered: Services and support for F-16C/D aircraft, 12 M61A1 20mm guns, modification kits, maintenance, flight training, spare and repair parts, support equipment, program management, publications and documentation, personnel training and training equipment, logistics personnel services and other related elements of program support.

(iv) Military Department: Air Force (NCL)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: None

(vii) Date Report Delivered to Congress: 12 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Singapore - F-16C/D Aircraft Support with M61A1 Guns

The Government of Singapore has requested a possible sale of services and support for F-16C/D aircraft, 12 M61A1 20mm guns, modification kits, maintenance, flight training, spare and repair parts, support equipment, program management, publications and documentation, personnel training and training equipment, logistics personnel services and other related elements of program support. The estimated cost is $287 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country which has been and continues to be an important force for economic progress in Southeast Asia.

This proposed sale will support Singapore's current and future F-16 aircraft inventory. The training portion is for a long term pilot training program in CONUS. Singapore will have no difficulty absorbing this support into its armed forces.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to Singapore.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 97–30994 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 98–18]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Assistance Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSAA/COMPT/RM, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 98–18, with attached transmittal and policy justification pages.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5000–04–M

DEFENSE SECURITY ASSISTANCE AGENCY

WASHINGTON, DC 20301-2800

0 9 NOV 1997

In reply refer to:
I-56706/97

Honorable Newt Gingrich
Speaker of the House of
Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, we are forwarding herewith Transmittal No. 98-18, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Taipei Economic and Cultural Representative Office (TECRO) in the United States for defense articles and services estimated to cost $280 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

MICHAEL S. DAVISON, JR.
LIEUTENANT GENERAL, USA
DIRECTOR

Attachments

Transmittal No. 98-18

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

(i) Prospective Purchaser: Taipei Economic and Cultural Representative Office (TECRO) in the United States pursuant to P.L. 96-8

(ii) Total Estimated Value:

Major Defense Equipment*	$ 0 million
Other	$ 280 million
TOTAL	$ 280 million

(iii) Description of Articles or Services Offered: The continuation of a pilot training program and logistics support for F-16 aircraft to include flight training, supply and maintenance support, spare and repair parts, support equipment, program management, publications and documentation, personnel training and training equipment, fuel and fueling services, and other related program requirements necessary to sustain a long term CONUS training program.

(iv) Military Department: Air Force (NHC)

(v) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vi) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: none

(vii) Date Report Delivered to Congress: 0 9 NOV 1997

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Taipei Economic and Cultural Representative Office (TECRO) in the United States - Pilot Training Program

The Taipei Economic and Cultural Representative Office (TECRO) in the United States has requested a possible sale of services related to the continuation of a pilot training program and logistics support for F-16 aircraft to include flight training, supply and maintenance support, spare and repair parts, support equipment, program management, publications and documentation, personnel training and training equipment, fuel and fueling services, and other related program requirements necessary to sustain a long term CONUS training program. The estimated cost is $280 million.

This proposed sale is consistent with the United States law and policy as expressed in Public Law 96-8.

The recipient needs these services and equipment in order to continue a long term pilot training program at Luke Air Force Base, Arizona. This program will enable the recipient to develop mission ready and experienced pilots through CONUS training.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

There are no offset agreements proposed to be entered into in connection with this potential sale.

Implementation of this possible sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to Taiwan.

There will be no adverse impact on U.S. defense readiness as a result of this possible sale.

[FR Doc. 97–30995 Filed 11–25–97; 8:45 am]
BILLING CODE 5000–04–C

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the President's Security Policy Advisory Board

ACTION: Notice.

SUMMARY: The President's Security Policy Advisory Board has been established pursuant to Presidential Decision Directive/NSC–29, which was signed by the President on September 16, 1994.

The Board will advise the President on proposed legislative initiatives and executive orders pertaining to U.S. security policy, procedures and practices as developed by the U.S. Security Police Board, and will function as a federal advisory committee in accordance with the provisions of Pub. L. 92–463, the ''Federal Advisory Committee Act.''

The President has appointed from the private sector, three of five Board members each with a prominent background and expertise related to security policy matters. General Larry Welch, USAF (Ret.) will chair the Board. Other members include: Admiral Thomas Brooks, USN (Ret.) and Ms. Niná Stewart.

The next meeting of the Board will be held on 12 December 1997, at 1330 hours at Marriott Hotel, 8026 Leesburg Pike, Tysons Corner, VA. 22182. The meeting will be open to the public.

For further information please contact Mr. Terence Thompson, *telephone:* 703–602–9969.

Dated: November 20, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–30997 Filed 11–25–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Department of the Army

Draft Environmental Impact Statement (DEIS) on the Disposal and Reuse of the Seneca Army Depot Activity, New York

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: The proposed action evaluated by this DEIS is the disposal of the Seneca Army Depot Activity (SEDA), New York, in accordance with the Defense Base Closure and Realignment Act of 1990, Public Law 101–510, as amended.

The DEIS addresses the environmental impacts of the disposal and subsequent reuse of the entire installation except for the property required to create and maintain an enclave for storage of hazardous materials and ores as directed by the BRAC Commission. Alternatives examined in the DEIS include encumbered disposal of the property, unencumbered disposal of the property and retention of the property in a caretaker status (i.e., the no action alternative). The Army's preferred alternative for disposal of SEDA property is encumbered disposal, with encumbrances pertaining to historical resources, remedial activities, easements, wetlands, groundwater use, and unexploded ordnance.

Disposal of the Depot property is the Army's primary action. Reuse of the property is a secondary action that will be taken by others. The DEIS also analyzes the potential environmental effects of reuse by means of evaluating intensity-based probable reuse scenarios. Appropriate to the Depot are low, medium-low, and medium intensity reuse scenarios reflecting the range of activities that could occur after disposal of the property.

The Army proposes to transfer the majority of the 10,594 acres to the Seneca County Industrial Development Agency (IDA). The U.S. Coast Guard would obtain 290 acres for continued use of a LORAN–C antenna station. The establishment of an enclave as directed by the BRAC Commission would require the Army's retention of 30 acres to be used for storage of hazardous materials and ores. This would leave approximately 10,274 acres available for transfer or conveyance to the IDA.

The Army will hold a public review meeting for this DEIS in January 1998. The location and date of the meeting will be announced in the local news media.

DATES: Written public comments received within the 45 days of the date of publication of the Environmental Protection Agency's Notice of Availability in the **Federal Register** will be addressed in the preparation of the Final EIS.

ADDRESSES: The DEIS is available for review at three libraries: the Waterloo Library and Historical Society, *Attn:* Ms. Mary Zingerella, 31 East Williams Street, Waterloo, NY 13165; Edith B. Ford Memorial Library, *Attn:* Mr. & Mrs. Henry Morris, 7169 North Main Street, Ovid, NY 14521; and the Geneva Free Library, *Attn:* Ms. Kim Iraci, 244 Main Street, Geneva, NY 14456. Comments can be addressed to and copies may be obtained by writing to Mr. Hugh McClellan, Corps of Engineers, Mobile District, *Attn:* SAMPD, P.O. Box 2288, Mobile, Alabama 36628–0001 or by facsimile at (334) 690–2605.

Dated: November 20, 1997.

Raymond J. Fatz,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health), OASA (I,L&E).

[FR Doc. 97–31080 Filed 11–25–97; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Armored Security Vehicle (ASV)

AGENCY: U.S. Army Tank-automotive and Armaments Command.

ACTION: Notice of intent.

SUMMARY: The Program Manager, Light Tactical Vehicles (PM LTV) has prepared a Life-Cycle Environmental Assessment (LCEA) which examines the potential impacts to the natural and human environmental from the life cycle activities of the Armored Security Vehicle (ASV). Based on the LCEA, PM LTV has determined that the proposed action is not a major Federal action significantly affecting the quality of the human environment, within the meaning of the National Environmental Policy Act (NEPA) of 1969. Therefore, the preparation of an environmental impact statement is not required and the Army is issuing this Finding of No Significant Impact (FONSI).

ADDRESSES: Written comments should be sent to, U.S. Army Tank-automotive and Armaments Command (TACOM), ATTN: AMSTA–DSA–LT (ASV), Warren, MI 48397–5000

FOR FURTHER INFORMATION CONTACT: For further information, or to obtain a copy of the ASV Life-Cycle Environmental Assessment contact Mr. Anthony Shaw, Weapon System Manager (810) 574–8654.

SUPPLEMENTARY INFORMATION:

a. Proposed Action

This LCEA examines the potential impacts to the natural and human environment from the procurement of the ASV to satisfy the Army's need for survivability in a Military Police (MP) mobile platform. The ASV will be used by MP three-man teams in highly exposed threat environments. Current funding is available to procure up to 195 vehicles.

b. Environmental Impact

The ASV life-cycle includes the transport of vehicles to test sites, testing, vehicle production, deployment and

operation of production vehicles and their eventual demilitarization. Potential environmental Impacts of these life-cycle stages may include Air Quality, Noise, Water, Soil and Groundwater, Hazardous Materials and Hazardous Wastes, and Flora, Fauna and Threatened or Endangered Species at each of these life-cycle phases.

c. Additional Findings

Impacts from the proposed action would be minimal and not significant for the following reasons:

(1) The ASV will be used in its intended environment. This intended environment includes vehicle production and some testing at the Contractor's facility, and the remainder of life-cycle activities at Army installations and facilities.

(2) The ASV is very similar to vehicles produced commercially and vehicles already in the Army inventory. It is being produced in low to moderate quantities and will not significantly increase the vehicle population at Army installations and facilities.

(3) The overall environmental risk associated with the ASV is very low. It does not introduce any new technologies or processes. Vehicle life cycle activities do not introduce any potential environmental impacts that are not already currently mitigated by Army policy and procedures.

(4) The ASV Project Manager has ensured that the Contractor producing the vehicle is environmentally compliant, has no permit violations, and has commercial practices for Hazardous Material Management and Pollution Prevention in production of the ASV.

(5) The ASV Product Manager recognizes that Army installations and facilities have environmental plans and measures in place to address vehicle life cycle activities very similar to that of the ASV to prevent, mitigate and remediate environmental damage caused by vehicle operation. Vehicle operations at these Army installations and facilities are in conjunction with normal activities that are already addressed in their site specific environmental impact statements.

d. Determination

It is therefore concluded that this program:

(1) Is not a major federal action significantly affecting the quality of human environment.

(2) Will not have a significant impact on the environment.

(3) Is not likely to be environmentally controversial.

(4) Will not likely result in litigation based on environmental quality issues.

(5) Does not require an Environmental Impact Statement (EIS).

Phillip O. Meengs,

Project Manager, Light Tactical Vehicles.

[FR Doc. 97–31036 Filed 11–25–97; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Corps of Engineers

Atlantic Coast of Long Island, From Fire Island Inlet to Montauk Point, New York (Reach 1—Fire Island Inlet to Moriches Inlet Interim Plan for Storm Damage Protection)

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The New York District of the U.S. Army Corps of Engineers is beginning preparation of a Draft Environmental Impact Statement (DEIS) for proposed measures for interim storm damage protection for Reach 1—Fire Island Inlet to Moriches Inlet (study area) of the Atlantic Coast of Long Island, from Fire Island Inlet to Montauk Point, New York. A Notice of Intent for the preparation of a DEIS for the Atlantic Coast of Long Island, from Fire Island Inlet to Montauk Point, New York Reformulation Study, a long-term solution for the entire 83 mile study area, has also been published in the **Federal Register** dated July 28, 1997 (Volume 62, Number 144). For this Notice of Intent, the Corps is considering interim protection measures to address critical areas due to recent storm activity which has resulted in continual erosion leading to a decrease in the width of beach and a loss of beach material. Due to the continued erosion and a lack of sufficiently high beaches, berms or dune systems, residential and commercial developments have become increasingly susceptible to storm damage from flooding and wave attack and may need to be addressed prior to completion of the Reformulation Study. The EIS will be prepared according to the U.S. Army Corps of Engineers procedures for implementing the National Environmental Policy Act of 1969, as amended, (NEPA), 42 U.S.C. 4332(2) (C), and consistent with the U.S. Army Corps of Engineers' policy to facilitate public understanding and scrutiny of agency proposals. This notice of intent is published as required by the President's Council on Environmental Quality regulations implementing the provisions of NEPA, 40 CFR Parts 1500–1508.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen A. Couch, Study Manager, (212) 264–9077; Mr. Peter M. Weppler, EIS Coordinator, (212) 264–4663; Planning Division, Corps of Engineers, New York District, 26 Federal Plaza, New York, New York 10278–0090.

SUPPLEMENTARY INFORMATION: The overall Fire Island Inlet to Montauk Point, New York, Combined Beach Erosion Control and Hurricane Protection Project was authorized by the River and Harbor Act of 1960 in accordance with the recommendations of the Chief of Engineers in House Document No. 425, 86th Congress dated June 21, 1960. The original authorized project provided for beach erosion control and hurricane protection along five reaches by means of widening the beaches along the developed areas, raising the dunes by artificial placement of suitable sand, grass planting on the dunes, and construction of interior drainage structures at Mecox Bay, Sagaponack Lake, and Georgica Pond. The project authorized construction of 50 groins subject to determination of their actual need. The authorization was subsequently modified by Section 103 of the River and Harbor Act of October 12, 1962, Section 31 of the Water Resources Development Act of 1974, Section 502 of the Water Resources Development Act of 1986, and Section 102 of the Water Resources Development Act of 1992. These modifications were made primarily to adjust the cost sharing provisions of the authorized project.

1. Location of Proposed Action

The project area is located entirely in Suffolk County, Long Island, New York, along the Atlantic and bay shore of the towns of Babylon, Islip, and Brookhaven. The study area is approximately 30 miles long. The study area includes Great South Bay which is connected to the Atlantic Ocean through Fire Island Inlet, a federal navigation channel. Great South Bay is connected to Moriches Bay by a narrow channel behind the barrier island. The westernmost portion of the study area, Fire Island Inlet, is located approximately 52 miles by water east of the Battery, New York. The project area includes the Atlantic Ocean and Great South Bay, Fire Island proper, Moriches Inlet, barrier beaches, the mainland of Long Island fronted by Fire Island Proper, as well as suitable offshore borrow areas that will supply material for beach construction and replenishment.

2. Description of Proposed Action

The basic design of the interim plan consists of beachfill with a minimum berm width of 90 feet (ft) at elevation +9.5 ft NGVD, and a minimum 25 ft wide dune at elevation +15 ft NGVD. Proposed dune slopes are 1V:5H to Mean Low Water (MLW), and 1V:30H below MLW.

Variations of this basic design plan occur between Kismet and Point O'Woods and at Old Inlet in the Federal Wilderness Area. The dune and berm elevations from Kismet to Point O'Woods were increased to 18 ft NGVD and 11.5 ft NGVD, respectively to provide a 44 year level of protection. This modification is necessitated by the low elevations north of the dune in these areas.

Due to the environmental sensitivity of the Wilderness Area, and concerns raised by the Department of the Interior, fill in Old Inlet has been deferred. The District instead recommends use of a feeder beach and stockpile at Smith Point County Park. The deferred construction could be analyzed and implemented in the future, to minimize the negative environmental impacts associated with repeated breach closure efforts.

3. Reasonable Alternative Actions

In addition to the ''No Action'' alternative, the interim storm damage protection study will consider variations of the beach fill alternative to identify a short term solution to the severe erosion that has occurred within the study area and which continues to threaten the mainland communities with increased exposure to storm damages.

4. Scoping Process

a. Public Involvement

Additional scoping correspondence detailing the proposed plan will be distributed to all interested public and private agencies and organizations with the intent of receiving opinions all from interested parties.

b. Scoping Meetings

The scoping meetings are intended to assist in defining the focus of the EIS issues. A public notice issued at a later date will provide the dates, times and places of the scoping meetings. Further, the U.S. Army Corps of Engineers will provide ample opportunity for public participation in defining the issues to be addressed in the EIS and in reviewing and commenting on the draft EIS. Additions to this mailing list can be made by notifying the project EIS coordinator.

c. Significant Issues Requiring In-Depth Analysis

1. Water Quality Impacts; 2. Archaeological and Cultural Resources Impacts; 3. Aquatic and Terrestrial Resources Impacts; 4. Impacts to Shorebird Populations; 5. Recreational Impacts; 6. Economic Impacts; 7. Impacts to Longshore Sand Transport.

d. Environmental Review and Consultation

Review will be conducted as outlined in the Council on Environmental Quality regulations dated November 29, 1983 (40 CFR parts 1500–1508) and U.S. Army Corps of Engineer regulation ER 200–2–2 dated March 4, 1988.

e. Federal Agency Participation in the EIS Process

Federal agencies with an interest in this EIS effort are requested to participate as cooperating agencies pursuant to 40 CFR Part 1501.6. All interested federal agencies are requested to submit a letter of intent to Colonel Gary Thomas, District Engineer at the above address.

5. Estimated Date of DEIS Availability

June 1998.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 97–31039 Filed 11–25–97; 8:45 am]

BILLING CODE 3710–06–M

DEPARTMENT OF DEFENSE

Corps of Engineers; Department of the Army

Notice of Intent To Prepare an Environmental Impact Statement (EIS) for the Stabilization of the Bluff Toe at Norco Bluffs

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Correction.

SUMMARY: In previous **Federal Register** notice (Vol 62, No. 105, page 29719) Monday, June 2, 1997, make the following corrections:

On Page 29719 in column two, Summary paragraph, lines six through eleven, the sentence should be changed to read ''The purpose of the proposed project is to stabilize the toe of the bluff parallel to Shadow Canyon Circle, Alahambra Street, and River Ridge Drive, as far upstream as Crest Drive, in the City of Norco, and thereby maintain the location of the 566 foot elevation line.''

On Page 29719 in column three, Availability of the Draft EIS paragraph, change the date from ''September 1997'' to ''March 1998.''

The above corrections are required to clarify the location of the proposed project which has been expanded to cover areas immediately upstream and downstream of the originally proposed project, and to inform individuals of the change in the availability of the draft EIS for publication and circulation.

FOR FURTHER INFORMATION CONTACT: Any comments on this increase in project area should be sent to Mr. Alex Watt, U.S. Army Corps of Engineers, Los Angeles district, Programs and Project Management Division at (213) 452–3860.

SUPPLEMENTARY INFORMATION: None.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 97–31037 Filed 11–25–97; 8:45 am]

BILLING CODE 3710–KF–M

DEPARTMENT OF DEFENSE

Department of the Army

Corps of Engineers

Availability of a Proposed Plan for the Formerly Utilized Sites Remedial Action Program (FUSRAP)

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of availability.

SUMMARY: During the 1940s, 1950s, and 1960s, the Ashland 1 (including Seaway Area D) and Ashland 2 Sites became contaminated as a result of disposal and relocation of residues from uranium processing, performed in support of the nation's early atomic energy program, at the Linde Site. The sites are being addressed under the Formerly Utilized Sites Remedial Action Program (FUSRAP). In December 1989, the U.S. Department of Energy (DOE) published a Notice of Intent to complete a Remedial Investigation/Feasibility Study-Environmental Impact Statement (RI/FS–EIS) for the Tonawanda (Ashland 1, 2, Seaway D, and Linde) Site. Since the issuance of that notice, DOE established a policy in June 1994 of incorporating National Environmental Policy Act (NEPA) values into Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) documentation. In accordance with that policy, likewise, the Corps does not intend to issue a separate Environmental Impact Statement for the Tonawanda Site. The Proposed Plan summarizes the findings of the Remedial Investigation and Feasibility

Study and identifies the preferred alternative for Ashland 1 (including Seaway Area D) and Ashland 2. The preferred alternative includes: Complete Excavation with Offsite Disposal of radioactively contaminated materials that exceed the 40 picocurie per gram Thorium-230 guideline. The Administrative Record file was established to support the Remedial Investigation and Feasibility Study at Ashland 1 and Ashland 2. The Administrative Record is a compendium of documentation that is compiled progressively throughout the decision-making process. The file contains documentation that will be relied upon in issuing a Record of Decision for Ashland 1 and Ashland 2. This notice establishes a 60-day public comment period for the Proposed Plan for Ashland 1 and Ashland 2, beginning November 10, 1997 and lasting through January 9, 1998. Written comments will be accepted anytime during this comment period and both oral and written comments will be accepted at a public meeting, which is scheduled to be held 7 to 9 p.m. on December 17, 1997, at the Phillip Sheridan Building, 3200 Elmwood Avenue, Kenmore, NY.

FOR FURTHER INFORMATION CONTACT: Copies of the Proposed Plan and further information may be requested from: U.S. Corps of Engineers, FUSRAP Public Information Center, 70 Pearce Avenue, Tonawanda, NY 14150, Telephone (716) 871–9660, ATTN: Ms. Sarah Snyder. Hours are 8:00 a.m. to 5:00 p.m., Monday through Thursday, and 9:00 a.m. to noon on Friday.

SUPPLEMENTARY INFORMATION: Written comments will be accepted if postmarked by January 8 at the following address: U.S. Army Corps of Engineers, FUSRAP Public Information Center, 70 Pearce Avenue, Tonawanda, NY 14150, ATTN: Ms. Sarah Snyder.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 97–31035 Filed 11–25–97; 8:45 am]

BILLING CODE 3710–GP–M

DEPARTMENT OF DEFENSE

Department of the Navy, DoD

Notice of Public Hearing for the Draft Environmental Impact Statement (DEIS) for the Outfall Replacement for Wastewater Treatment Plant at Fort Kamehameha, Pearl Harbor, Oahu, Hawaii

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, as implemented by the Council on Environmental Quality regulations (40 CFR Parts 1500–1508), the Department of the Navy (Navy) has prepared and filed with the U.S. Environmental Protection Agency a DEIS for the outfall replacement for Wastewater Treatment Plant at Fort Kamehameha, Pearl Harbor, Oahu, Hawaii.

The Navy proposes to construct a new concrete pipeline, 2.4 miles long and 42 inches in diameter, into open coastal waters to replace the existing outfall for effluent discharge from the Public Works Center, Pearl Harbor Wastewater Treatment Plant (WWTP). The present outfall discharges into the Pearl Harbor Estuary, which is classified Water Quality Limited Segment (WQLS) by the State of Hawaii. The classification limits the discharge of municipal and industrial wastewater effluents. The proposed action is needed to eliminate the discharge to the WQLS and associated future permit limitations and violations.

A Notice of Intent (NOI) to prepare the DEIS was published in the **Federal Register** on September 11, 1996. Two public scoping meetings were held on Oahu: (1) Honolulu: October 1, 1996, 7:00 p.m. to 10:00 p.m., Washington Intermediate School, 1633 South King Street and (2) Pearl Harbor: October 2, 1996, 7:00 p.m. to 10:00 p.m., Makalapa Elementary School, 4435 Salt Lake Boulevard.

The DEIS analyzes reasonable alternatives to the proposed action, such as upland disposal of treated effluent by subsurface injection, reclamation of effluent for reuse, and ''no action'' alternative. Based on analysis of the alternatives, the proposed action with appropriate mitigation has been presented to be the environmentally preferred alternative.

No decision on the proposed action will be made until the NEPA process has been completed.

The DEIS has been distributed to various federal, state and local agencies, local groups, elected officials, special interest groups and individuals. The DEIS is also available for review at local libraries as follows: Hawaii State Main Library, Salt Lake Moanalua Public Library, Aiea Public Library, Pearl City Public Library and Ewa Beach Public School Library, all of which are situated in the vicinity of Pearl Harbor.

ADDRESSES: The Navy will conduct a public hearing to receive oral and written comments concerning the DEIS on Wednesday, December 17, 1997, from 7:00 p.m. to 10:00 p.m., at the Radford High School Cafeteria, 4361 Salt Lake Boulevard, Honolulu.

A brief presentation will precede a request for public information and comments. Navy representatives will be available at the hearing to receive information and comments from agencies and the public regarding issues of concern. Federal, state and local agencies and interested individuals are invited to be present or represented at the hearing. Oral comments will be heard and transcribed by a stenographer. To assure accuracy of the record, all comments should be submitted in writing. Both oral and written statements will become part of the public record for this study. In the interest of available time, each speaker will be asked to limit oral comments to five minutes. Longer comments should be summarized at the public hearing and submitted in writing either at the hearing or mailed to the address below.

FOR FURTHER INFORMATION CONTACT: Please provide written comments by January 9, 1998, to Mr. Gary Kasaoka, Code 231GK, Pacific Division, Naval Facilities Engineering Command, Pearl Harbor, Hawaii 96860–7300, telephone (808) 471–9338, fax (808) 474–5909, or e-mail address: gkasaoka@efdpac.navfac.navy.mil.

Dated: November 21, 1997.

Michael I. Quinn,

LCDR, JAGC, USN, Alternate Federal Register Liaison Officer.

[FR Doc. 97–31094 Filed 11–25–97; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Proposed collection; comment request.

SUMMARY: The Deputy Chief Information Officer, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 26, 1998.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information

Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U. S. C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Deputy Chief Information Officer, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department, (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate, (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 20, 1997.

Gloria Parker,

Deputy Chief Information Officer, Office of the Chief Information Officer.

Office of the Under Secretary

Type of Review: Revision.
Title: Longitudinal Evaluation of School Change and Performance (LESCP).
Frequency: Annually.
Affected Public: State, local or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 13,690.
Burden Hours: 45,901.
Abstract: The LESCP is being conducted in response to the legislative requirement in P.L. 103–382, Section 1501 to assess the implementation of Title I and related education reforms. The information will be used to examine changes—over a 3-year period—that are occurring in schools and classrooms. Teacher and teacher aids will complete a mail survey, and district Title I administrators, school-based staff, and parents will be interviewed during on-site field work.

Office of the Under Secretary

Type of Review: New.
Title: Local Implementation of Federal Programs.
Frequency: One time.
Affected Public: State, local or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 3,176.
Burden Hours: 3,176.
Abstract: The Department of Education is charged with evaluating Title I of the Elementary and Secondary Education Act and other elementary and secondary education legislation enacted by the 103rd Congress. This study will collect information on the operations and effects at the district level of legislative provisions and federal assistance, in the context of state education reform efforts. Findings will be used in reporting to Congress and improving information dissemination. Respondents are local superintendents, directors of federal programs, directors of research and assessment, and school principals.

[FR Doc. 97–30974 Filed 11–25–97; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

ACTION: Submission for OMB review; comment request.

SUMMARY: The Deputy Chief Information Officer, Office of the Chief Information Officer, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 26, 1997.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Deputy Chief Information Officer, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: November 20, 1997.

Gloria Parker,

Deputy Chief Information Officer, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Type of Review: Revision.
Title: Applications for Assistance (sections 8002 and 8003) and State Certification Requests (section 8009)—Impact Aid.
Frequency: Annually.

Affected Public: Individuals or households; Federal Government; State, Local or Tribal Gov't, SEAs or LEAs.

Annual Reporting and Recordkeeping Hour Burden:

Responses: 925,698.

Burden Hours: 943,318.

Abstract: A local educational agency must submit an application to the Department to receive Impact Aid payments under sections 8002 or 8003 of the Elementary and Secondary Education Act (ESEA), and a State requesting certification under section 8009 of the ESEA must submit data for the Secretary to determine whether the State has a qualified equalization plan and may take Impact Aid payments into consideration in allocating State aid.

[FR Doc. 97–30975 Filed 11–25–97; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

President's Board of Advisors on Historically Black Colleges and Universities; Meeting

AGENCY: President's Board of Advisors on Historically Black Colleges and Universities, Department of Education.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and agenda of the meeting of the President's Board of Advisors on Historically Black Colleges and Universities. This notice also describes the functions of the Board. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act.

DATE AND TIME: December 18, 1997 from 9:00 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be held at the Sheraton City Centre Hotel located at 1143 New Hampshire Avenue, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Sterling Henry, White House Initiative on Historically Black Colleges and Universities, U.S. Department of Education, 600 Independence Avenue, SW, the Portals Building, Suite 605, Washington, DC 20202–5120. Telephone: (202) 708–8667.

SUPPLEMENTARY INFORMATION: The President's Board of Advisors on Historically Black Colleges and Universities was established under Executive Order 12876 of November 1, 1993. The Board is established to advise on the financial stability of Historically Black Colleges and Universities, to issue an annual report to the President on HBCU participation in Federal programs, and to advise the Secretary of Education on increasing the private sector role in strengthening HBCUs.

The meeting of the Board is open to the public. The meeting will be primarily devoted to the discussion of challenges facing historically black colleges and universities.

Records are kept of all Board procedures, and are available for public inspection at the White House Initiative on Historically Black Colleges and Universities located at 1250 Maryland Avenue, S.W., The Portals Building, Suite 605, Washington, DC, 20202, from the hours of 8:30 a.m. to 5:00 p.m.

Dated: November 19, 1997.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

[FR Doc. 97–31043 Filed 11–25–97; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Notice of Availability of the Final Environmental Impact Statement on the Disposal of the S3G and D1G Prototype Reactor Plants

AGENCY: Department of Energy.

ACTION: Notice of availability.

SUMMARY: The Department of Energy (DOE) Office of Naval Reactors (Naval Reactors) has published the Final Environmental Impact Statement on the Disposal of the S3G and D1G Prototype Reactor Plants. The Final Environmental Impact Statement was prepared in accordance with the National Environmental Policy Act (NEPA) of 1969; Council on Environmental Quality regulations implementing NEPA (40 CFR Parts 1500–1508); and DOE NEPA Implementing Procedures (10 CFR Part 1021). The Final Environmental Impact Statement and its supporting references are available to the public at the Saratoga Springs Public Library in Saratoga Springs and the Schenectady County Public Library in Schenectady, New York. The Final Environmental Impact Statement is also available by mail upon request.

SUPPLEMENTARY INFORMATION:

Background

The S3G and D1G Prototype reactor plants are located on the Kesselring Site near West Milton, New York, approximately 17 miles north of Schenectady. The S3G and D1G Prototype reactor plants first started operation in 1958 and 1962, respectively, and served for more than 30 years as facilities for testing reactor plant components and equipment and for training of U.S. Navy personnel. As a result of the end of the Cold War and the downsizing of the Navy, the S3G and D1G Prototype reactor plants were shut down in May 1991 and March 1996, respectively. Since then, the S3G and D1G Prototype reactor plants have been defueled and placed in a safe and stable protective storage condition. The Kesselring Site will not be released for other uses in the foreseeable future since two active prototype reactor plants continue to operate to perform training of U.S. Navy personnel and testing of naval nuclear propulsion plant equipment.

Alternatives Considered

1. Prompt Dismantlement—Preferred Alternative

The Final Environmental Impact Statement identifies prompt dismantlement as the preferred alternative. If selected, this alternative would be subject to the availability of appropriated funding. This alternative would involve the prompt dismantlement of the S3G and D1G Prototype reactor plants. All S3G and D1G Prototype reactor plant systems, components and structures would be removed from the Kesselring Site. To the extent practicable, the resulting low-level radioactive metals would be recycled at existing commercial facilities. The remaining low-level radioactive waste would be disposed of at the DOE Savannah River Site in South Carolina. The Savannah River Site currently receives low-level radioactive waste from Naval Reactors' sites in the eastern United States. Both the volume and radioactive content of the S3G and D1G Prototype reactor plant low-level waste fall within the projections of Naval Reactors' waste provided to the Savannah River Site, which are included in the *Savannah River Site Waste Management Final Environmental Impact Statement*, dated July 1995. For the purposes of providing an upper bound in transportation related risk analyses, transportation of low-level radioactive waste to the Hanford Site in Washington State is also evaluated. There are no current plans to ship low-level radioactive wastes from S3G and D1G Prototype reactor plant dismantlement activities to the Hanford Site. In the event that shipment of these wastes to Hanford Site becomes necessary, waste disposal plans and activities would comply with all applicable State and Federal statutes and regulations.

2. Deferred Dismantlement

The deferred dismantlement alternative would involve keeping the defueled S3G and D1G Prototype reactor plants in protective storage for 30 years before dismantlement. Deferring dismantlement for 30 years would allow nearly all of the cobalt-60 radioactivity to decay. Nearly all of the gamma radiation within the reactor plant comes from cobalt-60. The very small amount of longer-lived radioisotopes, such as nickel-59, would remain and would have to be addressed during dismantlement.

3. No Action

The no action alternative would involve keeping the defueled S3G and D1G Prototype reactor plants in protective storage indefinitely. Since there is some residual radioactivity with long half-lives, such as nickel-59, in the defueled reactor plant, this alternative would leave some radioactivity at the Kesselring Site indefinitely.

4. Other Alternatives Considered

The other alternatives considered include permanent on-site disposal. Such on-site disposal could involve building an entombment structure over the S3G and D1G Prototype reactor plants or developing a below-ground disposal area at the Kesselring Site. Another alternative would be to remove the S3G and D1G Prototype reactor plants as two large reactor compartment packages for offsite disposal. Each of these alternatives was considered but eliminated from detailed analysis.

Public Comments on the Draft Environmental Impact Statement

Naval Reactors held a public hearing with two sessions on the Draft Environmental Impact Statement in Milton, New York on August 13, 1997. Comments from 14 individuals and agencies were received in either oral or written statements at the hearing or in comment letters. Approximately one-third of the commenters expressed a preference for the preferred alternative, prompt dismantlement. Two commenters favored the deferred dismantlement alternative and the remaining commenters expressed no specific preference for any of the alternatives. Public comments resulted in only minor clarifications in the Final Environmental Impact Statement. Based on U.S. Environmental Protection Agency (EPA) review of the Draft Environmental Impact Statement, EPA rated the proposed project as ''LO'' (Lack of Objection). All of the comments and Naval Reactors'' responses are included in an appendix to the Final Environmental Impact Statement.

Preferred Alternative

Naval Reactors has identified the prompt dismantlement alternative as the preferred alternative since it is consistent with the Naval Reactors' record of managing waste efficiently and minimizing its generation. Prompt dismantlement would allow Naval Reactors to utilize an experienced work force that is presently located at the Kesselring Site. Prompt dismantlement could be accomplished safely, economically, and with a high degree of certainty that the environmental impacts would be small.

Availability of Copies of the Final Environmental Impact Statement

The Final Environmental Impact Statement has been distributed to interested Federal, State, and local agencies, and to individuals who have expressed interest. Copies of the Final Environmental Impact Statement and its supporting references are available for review at the Saratoga Springs Public Library at 49 Henry Street, Saratoga Springs, NY 12866, and at the Schenectady County Public Library at 99 Clinton Street, Schenectady, NY 12301. Requests for copies of the Final Environmental Impact Statement should be directed to Mr. A. S. Baitinger, Chief West Milton Field Office, Office of Naval Reactors, U.S. Department of Energy, P.O. Box 1069, Schenectady, NY 12301; telephone (518) 884–1234.

Issued at Arlington, VA this 18th day of November 1997.

F. L. Bowman,

Admiral, U.S. Navy Director, Naval Nuclear Propulsion Program.

[FR Doc. 97–31073 Filed 11–25–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Information Collection Submitted for Review and Request for Comments (FERC–511)

November 21, 1997.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of submission for review by the Office of Management and Budget (OMB) and request for comments.

SUMMARY: The Federal Energy Regulatory Commission (Commission) has submitted the energy information collection listed in this notice to the Office of Management and Budget (OMB) for review under provisions of Section 3507 of the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Any interested person may file comments on the collection of information directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission received no comments in response to an earlier **Federal Register** notice of August 21, 1997 (62 FR 44462) and has made this notation in its submission to OMB.

DATES: Comments regarding this collection of information are best assured of having their full effect if received on or before December 26, 1997.

ADDRESSES: Address comments to Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission, Desk Officer, 726 Jackson Place, N.W., Washington, D.C. 20503. A copy of the comments should also be sent to Federal Energy Regulatory Commission, Division of Information Services, Attention: Mr. Michael Miller, 888 First Street N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Michael P. Miller may be reached by telephone at (202) 208–1415, by fax at (202) 273–0873, and by e-mail at mmiller@ferc.fed.us.

SUPPLEMENTARY INFORMATION:

Description

The energy information collection submitted to OMB for review contains:

1. *Collection of Information:* FERC–511 ''Application for Transfer of License.''

2. *Sponsor:* Federal Energy Regulatory Commission.

3. *Control No.:* OMB No. 1902–0069. The Commission is now requesting that OMB approve a three-year extension of the current expiration date, with no changes to the existing collection. There is no change to the reporting burden. These are mandatory collection requirements.

4. *Necessity of Collection of Information:* Submission of the information is necessary to enable the Commission to carry out its responsibilities in implementing the provisions of the Federal Power Act (FPA). The information reported under Commission identifier FERC–511 is filed in accordance with Sections 4(e), and 8(FPA). Section 4(e) of the FPA authorizes the Commission to issue licenses for construction, operation and maintenance of dams, water conduits,

reservoirs, and transmission lines or other facilities necessary for the development, transmission and utilization of power from bodies of water Congress has jurisdiction over. Section 8 of the FPA provides that the voluntary transfer of any license can only be made with the written approval of the Commission. Any successor to the licensee may assign the rights of the original licensee, but is subject to all of the conditions of the license. The information is collected in the form of a written application for transfer of a license, executed jointly by the parties to the proposed transfer. It is used by the Commission staff to determine the qualifications of the proposed transferee to hold the license, and to prepare the transfer of the license order. Respondent Description: The respondent universe currently comprises on average, 23 applicants for transfer of a hydro electric license.

6. *Estimated Burden:* 920 total burden hours, 23 respondents, 1 response annually, 40 hours per response (average).

7. *Estimated Cost Burden to Respondents:* 920 hours ÷ 2,087 hours per year × $110,000 per year = $48,491.

Statutory Authority: Sections 4(e), 8 of the Federal Power Act (FPA), 16 U.S.C. 791a *et seq.*

Lois D. Cashell,

Secretary.

[FR Doc. 97–31066 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Information Collection Submitted for Review and Request for Comments (FERC–515)

November 21, 1997.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of submission for review by the Office of Management and Budget (OMB) and request for comments.

SUMMARY: The Federal Energy Regulatory Commission (Commission) has submitted the energy information collection listed in this notice to the Office of Management and Budget (OMB) for review under provisions of Section 3507 of the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Any interested person may file comments on the collection of information directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission received no comments in response to an earlier **Federal Register** notice of August 21, 1997 (62 FR 44463) and has made this notation in its submission to OMB.

DATES: Comments regarding this collection of information are best assured of having their full effect if received on or before December 26, 1997.

ADDRESSES: Address comments to Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission, Desk Officer, 726 Jackson Place, N.W., Washington, D.C. 20503. A copy of the comments should also be sent to Federal Energy Regulatory Commission, Division of Information Services, Attention: Mr. Michael Miller, 888 First Street N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Michael P. Miller may be reached by telephone at (202) 208–1415, by fax at (202) 273–0873, and by e-mail at mmiller@ferc.fed.us.

SUPPLEMENTARY INFORMATION:

Description

The energy information collection submitted to OMB for review contains:

1. *Collection of Information:* FERC–515 ''Hydropower License-Declaration of Intention.''

2. *Sponsor:* Federal Energy Regulatory Commission.

3. *Control No.:* OMB No. 1902–0079. The Commission is now requesting that OMB approve a three-year extension of the current expiration date, with no changes to the existing collection. There is an increase in the reporting burden due to an increase in the number of applicants who intend to undertake hydroelectric projects. These are mandatory collection requirements.

4. *Necessity of Collection of Information:* Submission of the information is necessary to enable the Commission to carry out its responsibilities in implementing the provisions of the Federal Power Act (FPA). The information reported under commission identifier FERC–515 is filed in accordance with Sections 23(b) of the FPA. Section 23(b) of the FPA authorizes the Commission to make a determination as to whether it has jurisdiction over a proposed hydroelectric project. Section 23(b) also requires that any person intending to construct project works on a navigable commerce clause water must file a declaration of their intention to do so with the Commission. If the Commission finds the proposed project will have an impact on ''interstate or foreign commerce'', then the person intending to construct the project must obtain a Commission license or exemption before starting constructions. Such sites are generally on streams defined as U.S. navigation waters, and over which the Commission has jurisdiction under its authority to regulate foreign and interstate commerce. The information is collected in the form of a written application, declaring the applicant's intent and used by Commission staff to research the jurisdictional aspects of the project. This research includes examining maps and land ownership records to established whether or not there is Federal jurisdiction over the lands and waters affected by the project. A finding of non-jurisdiction by the Commission eliminates a substantial paperwork burden for an applicant who might otherwise have to file a license or exemption application.

5. *Respondent Description:* The respondent universe currently comprises on average, 10 applicants for a declaration of intention (''DI'').

6. *Estimated Burden:* 800 total burden hours, 10 respondents, 1 response annually, 80 hours per response (average).

7. *Estimated Cost Burden to Respondents:* 800 hours ÷ 2,087 hours per year × $110,000 per year = $42,166, average cost per respondent = $4,216.

Statutory Authority: Sections 23(b), of the Federal Power Act (FPA), 16 U.S.C. 617.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31067 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–190–011]

Colorado Interstate Gas Company; Notice of Tariff Compliance Filing

November 20, 1997.

Take notice that on November 17, 1997, Colorado Interstate Gas Company (CIG), tendered for filing to become part of its FERC Gas Tariff, First Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing, to be effective October 1, 1997 and November 1, 1997, as applicable.

CIG states that on March 29, 1996, in Docket No. RP96–190–000, it filed to implement a general rate increase applicable to its transportation and storage services. Intensive settlement

discussions resulted in CIG filing on August 27, 1997, an Offer of Settlement (August 27 Settlement) which was supported or unopposed by all parties to the proceeding. CIG states it included pro forma tariff sheets as part of the August 27 Settlement. An order issued on October 16, 1997, in Docket No. RP96–190–009 approving the August 27 Settlement as a fair and reasonable resolution of the issues in the proceeding.

CIG further states that Section 2.10 of the August 27 Settlement provides for a filing to implement the terms of the August 27 Settlement on an interim basis pending Commission approval of the August 27 Settlement. On September 16, 1997, CIG filed tariff sheets to implement the August 27 Settlement on a interim basis. The tariff sheets that accompanied the interim filing were the same as the pro forma tariff sheets filed in the August 27 Settlement except they were filed as actual tariff sheets and on each of the filed tariff sheets there was a paragraph that would allow reinstatement of the superseded tariff sheet if the August 27 Settlement did not become effective.

CIG states it is filing to remove this paragraph from its tariff sheets as it is no longer necessary.

CIG states it filed on October 1, 1997, in Docket No. RP97–63–006, Sixth Revised Sheet No. 233, Second Revised Sheet No. 233A, Fifth Revised Sheet No. 234, Second Revised Sheet No. 234A and Fourth Revised Sheet No. 301. All these sheets were filed with the August 27 Settlement with the Section 2.10 paragraph included. CIG is filing substitute tariff sheets to remove this paragraph from both the interim tariff sheets and the RP97–63–006 tariff sheets.

Further, in Docket No. RP97–63–006 CIG states it incorrectly filed First Revised Sheet No. 281B, First Revised Sheet No. 281C and Original Sheet No. 281D. CIG is filing here to correct this pagination error. These sheets should have been filed in Docket No. RP97–63–006 as Second Revised Sheet No. 281B, Second Revised Sheet No. 281C and First Revised Sheet No. 281D. CIG is also filing Original Sheet No. 234D, which is the ''No Notice and Firm Storage Service Reservoir Inventory Limit'', which was inadvertently omitted when filing tariff sheets for Docket No. RP97–63–006. CIG states it has also reinstated nomination language referring to HUB Nominations on Second Revised Sheet No. 281B.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Regulations. All such protest must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31006 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–87–000]

Columbia Gas Transmission Corporation; Notice of Request Under Blanket Authorization

November 20, 1997.

Take notice that on November 12, 1997, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314–1599, filed in Docket No. CP98–87–000 a request pursuant to Sections 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.216) for authorization to abandon by retirement approximately 1.1 miles of 8-inch pipeline located in Hancock County, West Virginia, under Columbia's blanket certificate issued in Docket No. CP83–76–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Columbia proposes to abandon a section of lateral transmission Line 306 consisting of approximately 1.1 miles of 8-inch pipeline and appurtenances in Hancock County. Columbia was authorized to own and operate the facilities proposed for abandonment in Docket No. CP71–132 and Columbia has stated that there are no points of delivery from this Line 306 section. According to Columbia, the Line 306 section for which abandonment authority is requested is an uncoated, low pressure pipeline in need of replacement and cathodic protection due to its deteriorating condition. The proposed abandonment will avoid both annual operation and maintenance expenses as well as the costs of future pipeline replacement. Columbia states that these predictable and certain savings make the abandonment of this section of Line 306 the most practical and least costly alternative to Columbia without impacting Columbia's ability to render service.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31001 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–91–000]

Florida Gas Transmission Company; Notice of Request Under Blanket Authorization

November 20, 1997.

Take notice that on November 14, 1997, Florida Gas Transmission Company (FGT), 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251–1188, filed in Docket No. CP98–91–000 a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 18 CFR 157.212) for authorization to construct, own, and operate a lateral and a new meter station in Pasco County, Florida, under FGT's blanket certificate issued in Docket No. CP82–553–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

FGT proposes to construct a new meter station to serve Florida Power Corporation (FPC) at the FPC Anmclote Plant and a new lateral to extend from FGT's 30-inch West leg to the FPC Anclote Plant. The meter station is expected to accommodate the current

and future anticipated volumes of up to 100,000 MMBtu per day of natural gas. FGT estimates the cost of the construction of the proposed lateral at $13,363,000, of which amount FGT would not be reimbursed, and the construction cost related to the meter station to be $465,000, of which FGT would be reimbursed, exclusive of tax gross up.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31002 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP85–221–0977]

Frontier Gas Storage Company; Notice of Sale Pursuant to Settlement Agreement

November 20, 1997.

Take notice that on November 14, 1997, Frontier Gas Storage Company (Frontier), c/o Reid & Priest, Market Square, 701 Pennsylvania Ave., N.W., Suite 800, Washington, D.C. 20004, in compliance with provisions of the Commission's February 13, 1985, Order in Docket No. CP82–487–000, *et al.*, submitted an executed Service Agreement under rate Schedule LVS–1 providing for the possible sale of up to a daily quantity of 50,000 MMBtu, not to exceed 2,000,000 MMBtu of Frontier's gas storage inventory on an ''as metered'' basis to Rainbow Gas Company, for term ending December 31, 1998.

Under Subpart (b) of Ordering Paragraph (F) of the Commission's February 13, 1985, Order, Frontier is ''authorized to commerce the sale of its inventory under such an executed service agreement fourteen days after filing the agreement with the Commission, and may continue making such sale unless the Commission issues an order either requiring Frontier to stop selling and setting the matter for hearing or permitting the sale to continue and establishing other procedures for resolving the matter.''

Any person desiring to be heard or to make a protest with reference to said filing should, within 10 days of the publication of such notice in the **Federal Register**, file with the Federal Energy Regulatory Commission (888 First Street N.E., Washington, D.C. 20426) a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedures, 18 CFR 385.214 or 18 CFR 385.211. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–30998 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP85–221–098]

Frontier Gas Storage Company; Notice of Sale Pursuant to Settlement Agreement

November 20, 1997.

Take notice that on November 14, 1997, Frontier Gas Storage Company (Frontier), c/o Reid & Priest, Market Square, 701 Pennsylvania Ave., N.W., Suite 800, Washington, D.C. 20004, in compliance with provisions of the Commission's February 13, 1985, Order in Docket No. CP82–487–000, *et al.*, submitted an executed Service Agreement under Rate Schedule LVS–1 providing for the possible sale of 1,000,000 MMBtu of Frontier's gas storage inventory on an ''in place'' basis to Rainbow Gas Company.

Under Subpart (b) of Ordering Paragraph (G) of the Commission's February 13, 1985, Order, Frontier is ''authorized to consummate the proposed sale in place unless the Commission issues an order within 20 days after expiration of such notice period either directing that the sale not take place and setting it for hearing or permitting the sale to go forward and establishing other procedures for resolving the matter. Deliveries of gas sold in place shall be made pursuant to a schedule to be set forth in an exhibit to the executed service agreement.''

Any person desiring to be heard or to make a protest with reference to said filing should, within 10 days of the publication of such notice in the **Federal Register,** file with the Federal Energy Regulatory Commission (888 First Street N.E., Washington, D.C. 20426) a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 or 18 CFR 385.211. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–30999 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–157–008]

Gas Transport, Inc.; Notice of Compliance Filing

November 20, 1997.

Take notice that on November 17, 1997, Gas Transport, Inc. (GTI) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following substitute tariff sheets:

Effective November 1, 1993

Sub. Original Sheet No. 126
2nd Sub. Original Sheet No. 150
Sub. Original Sheet No. 203
Sub. Original Sheet No. 208
Sub. Original Sheet No. 213
Sub. Original Sheet No. 218

Effective June 1, 1997

2nd Sub. First Revised Sheet No. 195

GTI is filing 2nd Sub. First Revised Sheet No. 195 to comply with the condition in the letter order issued by the Commission on October 31, 1997, requiring GTI to revise its Interconnection Agreement to limit the scope of the terms to the Operator's obligation with respect to material changes in compressor operations that may affect delivery conditions at a receipt point.

GTI is filing the remaining tariff sheets to correct minor wording errors identified in the Commission's letter order.

GTI states that copies of this filing were served upon its jurisdictional customers and the Regulatory Commissions of the states of Ohio and West Virginia.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31008 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2674–003, Vermont]

Green Mountain Power Company; Notice of Intent To Conduct Public Scoping Meetings and Site Visit

November 20, 1997.

The Federal Energy Regulatory Commission (Commission or FERC) received an application from the Green Mountain Power Company (Green Mountain or Applicant) to relicense the Vergennes Hydroelectric Project No. 2674–003.The 2.4-megawatt project is located on Otter Creek in the city of Vergennes, Addison County, Vermont. The Commission will hold public and agency scoping meetings on December 11, 1997, for preparation of an Environmental Assessment (EA) under the National Environmental Policy Act (NEPA) for the issuance of a major license for the project.

Scoping Meetings

FERC staff will conduct one agency scoping meeting and one public meeting. The agency scoping meeting will focus on resource agency and non-governmental organization (NGO) concerns, while the public scoping meeting is primarily for public input. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EA. The times and locations of these meetings are as follows:

Agency Scoping Meeting

Date: Thursday, December 11, 1997.

Time: From 9:00 a.m. until 12:00 p.m.

Place: Vergennes Fire Station Meeting Room.

Address: Green Street, Vergennes, Vermont.

Public Scoping Meeting

Date: Thursday, December 11, 1997.

Time: From 7:00 p.m. until 10:00 p.m.

Place: Vergennes Fire Station Meeting Room.

Address: Green Street, Vergennes, Vermont.

To help focus discussions, we will distribute a Scoping Document (SD1) outlining the subject areas to be addressed at the meeting to the parties on the Commission's mailing list. Copies of the SD1 also will be available at the scoping meetings.

Site Visits

The applicant and FERC staff will conduct a project site visit beginning at 1:00 p.m. on December 10, 1997. All interested individuals, organizations, and agencies are invited to attend. All participants should meet at the Green Mountain Power Service Center, adjacent to the #9 Power House on Mechanic Street in Vergennes, Vermont. All participants are responsible for their own transportation to the side. Anyone with questions about the site visit should contact Mr. Michael Scarzello of Green Mountain at 802–660–5835.

Objectives

At the scoping meetings, the staff will: (1) summarize the environmental issues tentatively identified for analysis in the EA; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the EA, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the relative depth of analysis for issues to be addressed in the EA; and (5) identify resource issues that are of lesser importance, and, therefore, do not require detailed analysis.

Procedures

The meetings will be recorded by a stenographer and will become part of the formal record of the Commission proceeding on the project. Individuals presenting statements at the meetings will be asked to sign in before the meeting starts and to clearly identify themselves for the record. Speaking time for attendees at the meetings will be determined before the meeting, based on the number of persons wishing to speak and the approximate amount of time available for the session. All speakers will be provided at least 5 minutes to present their views.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meetings and to assist the staff in defining and clarifying the issues to be addressed in the EA.

Persons choosing not to speak at the meetings, but who have views on the issues, may submit written statements for inclusion in the public record at the meeting. In addition, written scoping comments may be filed with the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, until January 12, 1998. All filings should contain an original and eight copies, and must clearly show at the top of the first page ''Vergennes Hydroelectric Project, FERC No. 2674–003.''

For further information, please contact Lee Emery at (202) 219–2779.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31003 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP98–49–000]

Koch Gateway Pipeline Company; Notice of Report of Pooling Service

November 20, 1997.

Take notice that on November 14, 1997, Koch Gateway Pipeline Company (Koch) tendered for filing its report of the pooling service after one year of operation.

Koch states that this filing is being filed in compliance with Section 8 of the Pooling Rate Schedule (PS Rate Schedule). The Commission required Koch to file a report 45 days after the first year of operating experience. Koch states that the pooling service has been implemented successfully and that no changes are being proposed for this service at this time.

Koch states that copies of the filing are being served upon each of its customers, and other interested parties.

Any person desiring to be heard or protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission,

Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules of Practices and Procedure. All such motions or protests must be filed on or before November 28, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31013 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP98–8–001]

Mississippi River Transmission Corporation; Notice of Filing

November 20, 1997.

Take notice that on November 14, 1997, Mississippi River Transmission Corporation (MRT) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following revised tariff sheet to be effective November 1, 1997:

Substitute Twenty-Third Revised Sheet No. 7

MRT states that this filing is being made to comply with the Commission's order dated October 30, 1997, in the above-referenced docket.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with 18 CFR 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31011 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–253–004]

Natural Gas Pipeline Company of America; Notice of Proposed Changes in FERC Gas Tariff

November 20, 1997.

Take notice that on November 18, 1997, Natural Gas Pipeline Company of America (Natural) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, Sixth Revised Sheet No. 20, to be effective December 1, 1997.

Natural states that the purpose of this filing is to implement a change in the currently effective rates applicable to Rate Schedule DSS to reflect Settlement factors in accordance with a July 5, 1996, order issued in Docket Nos. RP96–253–000 and 001.

Natural requested any waivers which may be required to permit the tendered tariff sheet to become effective on December 1, 1997.

Natural states that copies of the filing have been mailed to Natural's customers, interested state regulatory agencies, and all parties set out on the official service list at Docket No. RP96–253.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31007 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–82–000]

Northern Natural Gas Company; Notice of Request Under Blanket Authorization

November 20, 1997.

Take notice that on November 12, 1997, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed a request with the Commission in Docket No. CP98–82–000, pursuant to Sections 157.205, and 157.212 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to install and operate a new delivery point authorized in blanket certificate issued in Docket No. CP82–401–000, all as more fully set forth in the request on file with the Commission and open to public inspection.

Northern proposes to install and operate a new delivery point, located in Green County, Wisconsin, which would accommodate natural gas deliveries to Wisconsin Gas Company (WGC) to be used to serve a local residential customer. Northern states that the proposed volumes to be delivered for WGC would be 1 MMBtu on a peak day and 104 MMBtu on an annual basis. Northern further states that the estimated cost of constructing the proposed delivery point would be $6,500.

Any person or the Commission's staff may, within 45 days after the Commission has issued this notice, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the allowed time, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the NGA.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31000 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–2–002]

Northern Natural Gas Company; Notice of Compliance Filing

November 20, 1997.

Take notice that on November 18, 1997, Northern Natural Gas Company (Northern), tendered for filing to become part of Northern's FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheet:

Second Substitute First Revised Sheet No. 211

Northern states that the above sheet addresses Northern's meter provisions and is being filed in compliance with the Commission's Letter Order issued December 22, 1995, in Docket No. RP96–2–001.

Northern states that copies of the filing were served upon Northern's customers and interested State Commissions.

Any person desiring to protest said filing should file protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. All protests will be considered by the Commission in determining the appropriate action to be taken in this proceeding, but will not serve to make protestant a party to the proceeding. Copies of this filing are on file with the Commission and are available for inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31005 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP98–51–000]

Pacific Gas Transmission Company; Notice of Proposed Change in FERC Gas Tariff

November 20, 1997.

Take notice that on November 14, 1997, Pacific Gas Transmission Company (PGT) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1–A: Third Revised Sheet No. 72 and Original Sheet No. 72A. PGT requested waiver to allow the above-referenced tariff sheets to become effective November 15, 1997.

PGT asserts that the purpose of this filing is to modify the credit-worthiness standards for firm transportation service to provide for a waiver of standard credit requirements for shippers seeking to acquire capacity for a term of five years or less.

PGT further states that a copy of this filing has been served on PGT's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed as provided in Section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31014 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP98–50–000 and RP98–50–001]

Raton Gas Transmission Company; Notice of Proposed Changes in FERC Gas Tariff

November 20, 1997.

Take notice that on November 14, 1997, Raton Gas Transmission Company (Raton) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, Second Revised Tariff Sheets Nos. 4 and 18 to become effective October 1, 1997.

On November 18, 1997, Raton filed in Docket No. RP98–50–001 its filing to include a ''redlined'' version showing additions and deletions to its tariff.

On September 27, 1997, Raton filed First Revised Sheets Nos. 4, 10, 18, and 23 to its FERC Gas Tariff, First Revised Volume No. 1, to incorporate, in its tariff, the tariff changes made effective as of October 1, 1996 by Raton's supplier, Colorado Interstate Gas Company (CIG), pursuant to Docket No. RP96–190. By orders issued October 25 and December 24, 1996, the Commission accepted Raton's filing in Docket No. RP96–391, and allowed Raton's tariff changes to be made effective as of October 1, 1996, subject to a flow through of any refunds received from CIG upon the termination of Docket No. RP96–190.

On September 16, 1997 CIG filed revised tariff sheets incorporating the rates agreed to by all parties in the settlement of Docket No. RP96–190 and the Commission has authorized CIG to make those tariff sheets effective as of October 1, 1997. Those revised tariff sheets will provide significant reductions in the cost of the transportation services provided by CIG to Raton, and Raton proposes to pass those rate reductions on to its customers.

Raton states that Second Revised Tariff Sheets Nos. 4 and 18, submitted by Raton, incorporate CIG's charges pursuant to its revised Rate Schedules NNT–1 and TF–1, certain surcharges which have been agreed to, and the supplemental seasonal TF–1 contract, pursuant to which Raton will receive transportation service from CIG effective October 1, 1997. The charges for the off-speak seasonal FT–1 volumes will be passed through as surcharges pursuant to Section 18.5. Refunds and/or credits which Raton will receive from CIG for the period October 1, 1996 through September 30, 1997, will be flowed through to Raton's customers.

Raton states that a full copy of its filing is being served upon each of its two customers and upon the New Mexico Public Service Commission.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, Washington, D.C. 20426 in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public

inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31012 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–343–002]

Sea Robin Pipeline Company; Notice of Proposed Changes to FERC Gas Tariff

November 20, 1997.

Take notice that on November 17, 1997, Sea Robin Pipeline Company (Sea Robin) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the revised tariff sheets set forth on Appendix A to the filing, pursuant to Section 4 of the Natural Gas Act and in compliance with the Commission's October 17, 1997, Order in Docket Nos. RP97–343–000 and 001 to become effective November 1, 1997.

On July 17, 1996, the Commission issued Order No. 587 in Docket No. RM96–1–000 which revised the Commission's regulations governing interstate natural gas pipelines to require such pipelines to follow certain standardized business practices issued by the Gas Industry Standards Board (GISB) and adopted by the Commission in Order No. 587. 18 CFR 284.10(b). On January 3, 1997, Sea Robin made its compliance filing submitting pro forma tariff sheets to comply with Order No. 587 in Docket No. RP97–224. On March 3, 1997, the Commission issued an order in said docket in response to Sea Robin's January 3, 1997 filing, requiring Sea Robin to file to implement a pooling service on its system.

Sea Robin filed tariff sheets on April 29, 1997, setting forth the terms and conditions under which Sea Robin proposed to implement a pooling service on its system. The Commission's October 17, 1997, Order approved implementation of a pooling service on Sea Robin's system on or before July 1, 1998, and required Sea Robin to clarify references in Section 5.10(c) regarding nomination of interruptible transportation and assignment of delivery points under Pooling Service Agreements and to allow for pool to pool transfers.

The compliance sheets filed by Sea Robin established Tier I and Tier II pools consistent with the Tier I and Tier II mechanism in Southern Natural Gas Company's Tariff to facilitate pool to pool transfers. In addition, Sea Robin has clarified in Section 5.10(c) that the intended purpose of the section was to establish a shipper's right to retain its primary delivery points rights under its FTS or FTS–2 Agreement or designate such rights to the pool. Since a FTS or FTS–2 shipper's right to a primary delivery point is capacity specific, it should not have to give away such rights to the pool if it wants to retain them. If a FTS or FTS–2 shipper does not designate to the pool its rights to a primary firm point, then the pool's priority at a delivery point for purposes of capacity allocation will be established on a secondary (B–1) firm basis.

Sea Robin also made some minor changes to the tariff sheets to incorporate its Rate Schedule FTS–2 and some language in its definition section previously approved by the Commission in Sea Robin's GISB compliance proceeding in Docket No. RP97–224. Sea Robin has requested to place the tariff sheets into effect November 1, 1997; and, consistent with the terms of the October 17, 1997, Order, Sea Robin has identified on the tariff sheets that it will implement pooling service on the system no later than July 1, 1998.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31009 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–344–003]

Texas Gas Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

November 20, 1997.

Take notice that on November 14, 1997, Texas Gas Transmission Corporation (Texas Gas) tendered for filing changes to its FERC Gas Tariff, First Revised Volume No. 1. This filing is in compliance with the Commission's Order issued October 30, 1997, in Docket No. RP97–344 at 81 FERC ¶61,118 (1997).

Substitute First Revised Sheet No. 166.
Substitute Second Revised Sheet No. 170.
Substitute First Revised Sheet Nos. 182–185

Texas Gas states that the instant filing is incorporating those changes directed by the October 30, 1997 Order, or are providing explanation where modifications have not been made.

Texas Gas requests an effective date of November 1, 1997, for the proposed tariff sheets.

Texas Gas further states that it has served copies of this filing upon the company's jurisdictional customers, interested state commissions, and all parties appearing on the official service list in Docket No. RP97–344.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests should be filed in accordance with Section 154.210 of the Commission's Regulations. Protests may be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31010 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP92–108–016 and RP92–137–049]

Transcontinental Gas Pipe Line Corporation; Notice of Report of Refunds

November 20, 1997.

Take notice on November 14, 1997, Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing a report of refunds pertaining to refunds distributed on October 14, 1997.

Transco states that the purpose of such refund was to comply with (i) the Commission's Order on Remand issued on June 12, 1997, regarding the distribution of excess interruptible transportation (IT) revenues for the period November 1, 1993 through August 31, 1995, and (ii) the Division of Audits letter order issued January 8, 1997, regarding IT revenues related to the Spider Field lateral.

Transco states that it is serving copies of the instant filing to the State Commissions of the recipients of the refund.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before November 28, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31004 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG98–9–000, et al.]

Cobisa-Person Limited Partnership, et al.; Electric Rate and Corporate Regulation Filings

November 19, 1997.

Take notice that the following filings have been made with the Commission:

1. Cobisa-Person Limited Partnership

[Docket No. EG98–9–000]

On November 14, 1997, Cobisa-Person Limited Partnership, 820 Gessner, Suite 930, Houston, Texas, 77024, filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Cobisa-Person Limited Partnership is a Delaware limited partnership. The general partners of Cobisa-Person Limited Partnership are Cobisa-Person Power Company, Inc.; Ibis Power Corporation; and Jacaranda Power Corporation. The sole limited partner of Cobisa-Person Limited Partnership is Cobisa Corporation. Cobisa-Person Limited Partnership plans to construct a nominal 106 megawatt gas and oil-fired combustion turbine in Bernalillo County, New Mexico. Electric energy produced by the Cobisa-Person Limited Partnership facility will be sold exclusively to the Public Service Company of New Mexico.

Comment date: December 10, 1997, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. R. Hadler and Company, Inc.

[Docket No. ER97–3056–001]

Take notice that on October 31, 1997, R. Hadler and Company, Inc., tendered for filing its revised Code of Conduct in the above-referenced docket.

Comment date: December 2, 1997, in accordance with Standard Paragraph E at the end of this notice.

3. PECO Energy Company

[Docket No. ER98–387–000]

Take notice that on October 30, 1997, PECO Energy Company (PECO) filed an executed Installed Capacity Obligation Allocation Agreement between PECO and Allegheny Energy Solutions Inc. (hereinafter Supplier). The terms and conditions contained within this Agreement are identical to the terms and conditions contained with the Form of Installed Capacity Allocation Agreement filed by PECO with the Commission on October 3, 1997, at Docket No. ER98–28–000. This filing merely submits an individual executed copy of the Installed Capacity Obligation Allocation Agreement between PECO and an alternate supplier participating in PECO's Pilot.

Copies of the filing were served on the Supplier and the Pennsylvania Public Utility Commission.

Comment date: December 2, 1997, in accordance with Standard Paragraph E at the end of this notice.

4. Sierra Pacific Power Company

[Docket No. ER98–415–000]

Take notice that on October 30, 1997, Sierra Pacific Power Company (Sierra) filed a revision to the General Transfer Agreement (GTA) between Sierra and Bonneville Power Administration (BPA).

Sierra states that the revision would increase the total monthly facilities charge from $132,656 to $134,556 to reflect a change in the percentage of initial capital investment used to calculate the Estimated O&M Charge. Sierra requests that the increased charge be made effective on October 31, 1997.

Copies of this filing were served upon the Public Utilities Commission of Nevada, the Public Utilities Commission of California, the Nevada Bureau of Consumer Protection and Bonneville Power Administration.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

5. Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company

[Docket No. ER98–433–000]

Take notice that on October 31, 1997, Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company (doing business and collectively referred to as GPU Energy) submitted for filing a Service Agreement between GPU Energy and its power marketing affiliate, GPU Advanced Resources. GPU Energy requested an effective date of November 1, 1997, for the Service Agreement.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

6. PP&L, Inc.

[Docket No. ER98–434–000]

Take notice that on October 31, 1997, PP&L, Inc., (formerly known as Pennsylvania Power & Light Company) (PP&L), filed a Service Agreement dated October 23, 1997, with GPU Advanced Resources (GPU), under PP&L's FERC Electric Tariff, Original Volume No. 5. The Service Agreement adds GPU as an eligible customer under the Tariff.

PP&L requests an effective date of October 31, 1997, for the Service Agreement.

PP&L states that copies of this filing have been supplied to GPU and to the Pennsylvania Public Utility Commission.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

7. Southwestern Public Service Company

[Docket No. ER98–435–000]

Take notice that on October 31, 1997, New Century Services, Inc., on behalf of Southwestern Public Service Company (Southwestern), submitted an executed umbrella service agreement under Southwestern's market-based sales tariff with Avista Energy, Inc., (Avista). This umbrella service agreement provides for Southwestern's sale and Avista's purchase of capacity and energy at market-based rates pursuant to Southwestern's market-based sales tariff.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

8. Maine Electric Power Company

[Docket No. ER98–436–000]

Take notice that on October 31, 1997, Maine Electric Power Company (MEPCO), tendered for filing a service agreement for Non-Firm Point-to-Point Transmission Service entered into with New Energy Ventures, LLC. Service will be provided pursuant to MEPCO's Open Access Transmission Tariff, designated rate schedule MEPCO—FERC Electric Tariff, Original Volume No. 1, as supplemented.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

9. Central Maine Power Company

[Docket No. ER98–437–000]

Take notice that on October 31, 1997, Central Maine Power Company (CMP), tendered for filing a service agreement for Non-Firm Point-to-Point Transmission Service entered into with NorAm Energy Services, Inc. Service will be provided pursuant to CMP's Open Access Transmission Tariff, designated rate schedule CMP—FERC Electric Tariff, Original Volume No. 3, as supplemented.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

10. PacifiCorp

[Docket No. ER98–438–000]

Take notice that on October 31, 1997, PacifiCorp, tendered for filing in accordance with 18 CFR Part 35 of the Commission's Rules and Regulations, a revision to Exhibit A, to Service Agreement No. 65 of PacifiCorp's FERC Electric Tariff, First Revised Volume No. 11.

Copies of this filing were supplied to PacifiCorp's Merchant Function, the Washington Utilities and Transportation Commission and the Public Utility Commission of Oregon.

A copy of this filing may be obtained from PacifiCorp's Regulatory Administration Department's Bulletin Board System through a personal computer by calling (503) 464–6122 (9600 baud, 8 bits, no parity, 1 stop bit).

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

11. Cinergy Services, Inc.

[Docket No. ER98–439–000]

Take notice that on October 31, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Power Sales Standard Tariff (the Tariff) entered into between Cinergy and Ontario Hydro (Hydro).

Cinergy and Hydro are requesting an effective date of October 7, 1997.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

12. Old Dominion Electric Cooperative

[Docket No. ER98–440–000]

Take notice that on October 31, 1997, Old Dominion Electric Cooperative (ODEC) submitted a Filing of Form of Service Agreement for market-based sales of power by it, in compliance with the Commission's Order Conditionally Accepting for Filing Proposed Market-Based Rates and Granting Waiver of Notice Requirement that was issued on October 17, 1997, in Docket No. ER97–4313–000.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

13. Tampa Electric Company

[Docket No. ER98–442–000]

Take notice that on October 31, 1997, Tampa Electric Company (Tampa Electric), tendered for filing a letter of commitment providing for the sale of capacity and energy to the Reedy Creek Improvement District (RCID) under Service Schedule J, of the Contract for Interchange Service between them. Tampa Electric requests that the letter of commitment be made effective on January 1, 1998.

Copies of the filing have been served on RCID and the Florida Public Service Commission.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

14. Indiana Michigan Power Company

[Docket No. ER98–444–000]

Take notice that on October 31, 1997, Indiana Michigan Power Company (I&M Power), will terminate the service that it currently provides to the City of Dowagiac, Michigan, (Dowagiac) under Federal Energy Regulatory Commission (FERC) Rate Schedule Volume No. 1 (effective date March 1, 1992), the Partial Requirements Contract between I&M Power and Dowagiac (FERC Rate Schedule, Original Volume No. 1).

I&M Power is terminating service to Dowagiac at Dowagiac's request. Dowagiac has notified I&M Power that, commencing February 28, 1998, it will purchase power from a supplier other than I&M Power.

This notice of termination has been served upon City Manager and Counsel for Dowagiac and the Michigan Public Service Commission.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

15. Commonwealth Edison Company

[Docket No. ER98–446–000]

Take notice that on October 31, 1997, Commonwealth Edison Company (ComEd) submitted for filing Short-Term Firm Service Agreements with Rainbow Energy Marketing Corporation (REMC), and Aquila Power Corporation (Aquila), and a Non-Firm Service Agreement with e prime, inc. (e prime), under the terms of ComEd's Open Access Transmission Tariff (OATT).

ComEd requests an effective date of October 8, 1997, for the service agreements, and accordingly seeks waiver of the Commission's requirements. Copies of this filing were served upon REMC, Aquila, e prime, and the Illinois Commerce Commission.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

16. Panda Power Corporation

[Docket No. ER98–447–000]

Take notice that on October 31, 1997, Panda Power Corporation (PPC), 4100 Spring Valley, Suite 1001, Dallas, Texas 75244, tendered for filing pursuant to Rules 205 and 207, a petition for waivers and blanket approvals under various regulations of the Commission and for an order accepting its FERC Electric Rate Schedule No. 1, to be effective November 1, 1997.

In transactions where PPC will sell electric energy and capacity at wholesale, it proposes to make such sales on rates, terms and conditions to be mutually agreed to with the purchasing party. PPC may engage in

electric energy and capacity transactions as a marketer and energy and capacity transactions as a broker.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

17. Great Bay Power Corporation

[Docket No. ER98–448–000]

Take notice that on October 31, 1997, Great Bay Power Corporation, tendered for filing a revised summary of activity for the quarter ending September 30, 1997.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

18. Cinergy Services, Inc.

[Docket No. ER98–450–000]

Take notice that on October 31, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Power Sales Standard Tariff (the Tariff) entered into between Cinergy and Interstate Power Company (Interstate).

Cinergy and Interstate are requesting an effective date of October 7, 1997.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

19. Louisville Gas and Electric Company

[Docket No. ER98–451–000]

Take notice that on October 31, 1997, Louisville Gas and Electric Company, tendered for filing copies of a service agreement between Louisville Gas and Electric Company and Market Responsive Energy Inc., under Rate GSS.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

20. New Century Services, Inc.

[Docket No. ER98–452–000]

Take notice that on October 31, 1997, New Century Services, Inc., on behalf of Cheyenne Light, Fuel and Power Company, Public Service Company of Colorado, and Southwestern Public Service Company (collectively Companies) tendered for filing an Umbrella Service Agreement under their Joint Open Access Transmission Service Tariff for Firm Point-to-Point Transmission Service between the Companies and Tenaska Power Services Company.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

21. New England Power Pool

[Docket No. ER98–453–000]

Take notice that on October 31, 1997, the New England Power Pool Executive Committee filed for acceptance a signature page to the New England Power Pool (NEPOOL), Agreement dated September 1, 1971, as amended, signed by EnergyEXPRESS, Inc., (EnergyEXPRESS). The NEPOOL Agreement has been designated NEPOOL FPC No. 2.

The Executive Committee states that the Commission's acceptance of EnergyEXPRESS's signature page would permit NEPOOL to expand its membership to include EnergyEXPRESS. NEPOOL further states that the filed signature page does not change the NEPOOL Agreement in any manner, other than to make EnergyEXPRESS a member in NEPOOL. NEPOOL requests an effective date of January 1, 1998, for commencement of participation in NEPOOL by EnergyEXPRESS.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

22. PP&L, Inc.

[Docket No. ER98–454–000]

Take notice that on October 31, 1997, PP&L, Inc. (formerly known as Pennsylvania Power & Light Company) (PP&L), filed a Service Agreement dated October 28, 1997, with DTE Energy Trading, Inc. (DTE), under PP&L's FERC Electric Tariff, Original Volume No. 5. The Service Agreement adds DTE as an eligible customer under the Tariff.

PP&L requests an effective date of October 31, 1997, for the Service Agreement.

PP&L states that copies of this filing have been supplied to DTE and to the Pennsylvania Public Utility Commission.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

23. PP&L, Inc.

[Docket No. ER98–455–000]

Take notice that on October 31, 1997, PP&L, Inc., (formerly known as Pennsylvania Power & Light Company)(PP&L), filed a Service Agreement dated October 20, 1997, with Ohio Edison Company (OEC) under PP&L's FERC Electric Tariff, Original Volume No. 5. The Service Agreement adds OEC as an eligible customer under the Tariff.

PP&L requests an effective date of October 31, 1997 for the Service Agreement.

PP&L states that copies of this filing have been supplied to OEC and to the Pennsylvania Public Utility Commission.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

24. Cinergy Services, Inc.

[Docket No. ER98–523–000]

Take notice that on November 3, 1997, Cinergy Services, Inc., on behalf of its Operating Company affiliates, The Cincinnati Gas & Electric Company and PSI Energy, Inc., (collectively referred to as Cinergy), tendered for filing an unexecuted form of Service Agreement under Cinergy's Open Access Transmission Tariff for certain retail customers who take or are eligible to take buy-through commodity service. Cinergy has requested an effective date of October 4, 1998, for the form of Service Agreement.

Copies of the filing have been served on the customers currently effected and the Indiana Utility Regulatory Commission and the Public Utilities Commission of the Ohio.

Comment date: December 2, 1997, in accordance with Standard Paragraph E at the end of this notice.

25. Maine Yankee Atomic Power Company

[Docket No. ER98–570–000]

Take notice that on November 6, 1997, Maine Yankee Atomic Power Company tendered for filing, pursuant to Section 205 of the Federal Power Act and Section 35.13 of the Commission's Regulations, an amendment to the power contracts for the sale of electricity for resale to ten New England utilities. Maine Yankee states that the amendment is designed to clarify the obligations of the purchasing utilities following the decision to cease power production at Maine Yankee's nuclear generating plant. Maine Yankee's filing also includes adjustments to amounts being amortized for unrecovered nuclear fuel, a revised schedule of decommissioning charges based on a new study of decommissioning costs, and adjustments to the billing for post retirement benefits other than pensions and to cease earning a current return on CWIP.

Maine Yankee states that the effects of the above adjustments would be an increase in those rate components of $5,096,102 as compared against the 1996 test year. However the projected reductions in operations and maintenance and other expenses due to the premature shutdown will result in an overall rate decrease of

approximately $60 million in 1998 as compared to the test year.

Maine Yankee states that copies of its filing have been provided to its jurisdictional customers, secondary customers and to state regulatory commissions in Connecticut, New Hampshire, Massachusetts, Maine and Rhode Island and the Office of the Public Advocate, State of Maine.

Comment date: December 2, 1997, in accordance with Standard Paragraph E at the end of this notice.

26. Indiana Michigan Power Company

[Docket No. SC98–1–000]

Take notice that on October 31, 1997, American Electric Power Service Corporation, as agent for Indiana Michigan Power Company (I&M), an operating company of the American Electric Power System, tendered for filing an estimate of, and a proposal to charge, stranded costs to the City of Dowagiac, MI (Dowagiac), through the rates for wholesale transmission service to Dowagiac, or to another Transmission Customer which serves Dowagiac, upon the termination of I&M's Municipal Resale Service (MRS) Agreement with Dowagiac. I&M requests an effective date of March 1, 1998, the day following such termination.

Copies of the filing have been served upon Dowagiac and the Michigan Public Service Commission.

Comment date: December 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–31068 Filed 11–25–97; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Parker-Davis Project Rate Adjustment; Notice of Rate Order No. WAPA–75

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of rate order.

SUMMARY: Notice is given of the confirmation and approval by the Deputy Secretary of the Department of Energy (DOE) of Rate Order No. WAPA–75 and Rate Schedules for Wholesale Firm Power Service (PD–F6) , Firm Transmission Service (PD–FT6), Firm Transmission Service of Salt Lake City Area Integrated Projects Power (PD–FCT6), and Nonfirm Transmission Service (PD–NFT6) placing into effect the rate methodology for determining rates for existing Parker-Davis Project (P–DP) contractors of the Western Area Power Administration (Western) on an interim basis. The rate methodology will remain in effect on an interim basis until the Federal Energy Regulatory Commission (FERC) confirms, approves, and places it into effect on a final basis or until superseded.

DATES: Rate Schedules PD–F6, PD–FT6, PD–FCT6, and PD–NFT6 will be placed into effect on an interim basis on the first day of the first full billing period beginning on or after November 1, 1997, and will be in effect until FERC confirms, approves, and places the rate schedules into effect on a final basis for a 59-month period, or until the rate schedule is superseded.

FOR FURTHER INFORMATION CONTACT: J. Tyler Carlson, Regional Manager, Western Area Power Administration, Desert Southwest Regional Office, P.O. Box 6457, Phoenix, AZ 85005, (602) 352–2453, or Joel K. Bladow, Assistant Administrator for Power Marketing Liaison, Room 8G–027, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–5581.

SUPPLEMENTARY INFORMATION: The proposed rate methodology is the result of Western, the Bureau of Reclamation, and existing P–DP customers working together to develop a methodology that would recover the project costs and accommodate advance funding for P–DP expenses. The changes made to the P–DP rate methodology are outlined as follows. The first change concerns the Cost Apportionment Study. The study, which demonstrates the distribution of costs between generation and transmission, has been changed as follows: (1) the Priority Use Power (PUP) contractors' delivery commitments are now included in the total amounts reflected in the generation and transmission delivery commitment figures; and (2) the amount of funds to be repaid through the collection of revenues through rates is now based on the single Fiscal Year (FY) projection, instead of a projected 5-year average calculation. These changes were required so the PUP contractors can demonstrate payment of their portion of generation and transmission costs, and to accommodate the yearly reconciliation of expenses under the advance funding agreements which have been executed with the PUP contractors and are currently being negotiated with the Firm Electric Service (FES) contractors.

The second change concerns the ratesetting methodology. The new rate methodology includes the PUP contractors' delivery commitments in the calculations of the rates. This was necessary so the PUP contractors can demonstrate payment of their portion of generation and transmission costs.

The third change concerns the billing for firm electric service. Due to the separation of the transmission component from the Capacity Rate, the FES contractors will be billed a Capacity Rate of dollars per kilowatt per month, an Energy Rate of mills per kilowatthour, and a Firm Transmission Rate of dollars per kilowatt per month.

The fourth change concerns the updating of the expense and other revenue estimates for FY 1997 and the cost evaluation period of FY 1998 through FY 2002 as a result of better data.

The final change concerns the significant decrease in the transmission contract rate of delivery (CROD) used to calculate the Firm Transmission Rate, Firm Transmission Rate of Salt Lake City Area Integrated Projects (SLCA/IP) Power, and Nonfirm Transmission Rate. The decrease in the CROD resulted primarily from changes in delivery commitments.

A comparison of the existing rates and rates for FY 1998 calculated in accordance with the proposed rate methodology are as follows:

COMPARISON OF EXISTING RATES AND PROPOSED RATE METHODOLOGY RATES

	Existing Rate (FY 1995)	Proposed Rate (FY 1998) [1]	Difference
Rate Schedule:	PD–F5	PD–F6	
Firm Capacity Rate ($/kW-month)	$1.92	$0.56	($1.36)
Firm Energy Rate (mills/kWh)	1.95	1.29	(0.67)
Composite Rate (mills/kWh)	6.33	2.57	(3.76)
Rate Schedule:	PD–FT5 & PD–FCT5	PD–FT6 & PD–FCT6	
Firm Transmission Rate ($/kW-month)	$0.96	$1.08	$0.12
Firm Transmission Rate for SLCA/IP ($/kW-month)	$0.96	$1.08	$0.12
Rate Schedule:	PD–NFT5	PD–NFT6	
Nonfirm Transmission Rate (mills/kWh)	2.19	2.47	0.28

[1] New rates will be calculated in accordance with the rate schedules each year by September 1. These rates represent FY 1998 only.

The decrease in the Firm Energy Rate and Firm Capacity Rate for FY 1998 can be attributed to a large revenue carryover balance from FY 1997, the removal of the transmission component from the Firm Capacity Rate which will be billed separately, and the inclusion of the contracted energy and capacity for the PUP contractors. The increase in the Firm Transmission Rate, Firm Transmission Rate of SLCA/IP Power, and Nonfirm Transmission Rate can be attributed to a significant decrease in the CROD used to calculate these rates even though there is a large revenue carryover balance from FY 1997.

Statement of Annual Revenue Requirement

The Annual Revenue Requirement Allocated to Generation and Transmission will be based upon the net amount between the estimated expenses and other revenue as presented in the Cost Apportionment Study. The Power Repayment Study (PRS) will document these expenses and other revenue. The difference between the estimated and the actual Annual Revenue Requirement Allocated to Generation and Transmission for the rate year will be used to adjust the next year's Annual Revenue Requirement.

By Amendment No. 3 to Delegation Order No. 0204–108, published November 10, 1993 (58 FR 59716), the Secretary of Energy (Secretary) delegated (1) the authority to develop long-term power and transmission rates on a nonexclusive basis to the Administrator of Western; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to FERC. Existing DOE procedures for public participation in power rate adjustments (10 CFR Part 903) became effective on September 18, 1985 (50 FR 37835).

These power and transmission rates are established pursuant to Section 302(a) of the Department of Energy (DOE) Organization Act, 42 U.S.C. § 7152(a), through which the power marketing functions of the Secretary of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902, 43 U.S.C. § 371 *et seq.*, as amended and supplemented by subsequent enactments, particularly Section 9(c) of the Reclamation Project Act of 1939, 43 U.S.C. § 485h(c), and other acts specifically applicable to the project system involved, were transferred to and vested in the Secretary, acting by and through the Administrator of Western.

Rate Order No. WAPA–75, confirming, approving, and placing the proposed rate methodology for determining rates for existing contractors from the P–DP into effect on an interim basis, is issued, and the new Rate Schedules PD–F6, PD–FT6, PD–FCT6, and PD–NFT6 will be submitted promptly to FERC for confirmation and approval on a final basis. Western is developing open access tariffs consistent with FERC Order No. 888 and intends to publish short-term rates by November 1997, and to submit long-term rates to the FERC by April 1, 1998.

Dated: November 18, 1997.

Elizabeth A. Moler,

Deputy Secretary.

Department of Energy Deputy Secretary

Order Confirming, Approving, and Placing the Parker-Davis Project Firm Power Service Rate, Firm Transmission Service Rate, and Nonfirm Transmission Service Rate Into Effect on an Interim Basis

November 1, 1997.

The rate methodology is established pursuant to Section 302(a) of the Department of Energy (DOE) Organization Act, 42 U.S.C. § 7152(a), through which the power marketing functions of the Secretary of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902, 43 U.S.C. § 371 et seq., as amended and supplemented by subsequent enactments, particularly Section 9(c) of the Reclamation Project Act of 1939, 43 U.S.C. § 485h(c), and other acts specifically applicable to the project system involved were transferred to and vested in the Secretary of Energy (Secretary), acting by and through the Administrator of Western.

By Amendment No. 3 to Delegation Order No. 0204–108, published November 10, 1993 (58 FR 59716), the Secretary delegated (1) the authority to develop long-term power and transmission rates on a nonexclusive basis to the Administrator of the Western Area Power Administration (Western); (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission. Existing DOE procedures for public participation in power rate adjustments (10 CFR Part 903) became effective on September 18, 1985 (50 FR 37835).

Acronyms and Definitions

As used in this rate order, the following acronyms and definitions apply:

$/kW-month: Monthly charge for capacity. $/kW-season and S/kW-year are converted to a monthly rate ($ per kilowatt per month) for billing purposes.

$/kW-season: Seasonal rate for capacity ($ per kilowatt per season). This is used with the Firm Transmission Rate of Salt Lake City Area Integrated Projects power.

$/kW-year: Yearly rate for capacity ($ per kilowatt per year). This is used with the Firm Transmission Rate and the Capacity Rate.

Annual Revenue Requirement: The revenue that Western needs to meet repayment criteria, which serves as the basis for allocation between generation and transmission.

Annual Revenue Requirement Allocated to Generation: The dollar amount that has been allocated to Generation. This amount is used to calculate the Energy Rate, Capacity Rate, and Composite Rate.

Annual Revenue Requirement Allocated to Transmission: The dollar amount that has been allocated to Transmission. This amount is used to calculate the Firm Transmission Rate, Firm Transmission Rate of Salt Lake City Area Integrated Projects, and Nonfirm Transmission Rate.

Annual Energy: The total annual energy entitlement for the PUP and/or FES contractors.

Capacity Rate: Expressed in $/kW-month and applied to each kW of the FES contractor's seasonal CROD and each kW over the FES contractor's seasonal CROD, as applicable.

Energy Rate: Expressed in mills per kilowatthour (mills/kWh) and applied each billing period to each kWh of the FES contractor's monthly energy entitlement, each kWh over the FES contractor's monthly energy entitlement, and to each kWh of excess energy sold, as applicable.

CIA: Compound Interest Amortization.

Cost Apportionment Study: A study which allocates P–DP's total costs and other revenue between generation and transmission.

CROD: Contract Rate of Delivery.

Customer Brochure: A document prepared for public distribution explaining the background of the rate proposal contained in this rate order.

DOE: Department of Energy.

DOE Order RA 6120.2: An order dealing with power marketing administration financial reporting.

FERC: Federal Energy Regulatory Commission.

FES: Firm Electric Service.

FY: Fiscal Year.

Interior: U.S. Department of the Interior.

kW: Kilowatt.

kW-month: Kilowatt-month.

kW-season: Kilowatt-season.

kW-year: Kilowatt-year.

kWh: Kilowatthour.

mills/kWh: Mills per kilowatthour—the unit of charge for energy.

NEPA: National Environmental Policy Act of 1969.

O&M: Operation and Maintenance.

P–DP: Parker-Davis Project.

Proposed Rate: A rate adjustment that the Administrator of Western recommends to the Deputy Secretary.

Provisional Rate: A rate which has been confirmed, approved, and placed into effect on an interim basis by the Deputy Secretary.

PRS: Power Repayment Study.

PUP: Priority Use Power.

Reclamation: Bureau of Reclamation, U.S. Department of the Interior.

Seasonal CROD: The CROD that FES contractors are entitled to during winter season and summer season. P–DP winter season is October through February and summer season is March through September. SLCA/IP winter season is October through March and summer season is April through October.

SLCA/IP: Salt Lake City Area Integrated Projects.

Western: Western Area Power Administration, U.S. Department of Energy.

Effective Date

The new rate methodology for determining the rates for existing P–DP contractors will become effective on an interim basis beginning November 1, 1997, and remain in effect pending FERC's approval on a final basis for a 59-month period, or until superseded.

Public Notice and Comment

The Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR Part 903, have been followed by Western in developing the method for determining the total Annual Revenue Requirement, Annual Revenue Requirement Allocated to Generation, Annual Revenue Requirement Allocated to Transmission, Energy Rate, Capacity Rate, Firm Transmission Rate, Firm Transmission Rate of SLCA/IP Power, and Nonfirm Transmission Rate.

The following summarizes the steps Western took to ensure involvement of interested parties in the rate process:

1. Review and discussion of the rate methodology and allocating factors were conducted at several meetings with the contractors and interested parties. These meetings were held October 24, 1996, November 18, 1996, January 16, 1997, April 21, 1997, and August 8, 1997.

2. Discussion of the changes to the proposed rate methodology and resulting rates were initiated at an informal P–DP contractor meeting held on May 7, 1997, in Phoenix, Arizona. At this informal meeting, Western explained the need for a change in the estimates and methodology used to calculate the charges and rates.

3. A **Federal Register** notice was published on May 23, 1997 (62 FR 28465), officially announcing the proposed firm power rate, firm transmission rate, and nonfirm transmission rate adjustment, initiating the public consultation and comment period, announcing the public information and public comment forums, and presenting procedures for public participation.

4. On June 3, 1997, a letter was mailed from Western to all P–DP firm power, firm transmission, and nonfirm transmission customers and other interested parties providing a copy of the P–DP Rate Brochure dated May 1997 which included a copy of the **Federal Register** notice of May 23, 1997.

5. At the public information forum held on June 10, 1997, Western and Reclamation representatives explained the proposed rate methodology, a change in the proposed billing procedures, and outlined the changes in the Annual Revenue Requirement for Rate Year 1998 in greater detail and answered questions.

6. The comment forum was held on July 14, 1997, to give the public an opportunity to comment for the record. Six persons representing customers and customer groups made oral comments.

7. On August 14, 1997, a letter was mailed from Western to all P–DP firm power, firm transmission, and nonfirm transmission customers and other interested parties providing a copy of the revised PRS and related tables. The letter stated the final proposed rates and reminder of the coming close of the comment period.

8. Six comment letters were received during the 90-day consultation and comment period. The consultation and comment period ended August 21, 1997. All formally submitted comments have been considered in the preparation of this rate order.

Project History

The Parker Dam Power Project was authorized by Section 2 of the Rivers and Harbors Act of August 30, 1935 (49 Stat. 1039), and the Davis Dam Project was authorized April 26, 1941, by the Acting Secretary of the Interior under provisions of the Reclamation Project Act of 1939 (43 U.S.C. 485, et seq.). The P–DP was formed by the consolidation of the two Projects under the terms of the Act of May 28, 1954 (68 Stat. 143).

Davis Dam, which creates Lake Mohave, provides regulation, both hourly and seasonally, of the water releases from Lake Mead (through Hoover Dam and Powerplant) to

facilitate water delivery for downstream irrigation requirements and for water delivery beyond the boundary of the United States as required by the Mexican Water Treaty. Operation of the powerplant began in January 1951 with a generating capacity of 225,000 kW. During the period 1974–1978 the generator nameplate capacity was increased to 240,000 kW by rewinding the generator stators.

Construction of Parker Dam was authorized for the purposes of controlling floods, improving river navigation, regulating the flow of the Colorado River, providing for storage and for the delivery of the stored waters thereof, for the reclamation of public lands and Indian reservations, and for other beneficial uses, and for the generation of electric energy as a means of making the P–DP a self-supporting and financially solvent undertaking.

Parker Dam was constructed by the Bureau of Reclamation (Reclamation) with funds advanced by the Metropolitan Water District of Southern California (MWD). Lake Havasu, the reservoir created behind Parker Dam, serves as the forebay from which water is diverted into the MWD aqueduct. The aqueduct delivers a major portion of California's entitlement of Colorado River water to southern California and is the diversion point for delivering Central Arizona Project water to Arizona. The reservoir operation is limited to minor storage fluctuations. The dam provides a head of approximately 75 feet for the Parker Powerplant. Reclamation began operation of Parker Powerplant in December 1942. Although the total generator nameplate capacity is 120,000 kW, the powerplant capacity is essentially limited to 104,000 kW because of operating constraints of downstream physical structures, primarily Headgate Rock Dam. Under contract, MWD is entitled to one-half of the net energy generated by Parker Powerplant at any given time.

All facilities of the P–DP were operated and maintained by Reclamation until the formation of the Department of Energy pursuant to the Department of Energy Organization Act (DOE Act), 42 U.S.C. Sections 7101 et seq., enacted by Congress on August 4, 1977. Pursuant to Section 302 of the DOE Act (42 U.S.C. 7152), responsibility for the power marketing functions of Reclamation, including the construction, operation, and maintenance of substations, transmission lines and attendant facilities was transferred to the Department of Energy. The responsibility for operation and maintenance of the dams and powerplants remains with Reclamation.

Power Repayment Studies

A PRS is prepared each FY to determine if power revenues will be sufficient to repay, within the prescribed time periods, all costs assigned to the power function. Repayment criteria are based on law, policies, and authorizing legislation. DOE Order RA 6120.2, Section 12b, requires that:

In addition to the recovery of the above costs (operation and maintenance and interest expenses) on a year-by-year basis, the expected revenues are at least sufficient to recover (1) each dollar of power investment at Federal hydroelectric generating plants within 50 years after they become revenue producing, except as otherwise provided by law; plus, (2) each annual increment of Federal transmission investment within the average service life of such transmission facilities or within a maximum of 50 years, whichever is less; plus, (3) the cost of each replacement of a unit of property of a Federal power system within its expected service life up to a maximum of 50 years; plus, (4) each dollar of assisted irrigation investment within the period established for the irrigation water users to repay their share of construction costs; plus, (5) other costs such as payments to basin funds, participating projects, or States.

Existing and Provisional Rates

A comparison of the existing rates and rates for FY 1998 calculated in accordance with the provisional rate methodology are as follows:

COMPARISON OF EXISTING RATES AND PROPOSED RATE METHODOLOGY RATES

	Existing Rate (FY 1995)	Provisional Rate (FY 1998) [1]	Percent Change (%)
Firm Power Service Rate Schedule:	PD–F5	PD–F6	
Capacity Rate ($/kW/month)	$1.92	$0.56	−70.83
Energy Rate (mills/kWh)	1.95	1.29	−34.36
Composite Rate (mills/kWh)	6.33	2.57	−59.40
Firm Transmission Service Rate Schedule:	PD–FT5	PD–FT6	
Firm Transmission Charge ($/kW-month)	$0.96	$1.08	12.50
Firm Transmission Charge for SLCA/IP ($/kW-month)	$0.96	$1.08	12.50
Nonfirm Transmission Service Rate Schedule:	PD–NFT5	PD–NFT6	
Nonfirm Transmission Charge (mills/kWh)	2.19	2.47	12.79

[1] New rates will be calculated in accordance with the rate schedules each year by September 1. These rates represent FY 1998 only.

Certification of Rate

Western's Administrator has certified that the rate methodology for determining the P–DP firm power rate, firm transmission rate, transmission service SLCA/IP rate, and nonfirm transmission rate, placed into effect on an interim basis herein are the lowest possible consistent with sound business principles. The rate methodology has been developed in accordance with administrative policies and applicable laws.

Discussion

Western is requesting approval to place into effect a ratesetting methodology that will be used each year to calculate the total Annual Revenue Requirement, Annual Revenue Requirement Allocated to Generation, Annual Revenue Requirement Allocated to Transmission, Capacity Rate, Energy Rate, Firm Transmission Rate, Firm Transmission Rate of SLCA/IP Power, and Nonfirm Transmission Rate. For FY 1998, the ratesetting methodology produces a decrease in the firm power rates for capacity and energy, and a rate increase for firm and nonfirm transmission service for the P–DP on an interim basis. Five major changes to the rate methodology are affecting these rates for the P–DP.

The first change concerns the Cost Apportionment Study. The study, which demonstrates the distribution of

costs between generation and transmission, has been changed as follows: (1) the PUP contractors' delivery commitments are now included in the total amounts reflected in the generation and transmission delivery commitment figures; and (2) the amount of funds to be repaid through the collection of revenues through rates is now based on the single FY projection, instead of a projected 5-year average calculation. These changes were required so the PUP contractors can demonstrate payment of their portion of generation and transmission costs, and to accommodate the yearly reconciliation of expenses under the advance funding agreements which have been executed with the PUP contractors and are currently being negotiated with the FES contractors.

The second change concerns the ratesetting methodology. The new rate methodology includes the PUP contractors' delivery commitments in the calculations of the rates. This was necessary so the PUP contractors can demonstrate payment of their portion of generation and transmission costs.

The third change concerns the billing for FES. Due to the separation of the transmission component from the Capacity Rate, the FES contractors will be billed a Capacity Rate of dollars per kilowatt per month, an Energy Rate of mills per kilowatthour, and a Firm Transmission Rate of dollars per kilowatt per month.

The fourth change concerns the updating of the expense and other revenue estimates for FY 1997 and the cost evaluation period of FY 1998 through FY 2002 as a result of better data.

The final change concerns the significant decrease in the transmission CROD used to calculate the Firm Transmission Rate, Firm Transmission Rate of Salt Lake City Area Integrated Projects Power, and Nonfirm Transmission Rate. The decrease in the CROD resulted primarily from changes in delivery commitments.

With these changes to the existing methodology, the proposed rate methodology will yield annual revenues sufficient to satisfy the cost-recovery criteria set forth in DOE Order RA 6120.2. The existing Annual Revenue Requirement and Annual Revenue Requirement for FY 1998 for the P-DP are as follows:

	Estimated Revenue (Rounded to Nearest $1,000)	
	Existing	FY 1998
Annual Revenue Requirement	$28,522	$25,036
Annual Revenue Requirement for Generation	4,495	3,459
Annual Revenue Requirement for Transmission	24,027	21,577

Statement of Revenue and Related Expenses

The Annual Revenue Requirement for Generation and the Annual Revenue Requirement for Transmission are based upon a ratebase PRS and a Cost Apportionment Study which estimates the annual costs less other revenues. The following table provides a summary of revenue and expense data through the 5-year period FY 1998–FY 2002 at the provisional rates, compared to the 5-year period FY 1996–FY 2000 at the current rates.

PARKER-DAVIS PROJECT COMPARISON OF 5-YEAR RATE PERIOD REVENUES AND EXPENSES

[$1,000]

	Current Rate PRS 1996–2000	Provisional Rate PRS 1998–2002	Difference
Total Revenues	$180,212	$189,728	$9,516
Revenue Distribution:			
O&M	114,874	123,447	8,573
Purchased Power	4,500	2,170	(2,330)
Other	1,017	769	(248)
nterest	56,452	58,342	1,890
Investment Repayment	3,014	3,496	482
Capitalized Expenses Repayment	355	$1,504	1,149
Total	180,212	189,728	9,516

Basis for Rate Development

The rates are calculated using the Annual Revenue Requirement for Generation and the Annual Revenue Requirement for Transmission as calculated in the Cost Apportionment Study. As a result of this study for FY 1998, 86.18 percent of the P-DP costs are to be recovered from the firm transmission service, while the remaining 13.82 percent of the costs are to be recovered from firm power and PUP service. The rate design consists of seven steps.

1. The data in the Cost Apportionment Study is updated yearly with the latest (1) approved budget plans for the next 5 years, (2) principal and interest payments derived from the PRS for the next 5 years, (3) estimate of other revenue, (4) number of electric service and transmission contractors for the next 5 years, (5) amount of energy commitments for the next 5 years, (6) amount of CROD for the next 5 years, (7) amount of in-service investments in the plant accounts since 1987, and (8) 5-year historical capitalized movable property expense data.

2. From the Cost Apportionment Study, the Annual Revenue Requirement Allocated to Generation and Transmission is derived on a yearly basis.

3. The firm transmission rate is developed by dividing the Annual Revenue Requirement Allocated to Transmission by the average monthly billing CROD, rounded to the penny, to determine the yearly rate. The monthly billing rate is equal to the yearly rate divided by 12, rounded to the penny. Transmission sales include the contracted transmission capacity with the firm transmission service customers, FES customers, and PUP customers.

4. The Capacity Rate, Energy Rate, and the Composite Rate are calculated. The Capacity Rate is calculated by taking 50 percent of the Annual Revenue Requirement Allocated to Generation divided by the sum of the Average Monthly Billing CROD for the PUP contractors and FES contractors, rounded to the penny, to determine the yearly rate. The monthly billing rate is equal to the yearly rate divided by 12, rounded to the penny.

The Energy Rate is calculated by taking 50 percent of the Annual Revenue Requirement Allocated to Generation divided by the sum of the Annual Energy obligation for the PUP contractors and the Annual Energy obligation for the FES contractors, rounded to two decimal places.

The composite rate is calculated by taking the Annual Revenue Requirement Allocated to Generation divided by the sum of the Annual Energy obligation for the PUP contractors and the Annual Energy obligation for the FES contractors, rounded to two decimal places.

5. The firm transmission rate for delivery of SLCA/IP power is determined by dividing the firm transmission service rate in half, rounded to the penny to determine the seasonal rate. The monthly billing rate

is equal to the seasonal rate divided by six, rounded to the penny.

6. The nonfirm transmission rate is calculated by taking the firm transmission rate yearly rate divided by the product of 8,760 multiplied by 60 percent with the result multiplied by 1,000, rounded to two decimal places.

7. The FES contractors are billed monthly an energy charge, a capacity charge, and a transmission charge. The contractor's monthly energy charge is equal to the contractor's monthly energy entitlement multiplied by the energy rate. The contractor's monthly capacity charge is equal to the contractor's seasonal billing CROD multiplied by the monthly capacity rate. The contractor's monthly transmission charge is equal to the contractor's seasonal billing CROD multiplied by the monthly firm transmission rate.

Comments

During the 90-day comment period, Western received six written comments either requesting information or commenting on the rate adjustment. In addition, six persons commented during the July 14, 1997, public comment forum. All comments were reviewed and considered in the preparation of this rate order.

Written comments were received from the following sources:

R. W. Beck, Arizona Public Service Company, Overton Power District No. 5 and Valley Electric Association, Irrigation & Electrical Districts Association of Arizona, K. R. Saline & Associates, and Citizens Utilities Company.

Representatives of the following organizations made oral comments:

Arizona Power Authority, Citizens Utilities Company and Arizona Public Service Company, Salt River Project, Irrigation & Electrical District Association of Arizona and the City of Needles, CA, Overton Power District No. 5, Valley Electric Association, and the Town of Fredonia, AZ, and K. R. Saline & Associates.

The comments received at the public meetings and in correspondence dealt with (1) the development of better allocators for apportioning the costs and other revenues between generation and transmission; (2) the finalization of budget estimates and what costs should go into those estimates; (3) the changes in contract relationships with contractors and their effect on the rates; and (4) the use of the PRS. The comments and responses, paraphrased for brevity, are discussed below. Direct quotes from comment letters are used for clarification where necessary.

Issue: A contractor commented that the ''customer allocator'' used in the Cost Apportionment Study does not sufficiently provide for a direct relationship between cost-causation and the recovery of expenses through rates. The customer requests serious consideration of this issue be addressed in the future.

Response: Western has given this issue serious consideration during this rate process and will continue to examine this issue during the next rate process. Additional information concerning the allocation factors is discussed below.

Issue: A customer commented that a reexamination of the cost allocation factors would not be cost beneficial and would result in only a minor change to the overall allocation percentages.

Response: At this time, Western cannot predict what the effect to the overall allocation percentages would be upon reexamination of the cost allocation factors. With the overall revenue requirement for the P–DP approaching $30 million, even a minor change to the overall allocation percentages may significantly affect some of Western's smaller customers.

Issue: A comment was made that the public comment period be continued for an additional 30 to 60 days in order to further review the cost allocation factors and to analyze the allocation of Western's operation expenses.

Response: At a meeting held with contractors and interested parties on January 16, 1997, it was agreed the cost allocation factors, as they currently exist, remain functional and that a better process does not exist. However, it was also agreed the allocation factors may be revisited during future rate processes. At another meeting with the contractors and interested parties held on August 8, 1997, it was once again agreed the current rate process move forward using the allocation factors that were documented and approved during the last rate process and reaffirmed during this current rate process. Once again it was agreed the cost allocation methods be reexamined during the next rate process.

Issue: A customer commented that Western review its current policies or develop new processes to mitigate the rate impacts to remaining customers when it enters new relationships with existing customers.

Response: Western will continue to seek to improve on existing procedures or develop new processes that will meet Western's legislated mandates in a fair and equitable manner. Furthermore, Western will continue to pursue sound business practices that produce the lowest possible rate to the extent possible.

Issue: A customer stated that staffing levels, below authorized levels, allowed a large portion of the projected current year carryover and suggested that Western perform a thorough review of its staffing requirements and provide supporting evidence to its customers of any increased staffing over current levels.

Response: Western is nearing completion of a transformation process that began in 1995 and is expected to be complete by June of 1998. The recommended staffing level was a result of a detailed and in-depth analysis that evaluated all of Western's processes and recommended the most effective and efficient staffing levels to meet Western's needs. Any variation from those levels would require another in-depth analysis. Western will continue to evaluate all processes for continuous improvement and will make adjustments to staffing levels as necessary to meet changing requirements.

Issue: A customer commented a review of the cost allocation of the Conservation and Renewable Energy Program costs be conducted and that these costs are not transmission related and should be allocated to generation.

Response: It is intended the allocation of the Conservation and Renewable Energy Program be reviewed during the next rate process.

Issue: A customer suggested that Western review the methodology used to allocate multiproject costs and general Western administration costs. Furthermore, another customer commented that FTE data should be based on actual staff levels, not authorized positions, and where possible, the use of direct allocations to responsible projects.

Response: The methodology for allocating multiproject costs was published in a report developed in cooperation with the DSW customers. A meeting was held with DSW customers in March 1997 to review the methodology for allocating multiproject costs. During that meeting, minor adjustments to the methodology were recommended and are in the process of being implemented. Western will continue to review the methodology to seek improvements. Any changes to the methodology will be done in a joint customer forum.

The method for distributing general Western administration costs is a Western-wide methodology that was implemented after a review of Western's operations by the firm of Deloitte and Touche. Any change to this

methodology would require involvement of all offices throughout Western, and involvement of Western's auditors.

Issue: A customer commented on a recent disclosure by Western that certain pension costs may be included in future rate processes and is of the opinion that these costs not be included for repayment unless legislatively mandated.

Response: Western will record the costs for pension and health benefits in the 1997 financial statements. However, the inclusion of these costs in the PRS will depend upon the outcome of a final decision on Western's legal authority to include these costs in the rate base.

Issue: A customer commented about waiting for several years for Reclamation's commitment to develop a 10-year planning process for Parker-Davis.

Response: Reclamation has begun to develop and implement its 10-year planning process for the Parker-Davis Project and intends for it to be a useful and beneficial process for obtaining customer comments and feedback.

Issue: A customer commented on the need to review the program function of the PRS and on the possibility of developing a more efficient tool for implementing the PRS function.

Response: Western remains open to implementing more efficient and effective processes in the best interests of the customers. Continual improvement of the PRS program is a goal and customer feedback is always welcome. In the forthcoming fiscal year, Western will once again look for ways to implement changes to the PRS program that provides for more efficient output.

Issue: A customer commented on the potential for large rate swings from year to year now that the rates for the Parker-Davis Project are being calculated on an annual basis and no longer on a 5-year average.

Response: The calculation of the rate on an annual basis performs two very critical functions. It allows for a synchronization of the costs shown in the Cost Apportionment Study with those in the PRS and it enables Western to perform an annual cost reconciliation to the Cost Apportionment Study without causing a divergence to the data in the PRS. In order to mitigate potential surprises to the customers in the 5-year out period, Western will continue to project the rates for those years thereby allowing contractors to adequately budget for those future costs or to mitigate those costs by providing feedback through Western and Reclamation's 10-year planning process.

Environmental Evaluation

In compliance with the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*; Council on Environmental Quality Regulations (40 CFR Parts 1500–1508); and DOE NEPA Regulations (10 CFR Part 1021), Western has determined this action is categorically excluded from the preparation of an environmental assessment or an environmental impact statement.

Executive Order 12866

DOE has determined this is not a significant regulatory action because it does not meet the criteria of Executive Order 12866, 58 FR 51735. Western has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by OMB is required.

Availability of Information

Information regarding this rate adjustment, including PRSs, comments, letters, memorandums, and other supporting material made or kept by Western for the purpose of developing the power rates, is available for public review in the Desert Southwest Regional Office, Western Area Power Administration, Office of the Assistant Regional Manager for Power Marketing, 615 South 43rd Avenue, Phoenix, Arizona 85009; and Office of the Assistant Administrator for Power Marketing Liaison, Room 8G–027, 1000 Independence Avenue SW., Washington, DC 20585.

Submission to Federal Energy Regulatory Commission

The rate herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and approval on a final basis. Western is developing open access tariffs consistent with FERC Order No. 888 and intends to publish short-term rates by November 1997, and submit long-term rates to the FERC by April 1, 1998.

Order

In view of the foregoing and pursuant to the authority delegated to me by the Secretary of Energy, I confirm and approve on an interim basis, effective November 1, 1997, Rate Schedules PD–F6, PD–FT6, PD–FCT6, and PD–NFT6 for the Parker-Davis Project. The rate schedule shall remain in effect on an interim basis, pending Federal Energy Regulatory Commission confirmation and approval of it or a substitute rate on a final basis, through September 30, 2002.

Dated: November 18, 1997.

Elizabeth A. Moler,

Deputy Secretary.

[Rate Schedule PD–F6; (Supersedes Schedule PD–F5)]

Schedule of Rates for Wholesale Firm Power Service

Effective: The first day of the first full billing period beginning on or after November 1, 1997, and remaining in effect through September 30, 2002, or until superseded, whichever occurs first.

Available: In the marketing area serviced by the Parker-Davis Project (P–DP).

Applicable: To the existing wholesale power customers for firm power service supplied through one meter at one point of delivery, unless otherwise provided by contract.

Character and Conditions of Service: Alternating current at 60 hertz, three-phase, delivered and metered at the voltages and points established by contract.

Monthly Charge: Energy Charge. Each Contractor shall be billed monthly an energy charge. This charge is equal to the Contractor's monthly energy entitlement multiplied by the Energy Rate (rounded to the penny). The Energy Rate shall be equal to 50 percent of the Annual Revenue Requirement Allocated to Generation divided by the sum of the Annual Energy entitlement to the P–DP Priority Use Power Contractors and the Annual Energy entitlement to the P–DP Firm Electric Service Contractors, rounded to two decimal places.

Capacity Charge: Each Contractor shall be billed monthly a capacity charge. This charge is equal to the Contractor's Seasonal Billing Contract Rate of Delivery (CROD) multiplied by the Capacity Rate, rounded to the penny. The Capacity Rate shall be equal to 50 percent of the Annual Revenue Requirement Allocated to Generation divided by the sum of the Average Monthly Billing CROD for the P–DP Priority Use Power Contractors and P–DP Firm Electric Service Contractors that is then divided by 12, rounded to the penny.

Transmission Charge. Each Contractor shall be billed monthly a transmission charge equal to the Contractor's Seasonal Billing Contract Rate of Delivery (CROD) multiplied by the rate calculated in accordance with PD–FT6, rounded to the penny.

Billing of Excess Energy: For each billing period in which there is excess energy available, offered, and delivered to the Contractor, such excess energy purchases shall be billed at the Energy Rate.

Billing for Unauthorized Overruns: For each billing period in which there is a contract violation involving an unauthorized overrun of the CROD, energy, and/or transmission obligations, such overruns shall be billed at 10 times (1) the Energy Rate for energy overruns, (2) the Capacity Rate for CROD overruns, and (3) the P–DP Firm Transmission Rate, then in effect as it may be amended, for transmission overruns.

For Transformer Losses: If delivery is made at transmission voltage but metered on the low-voltage side of the substation, the meter readings will be increased to compensate for transformer losses as provided for in the contract.

For Power Factor: The customer will normally be required to maintain a power factor at all points of measurement between 95-percent lagging and 95-percent leading.

[Rate Schedule PD–FT6; (Supersedes Schedule PD–FT5)]

Schedule of Rate for Firm Transmission Service

Effective: The first day of the first full billing period beginning November 1, 1997, and remaining in effect through September 30, 2002, or until superseded, whichever occurs first.

Available: Within the marketing area served by the Parker-Davis Project (P–DP).

Applicable: To existing firm transmission service customers where capacity and energy are supplied to the P–DP system at points of interconnection with other systems and transmitted and delivered, less losses, to points of delivery on the P–DP system specified in the service contract.

Character and Conditions of Service: Alternating current at 60 hertz, three-phase, delivered and metered at the voltages and points established by contract.

Monthly Rate: Transmission Service Charge: Each Contractor shall be billed a dollar per kilowatt per year rate for each kilowatt at the point of delivery, established by contract, payable monthly at a dollar per kilowatt per month rate. The yearly rate is equal to the Annual Revenue Requirement Allocated to Transmission divided by the Average Monthly Billing Contract Rate of Delivery, rounded to the penny. The monthly billing rate is equal to the dollar per kilowatt per year rate divided by 12, rounded to the penny.

Adjustments: For Reactive Power. There shall be no entitlement to transfer of reactive kilovoltamperes at delivery points, except when such transfers may be mutually agreed upon by contractor and contracting officer or their authorized representatives.

For Losses. Capacity and energy losses incurred in connection with the transmission and delivery of power and energy under this rate schedule shall be supplied by the customer in accordance with the service contract.

Billing for Unauthorized Overruns. For each billing period in which there is a contract violation involving an unauthorized overrun of the contractual firm transmission obligations, such overrun shall be billed at 10 times the above rates.

[Rate Schedule PD–FCT6; (Supersedes Schedule PD–FCT5)]

Schedule of Rate for Firm Transmission Service of Salt Lake City Area Integrated Projects Power

Effective: The first day of the first full billing period beginning on or after November 1, 1997, and remaining in effect through September 30, 2002, or until superseded, whichever occurs first.

Available: Within the marketing area served by the Parker-Davis Project (P–DP) transmission facilities.

Applicable: To existing Salt Lake City Area Integrated Projects (SLCA/IP) southern division customers where SLCA/IP capacity and energy are supplied to the P–DP system by the Colorado River Storage Project (CRSP) at points of interconnection with the CRSP system and for transmission and delivery on a unidirectional basis, less losses, to southern division customers at points of delivery on the P–DP system specified in the service contract.

Character and Conditions of Service: Alternating current at 60 hertz, three-phase, delivered and metered at the voltages and points of delivery established by contract.

Monthly Rate: Transmission Service Charge: Each Contractor shall be billed a dollar per kilowatt per seasonal rate for each kilowatt at the point of delivery, established by contract, payable monthly at a dollar per kilowatt per month rate. The seasonal rate is equal to the P–DP Firm Transmission Rate then in effect as it may be amended divided by 2, rounded to the penny. The monthly billing rate is equal to the dollar per kilowatt per season rate divided by six, rounded to the penny.

Adjustments: For Reactive Power. There shall be no entitlement to transfer of reactive kilovoltamperes at delivery points, except when such transfers may be mutually agreed upon by contractor and contracting officer or their authorized representatives.

For Losses. Capacity and energy losses incurred in connection with the transmission and delivery of power and energy under this rate schedule shall be supplied by the customer in accordance with the service contract.

Billing for Unauthorized Overruns. For each billing period in which there is a contract violation involving an unauthorized overrun of the contractual firm transmission obligations, such overrun shall be billed at 10 times the above rates.

[Rate Schedule PD–NFT6; (Supersedes Schedule PD–NFT5)]

Schedule of Rate for Nonfirm Transmission Service

Effective: The first day of the first full billing period beginning on or after November 1, 1997, and remaining in effect through September 30, 2002, or until superseded, whichever occurs first.

Available: Within the marketing area serviced by the Parker-Davis Project (P–DP) transmission facilities.

Applicable: To existing nonfirm transmission service customers where capacity and energy are supplied to the P–DP system at points of interconnection with other systems, transmitted subject to the availability of the transmission capacity, and delivered on a unidirectional basis, less losses, to points of delivery on the P–DP system specified in the service contract.

Character and Conditions of Service: Alternating current at 60 hertz, three-phase, delivered and metered at the voltages and points of delivery established by contract.

Monthly Rate: Nonfirm Transmission Service Charge: Each Contractor shall be billed monthly a mills per kilowatthour rate of scheduled or delivered kilowatthours at point of delivery, established by contract, payable monthly. This rate is equal to P–DP Firm Transmission dollar per kilowatt-year rate then in effect as it may be amended divided by (8,760 multiplied by 0.60) multiplied by 1,000, rounded to two decimal places.

Adjustments: For Reactive Power. There shall be no entitlement to transfer of reactive kilovoltamperes at delivery points, except when such transfers may be mutually agreed upon by contractor and contracting officer or their authorized representatives.

For Losses. Capacity and energy losses incurred in connection with the transmission and delivery of power and energy under this rate schedule shall be supplied by the customer in accordance with the service contract.

[FR Doc. 97–31074 Filed 11–25–97; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5928–1]

Agency Information Collection Activities: Proposed Collection; Emergency Clearance Request; Comment Request; Four Private Party Anecdotal Surveys Regarding Prospective Purchaser Agreements and Comfort/Status Letters

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that EPA has submitted an emergency clearance request for the following proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB): Four Private Party Anecdotal Surveys Regarding Prospective Purchaser Agreements and Comfort/Status Letters, EPA ICR Number 1837.01. The emergency clearance request has been submitted for emergency processing within 14 days after publication in the **Federal Register**. During this time period, EPA is soliciting comments on specific aspects of the proposed information collection.

DATES: Please submit comments on or before December 10, 1997.

ADDRESSES: U.S. Environmental Protection Agency, Office of Site Remediation Enforcement, 401 M Street, SW (MC 2273A), Washington, DC 20460. Interested persons may contact Elisabeth Freed at (202) 564–5117 for a copy of the ICR or see the EPA ICR website at http://www.epa.gov/icr. Refer to ICR Number 1837.01.

FOR FURTHER INFORMATION CONTACT: Elisabeth Freed, Office of Site Remediation Enforcement, Policy and Program Evaluation Division, (202) 564–5117, (202) 564–0093 (fax), freed.elisabeth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Affected entities: Entities potentially affected by this action are those which are non-government parties at sites where Prospective Purchaser Agreements and Comfort/Status Letters have been issued, or at sites where they have been sought, but not obtained. These parties may include, but are not limited to, lending officials, developers, and attorney representatives of parties to the site.

Title: Four Private Party Anecdotal Surveys Regarding Prospective Purchaser Agreements and Comfort/Status Letters, EPA ICR Number 1837.01, [Proposed Information Collection]

Abstract: In 1995, EPA issued guidance and policies concerning the use of Prospective Purchaser Agreements and Comfort/Status Letters. (See Guidance on Settlements with Prospec-tive Purchasers of Contaminated Property, published in May of 1995 and Policy on the Issuance of Comfort/Status Letters, published in November of 1996). Since that date, EPA has entered into 66 Prospective Purchaser Agreements and issued more than 200 Comfort/Status Letters. OSRE will use four anecdotal surveys to collect information from private parties (non-govern-ment personnel) at sites where Prospective Purchaser Agreements and Comfort/Status Letters have been issued, or where they have been sought but not obtained. OSRE will use the information collected to evaluate the effectiveness of the guidance on Prospective Purchaser Agreements and the Comfort/Status Letter policy. Responses to this information collection are strictly voluntary, and the information collection is a one-time effort. OSRE will ensure the confidenti-ality of the responses to the information collection by employing contractor support to collect the information and by limiting access to individual responses to EPA personnel overseeing the information collection. Using contractors to collect the information through telephone surveys is expected to increase the candor of the responses. Contractors will transcribe responses onto survey forms and will assist in compiling and analyzing the information. Only EPA personnel overseeing this information collection will have access to individual responses. All other personnel, as well as other interested parties, will be limited to examining only compiled summaries of data. This process will safeguard the confidentiality of the information. All contractors involved in the information collection have signed non-disclosure statements and Conflict of Interest assessments. These documents ensure that the contractors have examined the information collection assignment for possible conflicts of interest and have found none. They also ensure that contractors will not reveal any information they collect while conducting the surveys. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

EPA would like to solicit comments to:

(i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: This information collection is estimated to cost $28,882 and take 1048 hours. Note that although four survey instruments will be used in this information collection, each respondent will be asked to respond to only one survey instrument. Which instrument they will receive will be determined by their site type (site type is defined as participant or non-participant) and whether a Prospective Purchaser Agreement or a Comfort/Status Letter was involved at the site. There will be approximately 600 respondents, with an average response time of 36 minutes. This is a one-time information collection, and participation is strictly voluntary. Of the anticipated 1048 hours required for the information collection, 650 are estimated as EPA burden, and 398 are estimated as respondent burden. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: November 20, 1997.

Leslie A. Jones,

Acting Branch Chief of Site Remediation Enforcement, Policy Guidance Branch.

[FR Doc. 97–31141 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5927–9]

Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses; Approval of a Notification of Intent to Certify Equipment

AGENCY: Environmental Protection Agency.

ACTION: Notice of Agency Certification of Equipment for the Urban Bus Retrofit/Rebuild Program.

SUMMARY: The Agency received a notification of intent to certify equipment signed March 11, 1997 from Nelson Industries, Inc., Nelson Division (Nelson) with principal place of business at 1801 Highway 51 West, P.O. Box 428, Stoughton, WI, 53589 for certification of urban bus retrofit/rebuild equipment pursuant to 40 CFR 85.1401 through 85.1415. The equipment is applicable to petroleum-fueled Detroit Diesel Corporation (DDC) two-stroke/cycle engines originally installed in urban buses from model year 1979 to model year 1993, excluding the DDC 6L71TA 1990 model year engines, all alcohol fueled engines, and models which were manufactured with particulate trap devices. In addition, the equipment is applicable to engines which have been previously rebuilt using the certified DDC 6V92TA MUI or DDECII upgrade kits.[1] On July 11, 1997, EPA published a notice in the **Federal Register** that the notification had been received and made the notification available for public review and comment for a period of 45-days (62 FR 37228). EPA received no comments in response to that **Federal Register** notice. Subsequently, EPA has completed its review of this notification, and the Director of the Engine Programs and Compliance Division has determined that it meets all the requirements for certification. Accordingly, EPA certified this equipment in a letter to Nelson Industries dated October 14, 1997.

The certified equipment provides 25 percent or greater reduction in exhaust emissions of particulate matter (PM) for the engines for which it is certified. In addition, this equipment is certified as complying with a life cycle cost limit of $2,000 or less (in 1992 dollars).

The Nelson notification, as well as other materials specifically relevant to it, are contained in Public Docket A–93–42, category XIX, entitled ''Certification of Urban Bus Retrofit/Rebuild Equipment''. This docket is located in room M–1500, Waterside Mall (Ground Floor), U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

Docket items may be inspected from 8:00 a.m. until 5:30 p.m., Monday through Friday. As provided in 40 CFR Part 2, a reasonable fee may be charged by the Agency for copying docket materials.

DATES: The effective date of certification is October 14, 1997, established in a letter from EPA to Nelson Industries. This certified equipment may be used immediately by urban bus operators. The impact of this certification on transit operators is discussed in more detail in section IV of today's notice.

FOR FURTHER INFORMATION CONTACT: Tom Stricker, Engine Compliance Programs Group, Engine Program and Compliance Division (6403J), U.S. Environmental Protection Agency, 401 M St. SW, Washington, D.C. 20460. Telephone: (202) 564–9322.

SUPPLEMENTARY INFORMATION:

I. Background

By a notification of intent to certify signed March 11, 1997, Nelson applied for certification of equipment applicable to petroleum-fueled Detroit Diesel Corporation (DDC) two-cycle engines originally installed in an urban bus from model year 1979 to model year 1993, excluding the DDC 6L71TA 1990 model year engines and models which were manufactured with particulate trap devices or alcohol fueled. In addition, Nelson requested certification for engines rebuilt using the certified DDC 6V92TA MUI or DDECII upgrade kits when the CEM is installed at the same time as the DDC rebuild kit. The notification of intent to certify states that the equipment being certified is a catalytic exhaust muffler (Nelson converter), packaged as a direct replacement for the muffler. The application demonstrates that the candidate equipment provides a 25 percent or greater reduction in emissions of particulate matter (PM) for petroleum fueled diesel engines relative to an original engine configuration with no after treatment installed. Certification is applicable to engines that are rebuilt to original specifications, or in-use engines that are not rebuilt at the time the Nelson converter is installed provided the engine is calibrated to meet the original manufacturer's specifications and meets engine oil consumption limits specified by Nelson. According to Nelson, a 6-cylinder engine that uses more than one-and-a-half quarts of oil per 10 hours of operation, or an 8-cylinder engine that uses more than 2.0 quarts of oil per 10 hours of operation, must be rebuilt. The Nelson Converter is certified for use on engines rebuilt using new DDC certified rebuild kits only in those instances where the Nelson converter is installed at the same time the DDC rebuild kit is installed on the engine.

Using engine dynamometer testing in accordance with the Federal Test Procedure for heavy-duty diesel engines, Nelson documented a 53% PM reduction for the test engine retrofit with the Nelson Converter compared to a standard rebuild. The test engine with the certified retrofit equipment installed complies with applicable Federal emission standards for hydrocarbon (HC), carbon monoxide (CO), oxides of nitrogen (NO_X), and smoke emissions in addition to demonstrating reductions in PM exhaust emissions.

Table A below lists the engine models covered by this certification, and the PM level to which each model is certified. The Nelson equipment is certified to reduce PM emissions by 25 percent. The certification level (shown as ''PM Level with Converter'' in Table A) represents a 25 percent reduction in PM emissions compared to the pre-rebuild PM level shown in the table at 40 CFR Section 85.1403(c)(1)(iii)(A).

TABLE A.—CERTIFICATION LEVELS

Engine models	Model year	PM level with converter	Code	Family
6V92TA MUI[2]	1979–87	0.38	All	All.

[1] The DDC 6V92TA MUI upgrade kit was certified by EPA on October 2, 1995 (60 FR 51472). The DDC 6V92TA DDECII upgrade kit was certified by EPA on July 19, 1996 (61 FR 37738).

TABLE A.—CERTIFICATION LEVELS—Continued

Engine models	Model year	PM level with converter	Code	Family
	1988–1989	0.23	All	All.
6V92TA DDEC I	1986–89	0.23	All	All.
6V92TA DDEC II[3]	1988–91	0.23	All	All.
1992–93	0.19	All	All.	
6V71N	1973–87	0.38	All	All.
6V71N	1988–89	0.38	All	All.
6V71T	1985–86	0.38	All	All.
8V71N	1973–84	0.38	All	All.
6L71TA	1988–89	0.23	All	All.
6L71TA DDEC	1990–91	0.23	All	All.
8V92TA	1979–87	0.38	All	8V92TA.
	1988	0.29	All	
8V92TA..				
8V92TA–DDEC	1988	0.31	All	8V92TA–DDEC II.
8V92TA	1989	0.35	9E70	KDD0736FWH9.
8V92TA	1989	0.29	9A90	KDD0736FWH9.
8V92TA	1989	0.26	9G85	KDD0736FWH9.
8V92TA DDEC	1989	0.31	1A	KDD0736FZH4.
8V92TA	1990	0.35	9E70	LDD0736FAH9.
8V92TA DDEC	1990	0.37	1A	LDD0736FZH3.
8V92TA DDEC	1991	0.19	1A or 5A	MDD0736FZH2.
8V92TA DDEC	1992–93	0.16	1D	NDD0736FZH1 & PDD0736FZH X.
8V92TA DDEC	1992–93	0.22	6A	NDD0736FZH 1 & PDD0736FZH X.
8V92TA DDEC	1992–93	0.15	5A	NDD0736FZH 1 & PDD0736FZHX.
8V92TA DDEC	1992–93	0.19	1A	NDD0736FZH 1 & PDD0736FZHX.

[2] For 6V92TA MUI models that are rebuilt using a certified DDC emissions retrofit kit, Nelson is certifying the PM engine emissions to a level of 0.22 g/bhp-hr for the 1979 to 1987 models and to a level of 0.17 g/bhp-hr for the 1988–1989 models provided the Nelson converter is installed at the same time the rebuild with the DDC upgrade takes place. The DDC 6V92TA MUI upgrade kit certification notification was published in the **Federal Register** on October 2, 1995 (60FR51472).

[3] For the 6V92TA DDECII models that are rebuilt using a certified DDC emissions retrofit kit, Nelson is certifying the PM engine emissions to a level of 0.17 g/bhp-hr for 1988–1990 models provided the Nelson converter is installed at the same time the rebuild with the DDC upgrade takes place. The DDC 6V92TA DDECII upgrade kit certification notification was published in the **Federal Register** on July 19, 1996 (61 FR 37738).

Note: The original PM certification levels for the 1991 6V92TA DDEC II, 6LV71TA DDEC and 8V92TA DDEC engine models are based on Federal Emission Limits (FELs)under the averaging, banking and trading program. These limits are higher than the 1991 PM standard of 0.25 g/bhp-hr. The PM level listed in this table for the engines that are equipped with the Nelson converter provide at least a 25% reduction from the original certification levels. The 1992 to 1993 6V92TA DDEC II and 8V92TA DDEC engine models were also certified using FELs under the trading and banking program and likewise the PM levels for the engines equipped with the Nelson converter represent at least a 25% reduction from the original certification levels.

In addition to reducing PM emissions by 25% or more, this equipment is certified to comply with a life cycle cost limit of $2,000 or less (in 1992 dollars). The maximum purchase price for the Nelson converter is $2,091 (in August 1997 dollars), and the maximum installation time is stated to be 5 hours, or $201 (in August 1997 dollars). Nelson states that no additional maintenance cost is associated with use of the Nelson converter, and the test data demonstrate no fuel economy impact. Thus, the maximum total life cycle cost for this equipment is $2,292 (in August 1997 dollars), or $2,000 (in 1992 dollars). Although this equipment meets the life cycle cost limit associated with 25% reduction technology, this certification does not trigger any new program requirements for applicable engines. The requirement to use equipment certified to achieve at least a 25% reduction in PM has previously been triggered for some of these engines and is superseded by the 0.10 g/bhp-hr PM standard that has been triggered for 1979–89 DDC 6V92TA MUI engines. The impact of this certification on transit operators is discussed in more detail in section IV of today's notice.

II. Summary and Analysis of Comments

EPA received no comments in response to the July 11, 1997 **Federal Register** notice. However, EPA requested clarification from Nelson regarding several issues discussed below.

The Notification of Intent to Certify (NIC) describes the baseline rebuilt engine used in emissions testing as having 9G75 fuel injectors rated at 294 horsepower (HP). However, the NIC also states that the initial run-in power for the engine was 277 HP. Nelson was asked to explain this apparent discrepancy in rated HP versus observed HP. In response, Nelson states that the engine was rebuilt by DDC with 9G75 fuel injectors rated at 294 HP, although the engine only produced 277 HP upon initial run-in. Nelson states that the DDC power rating has a tolerance of plus/minus 5% (279 to 306 HP for a 294 HP rating). After additional break-in in the test cell, the engine produced 283 HP (within the tolerance range) as documented in the laboratory checklist contained in the NIC.

Nelson requested that certification be granted for the Nelson converter installed on rebuilt, and non-rebuilt engines. EPA requested that Nelson provide a rationale to support why the claimed PM reductions are appropriate for engines which have not been rebuilt. In response, Nelson states that the installation instructions provide criteria

which must be met in order to install the Nelson converter on non-rebuilt engines. These criteria include maintenance of the engine in accordance with the original engine manufacturer's specifications, adjustment of all adjustable parameters in accordance with manufacturer's specifications, and oil consumption criteria. For 6-cylinder engines, the oil consumption may be no greater than 1.5 quarts per 10 hours of service. For 8-cylinder engines, the oil consumption may be no greater than 2.0 quarts per 10 hours of service. These criteria are intended to ensure that the engine is operating within the worse-case PM level of 0.5 g/bhp-hr. In addition, Nelson states that certification testing demonstrated a PM removal of 0.16 g/bhp-hr on an engine emitting at 0.30 g/bhp-hr. Nelson states that it is reasonable to assume that an even greater mass of PM would be removed from an engine operating at 0.50 g/bhp-hr. Even if this is not the case, conservatively using a 0.16 g/bhp-hr of PM removal on such an engine results in a 32% reduction, which is still greater than the 25% reduction to which the equipment is certified. EPA believes that Nelson's response is adequate to support certification for applicable non-rebuilt engines. In addition, Nelson clarified that certification for use on engines rebuilt with new DDC certified rebuild kits is limited to instances where the Nelson converter is installed on the engine at the same time as the DDC rebuild kit.

As discussed in the July 11, 1997 **Federal Register** notice requesting public comment, EPA believes that the Nelson test engine meets the criteria for worse-case test engine, described at § 85.1406(a), for all two-stroke cycle engines (exclusive of the 1990 model year DDC 6L71TA), including both mechanically and electronically fuel injected engines. EPA reserves the right to request additional information showing that PM reduction does not vary significantly among engine families. However, because the Nelson test data indicate over a 50 percent PM reduction on the DDC 6V92TA MUI test engine, EPA believes it reasonable to expect that electronically-controlled engines, with the Nelson catalyst installed, will be capable of meeting the 25 percent reduction standard for which Nelson is requesting certification. EPA received no comments contrary to this position, and thus approves certification for both mechanically and electronically fuel injected engines as shown in Table A.

Finally, EPA notes that Nelson is required to provide a 100,000 mile emission defect warranty on the Nelson converter, and a 150,000 mile emission performance warranty per 40 CFR 85.1409. Use of the Nelson Converter on an engine utilizing a DDC certified upgrade kit does not in any way relieve Nelson of the required warranty responsibilities outlined above.

III. Certification

The Agency has reviewed this notification, along with comments received from interested parties, and finds that the equipment described in this notification of intent to certify:

(1) Reduces particulate matter exhaust emissions by at least 25 percent, without causing the applicable engine families to exceed other exhaust emissions standards;

(2) Will not cause an unreasonable risk to the public health, welfare, or safety;

(3) Will not result in any additional range of parameter adjustability; and,

(4) Meets other requirements necessary for certification under the Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses (40 CFR Sections 85.1401 through 85.1415). The Agency therefore certified this equipment in a letter to Nelson dated October 14, 1997, for use in the urban bus retrofit/rebuild program as discussed below in section IV.

IV. Transit Operator Requirements

Based on this certification, no new requirements are placed on operators and no operator will be required to purchase this equipment. For the 1979 through 1989 6V92TA MUI engine models, EPA has previously certified equipment which triggered the requirement to use equipment certified to the 0.10 g/bhp-hr level beginning September 15, 1997. Therefore, under Program 1, operators who rebuild or replace 1979 through 1989 model year DDC 6V92TA MUI engines after this date will be required to use equipment certified to meet the 0.10 g/bhp-hr PM level. For all other engine models to which this certification applies, EPA has previously certified equipment which triggered the requirement to use equipment certified as providing a minimum 25 percent reduction in PM beginning December 1, 1995. The Nelson converter is certified to reduce PM by at least 25 percent, and can be used under program 1 to meet this requirement for these other engine models until such time that equipment is certified to trigger the 0.10 g/bhp-hr emission standard for these engines for less than a life cycle cost of $7,940 (in 1992 dollars).

Operators who choose to comply with Program 2 and install the Nelson equipment, will use the specified PM emission levels in Table A in their calculation of fleet level attained.

Dated: November 19, 1997.

Robert Brenner,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 97–31138 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5927–8]

Request for Great Lakes Preproposals Through ''FY 98–99 Great Lakes Priorities and Funding Guidance''

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of funding availability.

SUMMARY: EPA's Great Lakes National Program Office (GLNPO) is now requesting the submission of preproposals for GLNPO funding. This request is part of the *FY98–99* Great Lakes Priorities and Funding Guidance (Funding Guidance). The Great Lakes Funding Guidance identifies Great Lakes priorities, solicits preproposals for assistance projects, and describes other Federal Great Lakes funding opportunities.

DATES: The deadline for submission of Preproposals is January 15, 1998.

ADDRESSES: Copies of the document are available by calling Larry Brail at 312–886–7474. It is also available through the GLNPO Internet home page (http://www.epa.gov/glnpo).

FOR FURTHER INFORMATION CONTACT: Mike Russ, EPA–GLNPO, G–17J, 77 West Jackson Blvd., Chicago, IL 60604, (312–886–4013/ russ.michael@epamail.epa.gov).

SUPPLEMENTARY INFORMATION: Under the Great Lakes Funding Guidance, Preproposals are requested for a total of up to $3.7 million in funding targeted to: Contaminated Sediments ($1.4 million), Pollution Prevention $700 thousand), Assessment/Indicators ($200 thousand), Habitat Protection and Restoration ($1.1 million), and Exotic Species ($300 thousand). A ''roadmap'' section describes some of the other Great Lakes Federal funding available through USEPA, the Natural Resources Conservation Service, the Fish and Wildlife Service, and the Army Corps of Engineers.

Dated: November 18, 1997.

Gary V. Gulezian,

Director, Great Lakes National Program Office.

[FR Doc. 97–31135 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–400120; FRL–5758–8]

Toxics Data Reporting Committee of the National Advisory Council for Environmental Policy and Technology; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act, EPA gives notice of a 2–day meeting of the Toxics Data Reporting Committee of the National Advisory Council for Environmental Policy and Technology. This will be the second meeting of the Toxics Data Reporting (TDR) Committee, whose mission is to provide advice to EPA regarding the Agency's Toxics Release Inventory (TRI) Program.

DATES: The public meeting will take place on December 9-10, 1997, from 8:30 a.m. to 5 p.m. Written and electronic comments in response to this notice should be received by December 5, 1997.

ADDRESSES: The meeting will be held at: L'Enfant Plaza, 480 L'Enfant Plaza SW., Washington, DC 20024, (202) 484–1000.

Comments and data may also be submitted electronically to: oppt.ncic@epamail.epa.gov. Follow the instructions under Unit II. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this action. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

FOR FURTHER INFORMATION CONTACT: Cassandra Vail, telephone: (202) 260–0675, fax number: (202) 401–8142, e-mail: vail.cassandra@epamail.epa.gov. or Michelle Price, telephone: (202) 260–3372, fax number: (202) 410–8142, e-mail: price.michelle@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

At the 2–day meeting, the TDR Committee will continue the discussions begun at the September 29-30 meeting regarding the Agency's interpretation of the EPCRA definition of ''release.'' In section 5 of the Form R, there have been a number of issues raised with regard to the definition of ''release,'' particularly with respect to Class I underground injection wells and RCRA Subtitle C Landfills. Several commenters believe that EPA's interpretation of the EPCRA definition of ''release'' will lead to the misperception that a reported EPCRA section 313 ''release'' necessarily results in an actual exposure of people or the environment to a toxic chemical. The TDR Committee will continue to discuss possible recommendations on ways to collect (including nomenclature and format changes) and disseminate the data that are consistent with the Agency's interpretation of the EPCRA definition of ''release'' and would address the concerns raised regarding public misperception.

In addition to the discussions on section 5, the TDR Committee will also be discussing how EPA characterizes the TRI data through the annual public data release. Concerns have been raised that EPA's presentation of the TRI data can lead to public misperception of the data. Some commenters have stated that because EPA uses the word ''release,'' TRI data leads to the misperception that a reported EPCRA section 313 ''release'' necessarily results in actual exposure of people or the environment to a toxic chemical. The Committee will be discussing possible recommendations on ways to more clearly present release data to the public to distinguish between the various methods of disposal while still making it possible to present meaningful statistics on a national basis about releases.

A meeting summary from the September 29-30 TDR Committee meeting will shortly be available on the TRI Home Page. The address of the TRI Home Page is http://www.epa.gov/opptintr/tri. This summary can be found under the heading ''TRI Stakeholder Dialogue.'' In addition, the agenda and an issue paper outlining topics for discussion at the December 9-10 Committee meeting will also be available at this same site prior to the meeting. Oral presentations or statements by interested parties will be limited to 5 minutes. Interested parties are encouraged to contact Cassandra Vail, to schedule presentations before the Committee.

II. Public Record and Electronic Submissions

The official record for this action, as well as the public version, has been established for this action under docket control number ''OPPTS–400120'' (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC.

Electronic comments can be sent directly to EPA at:

oppt.ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number ''OPPTS–400120.'' Electronic comments on this action may be filed online at many Federal Depository Libraries.

Dated: November 24, 1997.

Cassandra Vail,

Designated Federal Official, Office of Pollution Prevention and Toxics.

[FR Doc. 97–31298 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5927–5]

Science Advisory Board; Notification of Open Public Advisory Committee Meetings

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that two committees of the Science Advisory Board (SAB) will meet on the dates and times described below. All times noted

are Eastern Time. All meetings are open to the public. Due to limited space, seating at meetings will be on a first-come basis. For further information concerning specific meetings, please contact the individuals listed below. Documents that are the subject of SAB reviews are normally available from the originating EPA office and are *not* available from the SAB Office.

1. Clean Air Scientific Advisory Committee (CASAC)

The Clean Air Scientific Advisory Committee (CASAC) of the Science Advisory Board will meet on Monday, December 15, 1997 at the U.S. Environmental Protection Agency (USEPA), Environmental Research Center, Main Auditorium, Route 54 and Alexander Drive, Research Triangle Park, NC 27711. The meeting will begin at 9 am and end no later than 5 pm. At this meeting, the Committee will receive briefings from Agency Staff concerning: (a) the project work plan for preparation of the air quality criteria document for Carbon Monoxide (CO), which will serve as the scientific basis for the next periodic review of the CO National Ambient Air Quality Standards (NAAQS); (b) the schedule for the Particulate Matter (PM) NAAQS review; and (c) an overview of the Agency's plans for upcoming reviews of the other NAAQS. These briefings will help set the stage for subsequent meetings of the Committee as it begins its review responsibilities for the various NAAQS.

Interested parties may obtain a copy of the CO Project Work Plan by writing to the CO Project Manager, USEPA, Office of Research and Development, National Center for Environmental Assessment, Research Triangle Park, NC 27711 or by sending a request via fax (919–541–1818) or e-mail (ray.diane@epamail.epa.gov). The review schedule for the PM NAAQS is contained in 62 FR 55201 (October 23, 1997).

2. Research Strategies Advisory Committee (RSAC)

The Research Strategies Advisory Committee (RSAC) of the Science Advisory Board, will meet on Tuesday, December 16, 1997 in the Science Advisory Board Conference Room, Room 2103 Mall Level (entry near the Safeway Supermarket), U.S. Environmental Protection Agency Headquarters Building, 401 M St. SW, Washington, DC 20460. The meeting will begin at 8:30 am and end no later than 4:30 pm. The purpose of the meeting is to receive briefings from Agency Staff on the Office of Research and Development's (ORD) strategic planning and budgeting process and to discuss the upcoming RSAC review of the ORD budget and the role of RSAC in ORD's strategic planning process.

For Further Information

Members of the public desiring additional information about either meeting should contact Mr. Robert Flaak, Designated Federal Officer, Clean Air Scientific Advisory Committee (CASAC) and Research Strategies Advisory Committee (RSAC), Science Advisory Board (1400), Room 2812, U.S. EPA, 401 M Street, SW, Washington, DC 20460; telephone/voice mail at (202) 260–5133; fax at (202) 260–7118; or via the INTERNET at FLAAK.ROBERT @EPAMAIL.EPA.GOV. Those individuals requiring a copy of the draft Agenda for either meeting should contact Ms. Dorothy Clark at (202) 260–8414 or by FAX at (202) 260–7118 or via the INTERNET at CLARK.DOROTHY @EPAMAIL.EPA.GOV. Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found in The Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 260–8414.

Members of the public who wish to make a brief oral presentation to either Committee must contact Mr. Flaak in writing (by letter or by fax—see previously stated information) no later than 12 Noon Eastern Time, Tuesday, December 9, 1997 in order to be included on the respective Agenda. Public comments will be limited to five minutes per speaker or organization. The request should identify the name of the individual who will make the presentation, the organization (if any) they will represent, the name of the committee (CASAC or RSAC) they wish to address, any requirements for audio visual equipment (e.g., overhead projector, 35mm projector, chalkboard, etc), and at least 35 copies of an outline of the issues to be addressed or the presentation itself. Public comments should focus on scientific or technical aspects of the matters before the respective Committee at its meeting. There will be time allocated for public comment at subsequent meetings when the Committees are actually involved in substantive review activities.

Providing Oral or Written Comments at SAB Meetings

The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. In general, each individual or group making an oral presentation will be limited to a total time of ten minutes. For conference call meetings, opportunities for oral comment will be limited to no more than five minutes per speaker and no more than fifteen minutes total. Written comments (at least 35 copies) received in the SAB Staff Office sufficiently prior to a meeting date, may be mailed to the relevant SAB committee or subcommittee prior to its meeting; comments received too close to the meeting date will normally be provided to the committee at its meeting. Written comments may be provided to the relevant committee or subcommittee up until the time of the meeting.

A. Robert Flaak,

Acting Staff Director, Science Advisory Board.

[FR Doc. 97–31136 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00513; FRL–5758–5]

State FIFRA Issues Research and Evaluation Group (SFIREG); Open Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The State FIFRA Issues Research and Evaluation Group (SFIREG) will hold a 2–day meeting, December 8, and December 9, 1997. This notice announces the location and times for the meetings and sets forth the tentative agenda topics. The meetings are open to the public.

DATES: The SFIREG will meet on Monday, December 8, 1997, from 8:30 a.m. to 5 p.m. and Tuesday, December 9, 1997, from 8:30 a.m. to 12 p.m.

ADDRESSES: The meeting will be held at the National Airport Doubletree Hotel, 300 Army Navy Drive, Arlington-Crystal City, VA 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Elaine Y. Lyon, Office of Pesticide Programs (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 1921 Jefferson Davis Highway, Crystal Mall #2, Rm. 1113I, Arlington-Crystal City, VA; (703) 305–5306; (703) 308–1850 (fax); e-mail: Lyon.elaine.@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The tentative agenda of the SFIREG includes the following:

1. Update on the Food Quality Protection Act:

a. Tolerance reassessment program.

b. Minor crops - office interactions with USDA for use data collection.

c. Section 18 regulations.
2. Section 18 homepage.
3. Office of Enforcement and Compliance Assurance (OECA) Updates:
a. Performance partnerships status.
b. Urban pesticide initiative activities and states funding request.
c. Cooperative agreement issues.
4. Antimicrobial Issues:
a. Definition of pest in the antimicrobial rule.
b. Clarification of state support in the antimicrobial area.
c. Office of Enforcement and Compliance assurance plans for efficacy testing.
d. State lab involvement.
5. Performance Measures:
a. Results of September 1997 workshop.
b. Future activities.
c. OECA's direction regarding measures and GPRA.
6. Policy to address changes to worker risk mitigation measures.
7. Quality assurance/quality control/ national environmental laboratory program.
8. Pesticide regulatory education program course offerings.
9. Regional reports and introduction of issue papers.
10. Other topics as appropriate.

List of Subjects

Environmental protection.

Dated: November 20, 1997.

Jay Ellenberger,

Director, Field and External Affairs Division, Office of Pesticide Programs.

[FR Doc. 97–31129 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–777; FRL–5754–4]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–777, must be received on or before December 26, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller (PM 23), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703 305–6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–777] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–777] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 4, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BASF Corporation

PP 6F4604, 4F3041 and FAP 4H5428

EPA has received pesticide petitions (PP 6F4604, 4F3041, and FAP 4H5428) from BASF Corporation, 26 Davis Drive, Research Triangle Park, P.O. Box 13528, NC 27709, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.227 by

establishing and amending tolerances for residues of the herbicide dicamba in or on the raw agricultural commodities soybeans, wheat, barley, oats, corn, cotton, grasses and asparagus at the proposed tolerances as described below. The proposed analytical methods involve extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (gc/ecd). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. Metabolism is adequately understood on the basis of soybean, asparagus, cotton, sugarcane and published data on grass. In the majority of registered crops, the major metabolite is the 3,6 dichloro-5-OH-*o*-anisic acid. Tolerances are expressed as the dicamba parent plus the respective major metabolite.

2. *Analytical method*. BASF Corp. has provided suitable independently validated analytical methods for detecting and measuring levels of dicamba and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels described in these and the existing tolerances. Adequate methods are available in PAM-II for enforcement purposes. The analytical method involves extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (gc/ecd).

3. *Magnitude of the residue*—i. *Plant*. Residue trials have been conducted with dicamba on the crops for expanded use requested in the subject petitions. Multiple salts of dicamba were studied in side-by-side testing to confirm that no effect on magnitude of the residues was caused by the salt formulation type of the dicamba. The tolerances listed below are based on the maximum expected residue from geographically representative field trial data:

Proposed tolerances for combined residues of the herbicide dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-*o*-anisic acid in or on the raw agricultural commodities as follows 40 CFR 180.227(a): Cottonseed 3.0 parts per million (ppm); Corn, forage 3.0 ppm; Corn, fodder 3.0 ppm; Crop Group 17, Grass forage, fodder and hay Forage 125 ppm, Hay 200 ppm; Wheat, forage 80 ppm, Wheat, hay 20 ppm; 21 U.S.C. section 701 MRL Cottonseed meal 5.0 ppm; Wheat grain 2 ppm, Wheat straw 30 ppm; Barley grain 2 ppm; Barley straw 30 ppm.

Proposed tolerances for combined residues of the herbicide dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-2-hydroxybenzoic acid in or on the raw agricultural commodities as follows 40 CFR 180.227(b): Soybean grain 4 ppm, Soybean hulls 13 ppm; Asparagus 3.5 ppm.

Only newly generated data, or data not implicated in the CRAVEN Laboratories indictment are used to support the subject petitions.

Dicamba residues concentrate in the following commodities: soybean hulls; sugarcane molasses; cottonseed meal.

ii. *Animal*. The amended uses proposed do not yield secondary residues in meat and milk above the tolerances already published under 40 CFR 180.227. Data from metabolism and feeding studies in poultry have established that the maximum expected dietary burden from crops treated with dicamba will not result in quantifiable residues above the limits of the analytical method.

B. Toxicological Profile

Data are provided that are representative of the mammalian toxicity effects of dicamba and are part of the many studies conducted to support the BASF Corp. assertion of safety of dicamba to humans.

1. *Acute toxicity*—i. Oral Rat LD_{50}: 1,879 mg/kg (m); 1581 mg/kg (f).

ii. Acute Dermal Rat LD_{50}: > 2,000 kg/kg (m/f).

iii. Acute Inhalation Rat LC_{50}: > 9.6 mg/L (m/f).

iv. Primary Eye Irritation: Extremely irritating and corrosive to the eye.

v. Primary Dermal Irritation Rabbits: Not a primary skin irritant.

vi. Dermal Sensitization Guinea Pigs: Moderate potential to cause dermal sensitization.

vii. Acute Neurotoxicity: NOEL <300 mg/kg (lowest dose tested). Neurobehavioral effects were observed at all dose levels but primarily at the initial 1.5 hr post-dose testing only. No neurobehavioral effects were noted by day 14 after treatment and no neuropathological effects were found indicating there are no persistent effects on the nervous system.

2. *Genotoxicity*. Ames: Negative; *In vitro* chromosome aberration in Chinese Hamster Ovary: Negative; Sex-linked recessive lethal in Drosophila: Negative; Chromosome aberrations in rat bone marrow: Negative; Mitotic recombination: Negative; UDH (UDS with WI-38 human lung fibroblasts: Negative; DNA damage as detected with repair deficient prokaryote *E. coli*: Positive; DNA damage as determined with repair deficient eukaryote *S. typhimurium*: Negative; UDS in human lung lymphocytes with activation: Negative; Sister chromatid exchange in human cultured lymphocytes: slight increase. Overall weight of the evidence from all studies indicates that dicamba is not genotoxic.

3. *Reproductive and developmental toxicity*—i. *Rodent developmental toxicity rat*. Oral doses of 0, 64, 160, or 400 mg/kg were administered daily during gestation days 6 to 19. Maternal toxicity occurred at the high dose as evidenced by mortality of four animals, clinical signs and decreased weight gain. The numbers of implantations, resorptions, and fetuses for test animals were similar to those numbers for control animals. No fetal abnormalities were attributed to exposure to dicamba. Therefore, technical dicamba was not found to be teratogenic. Maternal toxicity was found only at the HDT with a NOEL of 160 mg/kg/day. The developmental NOEL was the highest dose tested of 400 mg/kg/day.

ii. *Rabbit developmental toxicity*. Dicamba was administered orally (undiluted) via capsule to groups of 20 artificially inseminated New Zealand White rabbits at dose levels of 0, 30, 150, or, 300 mg/kg on days 6-18 of presumed-gestation. Females were sacrificed on Day 29 of presumed gestation. Maternal toxicity occurred at 150 and 300 mg/kg/day as evidenced by clinical signs and either body weight loss or reduced weight gain. Abortions occurred at 150 and 300 mg/kg/day. No significant differences were obtained in litter averages for corpora lutea, implants, litter sizes, resorption sites, percent male fetuses, fetal body weight, percent resorbed conceptuses or number of does with any resorptions. No gross external, soft tissue or skeletal alterations in fetuses were considered to be related to treatment. Therefore, dicamba was found to be not teratogenic. The maternal no-observed-adverse-effect-level (NOAEL) for technical dicamba to pregnant rabbits was 30 mg/kg/day. Levels of 150 and 300 mg/kg caused abortions, but were at significant maternally toxic doses. The developmental NOAEL was the highest dose tested, 300 mg/kg/day.

iii. *Two-generation reproduction rat*. Potential effects on growth and reproductive performance were assessed over 2-generations of rats maintained on diets containing Technical Dicamba at concentrations of 0 (control), 500, 1,500,

or 5,000 ppm. Parental toxicity occurred at 5,000 ppm in the form of lower weight gain in females and increased liver weights of both sexes. Exposure at 5,000 ppm was associated with a slower growth rate of F1 pups prior to weaning and resulted in lower initial body weights in those selected as parental animals. The lower body weight was associated with a decrease in both food consumption and water intake. Sexual maturation was slightly delayed among males, but was likely associated with the initial reduced growth rate. F2 pup weights were reduced at 3,000 and 1,500 ppm. There were no treatment-related effects on reproductive ability at any level. The NOEL and LOEL for systemic toxicity were 1,500 (approx. 130 mg/kg/day) and 5,000 ppm, respectively. The NOEL and LOEL for pup toxicity were 500 (approx. 45 mg/kg/day) and 1,500 ppm, respectively.

4. *Subchronic toxicity*—i. *Twenty-one-day Dermal.* Technical dicamba was applied dermally to rabbits for 5 days a week for three weeks at dosage levels of 0, 100, 500 and 2,500 mg/kg/day. There were no systemic effects at any level of treatment. Skin irritation was evident at all treatment levels, but consisted of only a slight erythema at 100 mg/kg/day. The systemic NOEL was the highest dose tested of 2,500 mg/kg/day.

ii. *Thirteen-week rodent feeding (rat).* Rats were offered technical dicamba at dietary concentrations of 0, 1,000, 5,000, or 10,000 ppm. The mean body weight and food consumption values for the high dietary level animals were decreased from the control values. No adverse treatment-related findings were noted in either the blood parameters investigated or necropsy evaluation. Microscopic examinations of the liver revealed an absence or reduction of cytoplasmic vacuolation in the hepatocytes of the high dietary level animals. The NOEL was 5,000 ppm (342 mg/kg/day males, 392 mg/kg/day females).

iii. *Thirty-eight-week non-rodent (dog).* In a dose-range finding study for a subsequent chronic dog study, a small number of dogs were treated via the feed with technical dicamba at dosage levels of 0, 1,000, 2,500 and 5,000 ppm for four to eight weeks. Decreased food consumption occurred in all dose groups during the first week of treatment, and persisted in some dogs at 2,500 and 5,000 ppm. Decreased body weight gains or weight loss were noted in the treatment groups. The NOEL from the one-year dog study discussed below is used to satisfy the requirement for the subchronic dog NOEL.

iv. *Sub-chronic neurotoxicity.* Rats were fed technical dicamba for 13 weeks at dosage levels of 0, 3,000, 6,000 and 12,000 ppm. Body weights were slightly reduced in high dose animals. Neurobehavioral effects were noted at the high dose and consisted primarily of signs associated with rigidity in response to handing. No histopathological effects on the peripheral or central nervous system were noted. The neurotoxicity NOEL was established at 6,000 ppm (401 mg/kg/day males, and 472 mg/kg/day, females).

5. *Chronic toxicity*—i. *Chronic toxicity-dog.* Technical Dicamba was offered orally at dietary concentrations of 0 (Control), 100, 500, or 2,500 ppm to dogs for 1 year. Initially, a decrease in food consumption was noted mainly among males at 500 and 2,500 ppm. This was most notable in a single 2,500 ppm male resulting in almost no food consumed for the 1st 3 weeks of feeding. Following administration of the 2,500 ppm diet in a water slurry during weeks 4-6, this male was placed back on feed and food consumption stabilized. There appears to be a limit to the amount of material that can be added to the feed before dogs will not consume the diet. The 2,500 ppm level was considered close to the maximum that could be employed, as 1 dog failed to consume the diet when offered in the usual form. Due mainly to the aforementioned male, mean body weight of 2,500 ppm males did not increase until week 5. The overall body weight gain for the 1 year period was comparable for all groups. It was concluded that aside from the lower food consumption, there were no effects due to treatment with dicamba. The no-effect level for toxicity was the highest dose tested of 2,500 ppm (approx. 59 mg/kg/day males, 57 mg/kg/day females).

ii. *Chronic feeding/oncogenicity in rat.* Groups of 60 rats/sex were maintained on diets containing technical dicamba at concentrations of either 0, 50, 250, or 2,500 ppm. An interim sacrifice of 10/sex/level was conducted at 12 months. Initially scheduled as a 27 month (108 week) study, males were sacrificed at 115 weeks and females at 118 weeks due to high survival rates.

There were no effects due to treatment on any chronic toxicity parameters investigated. In males, no statistically significant differences in data for all tumors combined, all benign tumors combined, and all malignant tumors combined were obtained. A slight increase in malignant lymphoma was not statistically significant (pairwise comparisons) and was not considered to be toxicologically significant. A slight increase in thyroid parafollicular cell carcinoma in the high treatment group was noted but was not statistically significant in pairwise comparisons. In females, no statistically significant differences were noted in comparisons with all tumors combined, all benign tumors combined, and all malignant tumors combined or in any individual tumor type.

In summary, no signs of toxicity related to administration of dicamba were noted. Dicamba was not oncogenic. Based on the results of the study, the no effect level was considered to be 2,500 ppm (107 mg/kg/day males and 127 mg/kg/day females).

iii. *Oncogenicity in mice.* Groups of mice were fed diets containing dicamba at concentrations of 0, 50, 150, 1,000, or 3,000 ppm. Males were killed following 89 weeks of feeding and females were killed following 104 weeks of feeding. Reduced body weight gain (not statistically different) was noted among 3,000 ppm females. Increased mortality noted among 3,000 ppm males was considered unlikely to be related to treatment but could not be completely excluded. An increased incidence in lymphoid tumors, showing a statistical significance at 150 and 1,000 ppm, occurred in females. However, the incidence at 3,000 ppm did not statistically differ from control. Additionally, there was no significant trend with dosage and the values for treated females were within historical control data. The incidence of benign and malignant tumors in all tissues were similar for treated and control animals. The NOEL was determined to be 1,000 ppm (108 mg/kg/day in males and 121 mg/kg/day in females). However, the RfD best committee chose to establish the NOEL at 3,000 ppm and stated that no LOEL had been established.

6. *Estrogenic or other endocrine effects.* No specific tests have been conducted to determine endocrine-disrupting effects. However, extensive subchronic and chronic tests have been conducted in several species, and results have demonstrated no effects on the endocrine system.

7. *Animal metabolism.* Dicamba has been tested in rats, dogs, cattle, goats and hens. In all cases, dicamba is excreted very rapidly, mainly as unchanged dicamba and to a lesser extent as 3,6-dichloro-2-hydroxybenzoic acid with trace amounts of 3,6-dichloro-5-hydroxy-*o*-anisic acid. The results of these studies demonstrate that dicamba is not persistent and does not accumulate in animals.

8. *Metabolite toxicity.* Toxicity of the metabolites of dicamba to humans is concurrently evaluated during toxicity testing because both plant and animal

metabolites are formed during the course of toxicity tests. Both plant and animal major metabolites are considered not of toxicological concern.

C. Aggregate Exposure

1. *Dietary exposure.* Exposure from the use of Dicamba in the culture of wheat, barley, oats, millet, sorghum, corn, soybeans, grasses, cotton, sugarcane and asparagus crops is discussed under the below topics of food and drinking water.

2. *Food.* The subject petition amends these uses but does not add new crops. The potential dietary exposure of the population to residues of dicamba or its metabolites is calculated based on the Theoretical Maximum Residue Contribution (TMRC) for all crops with dicamba use. The TMRC is a worst case estimate of dietary exposure since it assumes that 100 percent of all crops for which tolerances are established are treated with dicamba, and that pesticide residues are present at the tolerance levels. The resulting dietary exposure estimate therefore overestimates exposure and is considered conservative. The number is then determined to be a percentage of the EPA decided Reference Dose (RfD). Dietary exposure may occur from crop commodities and meat and milk. Based on the EPA DRES model BASF Corp. has estimated that the average US population dietary exposure to dicamba to be only 1.87% percent of the RfD. This number is very low and considered very safe as an active ingredient is allowed up to 100% before less conservative risk assessment measures are initiated.

Acute dietary analysis compared the daily dietary exposure to the lowest NOEL for acute and subchronic studies. EPA's current policy for Tier I analysis uses the conservative assumption that all residues are at a high end estimate or maximum, typically taken as the tolerance value. Acute dietary assessment for dicamba is made by comparing the ratio of exposure and the NOEL from acute neurotoxicity of 300 mg/kg/day to achieve a Margin of Exposure (MOE). A MOE of 300 is required because a NOEL was not reached in the acute neurotoxicity test. The following MOE values are obtained for key population subgroups.

Population Subgroup	Margin of Exposure
US Population	6000
Infants <1 year	3000
Children 1 to 6	3000
Females 13+ years	17000
Males 13+ years	10000

3. *Drinking water.* Dicamba has been used commercially for in excess of 30 years. From available public data, detections in ground water from commercial uses have been very low and infrequent. The typical level found in ground water is less than 5 ppb. This should be compared to the current Health Advisory Level (HAL) of 200 ppb and the anticipated HAL of 3,000 ppb under the newly revised RfD of 0.45 mg/kg/d.

These infrequent and low levels of detection in groundwater demonstrate that significant movement of dicamba is not likely and is not a considerable factor in assessing human health risk.

4. *Non-dietary exposure.* Non-dietary exposure would mainly occur from the use of dicamba for broadleaf weed control on residential or recreational turf. BASF is currently collecting data on the potential exposure from non-dietary sources such as residential turf use. However, no reliable information is currently available for risk assessment at this time. This petition is only related to already approved crop uses and therefore non-dietary route of exposure is not considered to be a factor in assessing additional human risk.

D. Cumulative Effects

Dicamba belongs to the benzoic acid class of compounds. There are no other compounds of this class in significant use and none in food use. Therefore, cumulative effects from dietary or non-occupational exposure from pesticides of similar chemistry are considered unlikely. BASF Corp. does not have reliable data to indicate a common mechanism of toxicity to other compounds. Therefore cumulative effects from common mechanisms of action are also unlikely.

E. Safety Determination

The RfD for dicamba is 0.45 mg/kg/d. The RfD is a level at or below which daily aggregate exposure over a lifetime will not cause appreciable human health risk. The estimates of exposure are based on conservative assumptions that all crops with a tolerance for dicamba are treated and that all residues found are at the maximum or tolerance level.

1. *U.S. population.* Using the conservative assumptions described above, BASF Corp. has estimated that the US population dietary exposure to dicamba is 1.87% percent of the RfD.

2. *Infants and children.* Dicamba was not teratogenic in either rats or rabbits despite testing to maternally toxic doses. No developmental toxicity was observed in rats and the only effect observed in rabbits were abortions at clearly maternally toxic doses. Dicamba produced no effects on reproduction in a 2-generation study in rats. The only effect observed was a decrease in pup body weight at the high dose which also produced parental toxicity, and at the mid-dose that was relatively high (130 mg/kg/day). Based on the weight of evidence from all reproductive and developmental studies, no selective toxic efects on infants and children are expected, and no additional safety factor is warranted.

Using the conservative assumptions described above, BASF Corp. has estimated the dietary exposure to infants and children as percent of the RfD. From the current and new proposed use of dicamba dietary exposure for the most sensitive subgroups are 6.65% for non-nursing infants (<1 yr old) and 4.6% for children 1 to 6 yrs old.

Aggregate exposure due to the combined residues in food, drinking water and non-dietary exposure through direct contact with residues in a residential setting (lawn) should be pursued through the use of a reserve risk approach. The elements for consideration are therefore estimated as follows:

Food: Total Population 1.87%
Non-nursing Infants <6 yrs . . . 6.7%
Water/Lawn: Low human risk. . . . . .
expected to be inconsequential

BASF Corp. believes that the water and non-dietary exposure risk for the most sensitive subgroup is inconsequential due to demonstrated low findings in water relative to the HAL and low toxicity to humans with respect to oral, dermal and inhalation exposure.

Aggregate exposure is therefore estimated to be less than 10% of the RfD for the most sensitive population subgroup. Therefore, BASF Corp. concludes that there is reasonable certainty that no harm will result from aggregate exposure of residues of dicamba or its metabolites including all dietary and other non-occupational exposures.

F. International Tolerances

No international tolerances have been established under CODEX. Therefore there is no need to ensure consistency.

[FR Doc. 97–30813 Filed 11–25–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–776; FRL–5753–3]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–776, must be received on or before December 26, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The Regulatory Action Leader listed in the table below:

Regulatory Action Leader	Telephone Number/E-mail Address	Office Location/Address
Driss Benmhend	703–308–9525, e-mail: benmhend.driss@epamail.epa.gov.	5th floor CS#1, 2800 Crystal Drive, Arlington, VA 22202
Michael Mendelsohn.	703–308–8715, e-mail: mendelsohn.mike@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–776] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–776] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 18, 1997.

Janet Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Engelhard Corporation

PP 7E4908

EPA has received a pesticide petition (PP 7E4908) from Engelhard Corporation, 101 Wood Avenue, Iselin, NJ 08830, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a, to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of kaolin in or on all food commodities. Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Engelhard Corporation has submitted the following summary of information, data, and arguments in support of their pesticide petition.

A. Proposed Use Practices

Kaolin is to be used as an aid in control of damage to plants from insects, mites, fungi, and bacteria. Kaolin is used at the rates of 6.25 to 12.4 lbs/acre for row crop vegetables, 25 to 175 lbs/acre for tree fruit crops, and 12.5 to 37.5 lbs/acre for small fruit crops. Treatment is made prior to leaf or plant emergence and applied to crops at 7 to 10 day

intervals depending on the pest to be controlled. Dosage rates are applied with standard spray equipment.

B. Product Identity/Chemistry

Kaolin is a white, nonporous, nonswelling, natural occuring aluminosilicate mineral with the chemical formula $Al_4Si_4O_{10}(OH)_8$. Kaolin is one of the most highly divided and highly refined naturally occurring minerals. Median particle size of commercial products vary between 0.1 – 10 microns. Kaolin is nonreative. Its hydrophilic surface allows kaolin to be easily dispersed in water at neutral pH values of 6–8. Common physical properties of kaolin are: platy shape, high brightness (80–95), specific gravity 2.58–2.63, refractive index 1.56–1.62, and Mohs hardness 2–3.

C. Toxicological Profile

Acute toxicity. An acute oral toxicity limit test, acute dermal toxicity test on the active ingredient and an acute oral toxicity test, a primary skin irritation test, and primary eye irritation test on the end use product have been submitted. The acute oral limit dose test on the active ingredient showed that the single dose Acute Oral LD_{50} is greater than 5,000 mg/kg of bodyweight of rats. The acute dermal toxicity limit test on the active ingredient showed that the single dose Acute Dermal LD_{50} is greater than 5,000 mg/kg of bodyweight. The primary skin irritation study on the end use product showed that the test substance is classified as slightly irritating to the skin. The primary eye irritation study on the end use product showed that the test substance is classified as minimally irritating and non-irritating to the unrinsed and rinsed eye respectively.

Kaolin is used as an indirect food additive for paper/paper board dry food contact, adhesives, polymeric coatings, rubber articles, and cellophane. Kaolin is used in pharmaceuticals, tablet diluents, poultices, and surgical dusting powders. Kaolin is used as a cosmetic in face powders, face masks, and face packs. Kaolin is used in health products and toiletries, toothpaste, and antiperspirants. Kaolin can be used directly in foods as an anti-caking agent (up to 2.5%). Kaolin has GRAS (Generally Recognized as Safe) status under 21 CFR 186.1256 and is generally recognized as safe ''As an indirect human food ingredient with no limitation other than current good manufacturing practice.''

D. Aggregate Exposure

1. *Dietary exposure*. Dietary exposure of kaolin via food or water is difficult to estimate due to the use of kaolin in thousands of products. Kaolin is an inert mineral naturally occuring in the environment, and has no known toxicological effects.

2. *Non-dietary exposure, non-occupational exposure*. Increased non-dietary exposure of kaolin via lawn care, topical insect repellents, etc., is not applicable to this application.

E. Cumulative Exposure

Kaolin has no mode of toxicity and therefore cumulative exposure is not applicable. Kaolin is used in thousands of products as well as being a naturally occurring part of the environment. Cumulative exposure is not possible to calculate nor is it necessary due to the non-toxic nature of kaolin.

F. Endocrine Disruptors

Engelhard Corporation has no information to suggest that kaolin will adversely affect the immune or endocrine systems.

G. Safety Considerations

The lack of toxicity of kaolin is demonstrated by the above summary. Based on this information, the aggregate exposure to kaolin over a lifetime should not pose appreciable risks to human health. There is a reasonable certainty that no harm will result from aggregate exposure to kaolin residues. Exempting kaolin from the requirement of a tolerance should be considered safe and pose insignificant risk.

H. Analytical Method

An analytical method for residues is not needed as this petition requests an exemption from the requirement of a tolerance.

I. Existing Tolerances

Kaolin is exempted from the requirement of a tolerance ''when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.'' (40 CFR 180.1001).

The registrant does not know if international tolerance exemptions exist. (Driss Benmhend).

2. Plant Genetic Systems (America) Inc.

PP 7G4921

EPA has received pesticide petition (PP 7G4921) from Plant Genetic Systems (America), Inc., 7200 Hickman Road, Suite 202, Des Moines, IA 50322, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a temporary exemption from the requirement of a tolerance for residues of the plant-pesticide *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in corn for feed use only. The summary of the petition published in this notice was proposed by the petitioner. This request proposes to amend Experimental Use Permit, 70218–EUP–1, issued to Plant Genetic Systems (America), Inc. on February 5, 1997, issued under crop destruct conditions.

Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Plant Genetic Systems (America) has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Plant Genetic Systems (America) and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Bacillus thuringiensis subsp. *tolworthi* Cry9C Protein Uses

Corn plants have been protected from lepidopteran insect pests such as European corn borer *Ostrinia nubilalis* (Huber), by expressing a Cry9C protein. The Cry9C protein expressed by the corn plants corresponds to the insecticidal moiety of the Cry9C crystal protein of a *Bacillus thuringiensis* subsp. *tolworthi* strain. Transgenic corn plants, expressing Cry9C protein, represents an excellent addition to growers' options for insect control that reduces or eliminates the need for chemical inputs and fits well within an integrated pest management program.

B. Product Identity/Chemistry

The cry9C gene, was isolated from the *Bacillus thuringiensis tolworthi* strain, truncated and modified before it was stably inserted into corn plants. The tryptic core of the microbially produced Cry9C delta-endotoxin is similar to the Cry9C protein found in event CBH351. The Cry9C protein was produced and purified from a bacterial host, for the purposes of mammalian toxicity studies. Product analysis that compared the Cry9C protein from the two sources included: SDS-PAGE, Western blots, *N*-terminal amino acid sequencing, glycosylation tests (for possible post-translational modifications) and insect bioassays.

No analytical method is included since this petition requests a temporary exemption from the requirement of a tolerance.

C. Mammalian Toxicological Profile

Bacillus thuringiensis proteins have been used commercially for more than 30 years without any evidence for adverse health effects. *Bacillus thuringiensis* mode-of-action can be divided into a series of critical steps: ingestion by the insect, specific binding to brush border membrane receptors, membrane insertion, and pore formation thus destroying the midgut lining and causing death of the insect. *Bacillus thuringiensis* proteins do not bind or cause these types of effects to mammalian gut membranes. The extensive mammalian toxicity studies performed to support the safety of *Bacillus thuringiensis* - containing pesticides clearly demonstrate that the tested isolates are not toxic or pathogenic (McClintock, *et al.*, 1995, Pestic. Sci. 45:95–105). Although *Bacillus thuringiensis* strains have been used for decades as sprayable microbial products, no confirmed cases of allergic reactions have been documented, despite dermal, oral and inhalation exposures. A reference to this is made by the EPA in a **Federal Register** notice, dated August 16, 1995 (60 FR 42443) (FRL–4971–3).

The Cry9C protein insecticidal mode-of-action is apparently similar to that of the well known Cry1A proteins. In addition to the safe history of *Bacillus thuringiensis* proteins outlined above, several other studies were performed to evaluate mammalian safety of the Cry9C protein. An acute toxicological study was performed with mice, which demonstrated that the Cry9C protein had an LD_{50} >6,500 mg/kg. A test for *in vitro* digestibility under simulated gastric conditions showed that the Cry9C protein found in bacteria and the protein produced in plants was stable for 4 hours when exposed to simulated gastric juice. However, an amino acid sequence homology search performed using three different data banks (against 135,867 sequences) only found homology to other related *Bacillus thuringiensis* proteins. To determine possible short stretch homology, an 8-amino acid homology search was also performed. Except with the *Bacillus thuringiensis* proteins, no identical 8-amino acid peptide sequences could be detected in the searches. Therefore, it is unlikely that Cry9C protein would have significant allergenic potential.

The Cry9C protein or metabolites of the protein are not expected to interact with the immune or endocrine system, since the protein sequence does not match any known allergens or hormones. Since proteins, in general, are not known to be carcinogenic it is unlikely that the Cry9C protein would have carcinogenic properties.

All living organisms contain DNA and there are no examples of nucleic acids causing any toxicological effects from dietary consumption. The genetic material necessary for the production of the Cry9C protein in plants includes the genetic construct that encodes the Cry9C protein and all other necessary genetic elements for it's expression. These elements include: a promotor, polylinker sequences, leader sequences and terminators and none of which are expected to cause any toxicological effects.

Taken together, the data supports the lack of mammalian toxicological effects for the plant-pesticide *Bacillus thuringiensis* subsp. *tolworthi* Cry9C protein and the genetic material necessary for the production of this protein in corn for feed use only.

D. Aggregate Exposure

Since the Cry9C protein is expressed in plant tissues, dermal or inhalation will be negligible to non-existent. Drinking water is unlikely to be contaminated with Cry9C protein due to the rapid degradation of plant materials in the soil. Furthermore, no direct human dietary exposure to Cry9C protein will occur since this request is for animal feed use only.

E. Cumulative Effects

The unique mode-of-action of Bt proteins in general, coupled with the lack of mammalian toxicity for the Cry9C protein provides no basis for the expectation of cumulative effects with other compounds.

F. Safety Determination

Bt microbial pesticides containing Cry proteins have been applied for more than 30 years to food and feed crops consumed by the US population. There have been no human safety problems attributed to Cry proteins. The extensive mammalian toxicity studies performed to support the safety of *Bacillus thuringiensis* - containing pesticides clearly demonstrate that the tested isolates are not toxic or pathogenic (McClintock, et al., 1995, Pestic. Sci. 45:95–105). The lack of mammalian toxicity of the Cry9C protein provides support for our request of a temporary exemption from the requirement of a tolerance set forth in this petition. Non-dietary exposure of infants, children or the US population in general, to the Cry9C protein expressed in corn plant materials, are not expected due to the uses of this product for animal feed use only.

G. Existing Tolerances

No tolerances or tolerance exemptions have been granted for the *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in corn for feed use only. (Michael Mendelsohn)

[FR Doc. 97–31131 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–779; FRL–5755–6]

Notice of Filing of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–779, must be received on or before December 26, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m.,

Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: James Tompkins, Registration Division (7505C) Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 265, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-7801; e-mail: tompkins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–779] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF–779] and appropriate petition number. Electronic comments on notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 4, 1997

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Rhone-Poulenc Ag Company

PP 3F4233

EPA has received a pesticide petition (PP 3F4233) from Rhone-Poulenc Ag Company, 2 Alexander Drive, Research Triangle Park, NC 27709, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to extend the current time-limited tolerances for bromoxynil and its metabolite DBHA (3,5-dibromo-4-hydroxybenzoic acid) resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton in or on the raw agricultural commodities undelinted cottonseed at 7 parts per million (ppm), cotton gin byproducts at 50 ppm, and cotton hulls at 21 ppm for a 1–year period and to increase the current acreage limitation from 3% to 10% of the U. S. cotton acreage (1,300,000 acres). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The nature of the bromoxynil residue in bromoxynil-tolerant cotton is considered to be adequately understood. The two major components of the terminal residue are parent bromoxynil and the metabolite 3,5-dibromo-4-hydroxybenzoic acid (DBHA).

2. *Analytical method*. Adequate analytical methodologies for both parent bromoxynil and the DBHA are available for enforcement purposes. The method involves sample reflux in methanolic KOH, partitioning with ether/hexane and analysis by Gas Chromatography. Limits of quantitation allow monitoring of residues in cotton commodities at or above tolerance levels. Multiresidue testing with DBHA has been conducted and submitted to FDA.

3. *Magnitude of residues*. Available magnitude of the residue data from a 60 day phi crop field residue study conducted at a maximum application rate of 4.5 lb active ingredient/acre indicate that the currently established time-limited tolerances for bromoxynil and DBHA will not be exceeded when Buctril 4EC herbicide is used according to approved label directions.

B. Toxicological Profile

1. *Acute toxicity*. A complete battery of acute toxicity studies for bromoxynil (phenol) has been conducted. The acute oral toxicity study in rats resulted in a LD_{50} of 81 milligrams/kilogram (mg/kg) (males) and a LD_{50} of 93 mg/kg (females). The acute dermal toxicity study in rabbits resulted in a LD_{50} of >2,000 mg/kg for both males and females. The acute inhalation study in rats resulted in a LC_{50} of 0.269 milligram/liter (mg/L) for males and 0.150 for females. The primary eye irritation study showed corneal opacity resolved within 3 days, iritis resolved within 4 days and conjuctival irritation which persisted for 10 days. There was no irritation in the primary dermal irritation study and the dermal sensitization study in guinea pigs was negative.

2. *Genotoxicty*. Mutagenicity studies conducted include an unscheduled DNA synthesis study-rat primary hepatocytes (negative); *in vitro* transformation assay-mouse cells (negative); sister chromosomal exchange study-CHO cells (negative); forward mutation study-mouse lymphoma cells (negative without activation and positive with activation); DNA repair test-*E. Coli* (positive); *in vitro* chromosomal aberration (negative without activation and positive with activation); two separate micronucleus assays (both negative); forward mutation-CHO cells (negative); and *Salmonella typhimurium* reverse mutation assay (negative with and without activation). Rhone-Poulenc considers bromoxynil (phenol) and DBHA to be non-mutagenic.

3. *Reproductive and developmental toxicity*. A teratology study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 4, 12.5, or 40 mg/kg/day. The maternal no-observed-effect level (NOEL) and lowest-observed-effect level

(LEL) are 12.5 and 40 mg/kg/day respectively. The developmental NOEL and LEL are 4.0 and 12.5 mg/kg/day, respectively. Maternal body weights and food consumption were reduced in the high dose group. Fetal effects observed were reduced body weight, with associtaed decreases in ossification. An increase in 14th ribs was observed in the mid and high dose levels. A teratology study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 5, 15, or 35 mg/kg/day. The maternal NOEL and LEL are 5.0 and 15 mg/kg/day, respectively. The fetotoxicity and developmental NOEL and LEL are less than 5 and 5 mg/kg/day, respectively. Significant maternal mortality and decreased body weight gain were associated with the high dose, indicating that the maximum tolerance dose was exceeded. Decreases in maternal body weight gain were also observed in the mid and low dose levels. At the mid-dose level a statistically significant increase in the number of fetuses with supernumerary ribs, a common fetal variant was observed. A teratology study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 1.7, 5, or 15 mg/kg/day. The maternal NOEL and LEL are 5 and 15 mg/kg/day, respectively. The developmental NOEL and LEL are 5 and 15 mg/kg/day, respectively. This study was classified as unacceptable, primarily due to reporting deficiendies. A teratology study was conducted with rabbits administered (orally) bromoxynil phenol at dose levels of 0, 15, 30, or 60 mg/kg/day. The maternal NOEL and LEL are 15 and 30 mg/kg/day, respectively. The developmental NOEL and LEL are less than 15 and 15 mg/kg/day, respectively. Significant body weight gain decrements were reported at the two highest dose levels along with observed decreases in food consumption. The severe maternal toxicity among high dose dams was associated with fetoxicity and teratogenicity. A slight, nonsignificant increase in supernumerary ribs was reported at the mid and low dose levels. A teratology study was conducted with mice administered (orally) bromoxynil phenol at dose levels of 0, 11, 32, or 96 mg/kg/day. Maternal mortality was observed at 32 and 96 mg/kg/day. Fetal body weight was decreased at the top dose level, associated with a decrease in caudal vertebral ossification and an increase in supernumerary ribs. The maternal NOEL and LEL are 11 and 32 mg/kg/day respectivel. The developmental NOEL and LEL are 32 and 96 mg/kg/day, respectively.

A reproduction study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0. 0.8, 4, or 21 mg/kg/day in the diet. The systemic adult rat NOEL is 4 mg/kg/day and the LEL is 21 mg/kg/day. The reproductive NOEL is 21 mg/kg/day, and the LEL is greater than 21 mg/kg/day. The postnatal developmental NOEL is 4 mg/kg/day, and the LEL is 21 mg/kg/day. Body weight gain decrements were reported. However, no adverse effects on fertility, fecundity, reproductive performance or pre and postnatal development were observed. A reproduction study was conducted with rats administered (orally) bromoxynil phenol at dose levels of 0, 1.5, 5, or 15 mg/kg/day in the diet. The systemic rat NOEL is 1.5 mg/kg/day, and the LEL is is 5 mg/kg/day. The reproductive NOEL is 15 mg/kg/day, and the LEL is greater than 15 mg/kg/day. The offspring developmental NOEL is 5 mg/kg/day and the LEL is 15 mg/kg/day. Body weight gain decrements were reported. However, no adverse effects on fertility, fecundity, reproductive performance or pre and postnatal development were observed.

Based on the studies discussed above, it is concluded that bromoxynil is not teratogenic at doses that are not maternally toxic. In addition, bromoxynil is not considered a reproductive toxicant and shows no evidence of endocrine effects.

4. *Subchronic toxicity*. In a 12–week range-finding study, bromoxynil (phenol) was administered in the diets of male and female CD-1 mice at dose levels of 0, 1.3, 3.9, 13, 39, 130, or 390 mg/kg/day. For male mice, the NOEL is 3.9 mg/kg/day and the LOEL is 13 mg/kg/day based on increased liver weights and hepatocellular hypertrophy. In female mice, the NOEL is 13 mg/kg/day and the LOEL is 39 mg/kg/day based on increased liver weights, hepatocellular hypertrophy, hepatocellular degeneration, and hepatocellular vacuolization. In a 13–week subchronic feeding study, bromoxynil (phenol) was administered in the diet to male and female Sprague-Dawley rats at dose levels of 0, 28, 58, or 168 mg/kg/day. For male rats, the NOEL is 28 mg/kg/day and the LOEL is 58 mg/kg/day based on decreased body weight gain, increased ALT and increased alkaline phosphatase. For female rats, no NOEL was determined in this study and the LOEL is 35 mg/kg/day based on decreased body weight gain. In a 13–week range-finding study, bromoxynil (phenol) was administered orally to male and female dogs at doses of 0, 1, 5, 8, 12, 16, 20, 30, 40, or 50 mg/kg/day. For males, no NOEL was determined and the LOEL is 1 mg/kg/day based on decreased body weight gain. For females, the NOEL is 1 mg/kg/day and the the LOEL is 5 mg/kg/day based on decreased body weight gain, panting and liquid feces. In a 21 day subchronic dermal study, bromoxynil (phenol) was applied to skin of male and female New Zealand white rabbits at doses of 0, 30, 300, or 1,000 mg/kg/day for 6 hours/day, 5 days/week. Treatment produced no observable dermal or systemic toxicity, therefore the NOEL is 1,000 mg/kg/day.

5. *Chronic toxicity*. A 1–year oral study was conducted with dogs administered bromoxynil (phenol) at dose levels of 0, 0.1, 0.3, 1.5, and 7.5 mg/kg/day in capsules. The NOEL/LEL is 1.5 mg/kg/day for both females and males based on decreased body weight gain, decreased RBC count, decreased hemoglobin, decreased PCV, and increased liver weights. The chronic dog study was determined by Rhone-Poulenc to be the most appropriate study for setting the Reference Dose (RfD) of 0.015 mg/kg/day (includes a hundredfold safety factor).

A 2–year combined chronic toxicity/carcinogenicity study was conducted with rats administered (oral) dosages of 0, 60, 190, or 600 ppm (0, 2.6, 8.2, or 28 mg/kg/day in males; 0, 3.3, 11.0, or 41 mg/kg/day in females) bromoxynil phenol in the diet. In males the no-observed-effect-level (NOEL) for systemic toxicity is 2.6 mg/kg/day, and the lowest-effect-level (LEL) is 8.2 mg/kg/day. In females, the NOEL is 3.3 mg/kg/day, and the LEL is 11.0 mg/kg/day. This study did not demonstrate any increase in tumor incidences in either male or female rats.

A 2–year combined feeding/carcinogenicity study was conducted with rats administered bromoxynil phenol in the diet at dose levels of 0, 10, 30, or 100 ppm (0, 0.5, 1.5, or 5 mg/kg/day). In both males and females, the NOEL and LOEL for systemic toxicity was 5 mg/kg/day and >5 mg/kg/day, respectively. At the highest dose tested, increased liver weights were observed at 12 months, but not at 24 months. This study was considered negative for carcinogenicity. An 18 month carcinogenicity study was conducted with mice administered bromoxynil phenol at dose levels of 0, 10, 30, or 100 ppm (0, 1.3, 3.9, or 13 mg/kg/day) in the diet. For males, dose related increases in hyperplastic nodules and liver adenomas/carcinomas were observed which were statistically significant at the 100 ppm. Increased relative liver weights were also observed. In females,

increased absolute liver weights and relative liver and kidney weights were observed. The study was considered negative for carcinogenicity for females. An 18 month carcinogenicity study was conducted with mice administered bromoxynil phenol at dose levels of 0, 20, 75, or 300 ppm (0, 3.1, 12 or 46 mg/kg/day in males and 0, 3.7, 14, or 53 mg/kg/day in females). Mice given 300 ppm had significantly increased absolute and relative liver weights. Histopathology of the liver revealed increased hepatocellular hypertrophy, hepatocellular degeneration, necrosis of individual hepatocytes, and pigment accumulation in hepatocytes and Kupffer cells. Male mice had statistically significant increased numbers of hepatocellular adenomas and carcinomas at 20 ppm, but not 75 ppm. In contrast, no significant increase in tumor incidence was observed for female mice by pair-wise analysis. The trend test was significant for adenomas or carcinomas in females, only at $p<0.05$, not $p<0.01$ as would be appropriate for this type of tumor. The trend is due entirely to the high dose group and therefore is of questionable validity. It is concluded that bromoxynil is a weak, single sex, single species, non-metastic, single target organ carcinogen, inducing hepatocellular tumors in male mice exposed to 300 ppm for 18 months. These tumors and associated histopathological findings are consistent with secondary mechanisms such as peroxisome proliferation, a mechanism known to have marked species differences and questionable relevance for humans. It is the opinion of Rhone-Poulenc that the data are not suitable for quantitative risk assessment. A threshold safety factor approach is more appropriate and is commonly used for single sex, single species carcinogens such as bromoxynil that are thought to work through secondary mechanisms. For the purposes of this tolerance petition, risk assessments have been performed using a low dose linear extrapolation model (Q_1* is 1.03×10^{-1}).

6. *Animal metabolism*. Results of a bromoxynil metabolism study with the rat (octanoate) demonstrated that 2 mg/kg of radiolabeled bromoxynil octanoate was rapidly absorbed, hydrolyzed to bromoxynil phenol, distributed, and excreted in rats following repeated oral administration. The urine was the major route of excretion, representing 80.24% of the administered dose in males and 67.91% in females at 7 days post-dosing. Tissue distribution was similar for both sexes with the highest radioactivity recovered in the liver and kidney. Similar results were obtained in a separate rat metabolism study conducted with bromoxynil heptanoate.

7. *Metabolite toxicology*. DBHA (3,5-dibromo-4-hydroxybenzoic acid) is a major plant metabolite of bromoxynil only in bromoxynil-resistant transgenic cotton. Acute oral toxicity testing with DBHA in rats resulted in an LD_{50} of >2,000 mg/kg. Acute dermal toxicity testing with DBHA in rabbits resulted in an LD_{50} of >2,000 mg/kg. The primary dermal irritation study with DBHA in rabbits indicated DBHA to be a slight irritant, and DBHA was not a dermal sensitizer in Guinea pigs. Mutagenicity studies conducted with DBHA include a Salmonella typhimurium reverse mutation assay (negative with and without activation); micronucleus assay (negative); and $TK^{+/-}$ mouse lymphoma assay (negative with and without metabolic activation). In subchronic feeding studies in the rat, DBHA was administered by oral gavage to groups of Sprague-Dawley rats for 28 days at dose levels of 25, 50, 100 and 250 mg/kg/day. No toxicologically meaningful changes were observed in any of the parameters measured in this study. The NOEL and LEL for this study were 250 and >250 mg/kg/day, respectively.

C. Aggregate Exposure

1. *Dietary (food) exposure*. For the purpose of estimating the potential human dietary exposure resulting from bromoxynil use on cotton under the existing tolerances, anticipated residues of bromoxynil and DBHA were used. Anticipated residue values of 1.44 ppm (cottonseed), 8.74 ppm (cotton gin trash), and 0.43 ppm (cottonseed meal) were derived by taking the mean residue values from available crop field trials conducted at the 4.5 lb/A broadcast rate and adjusting by a factor of 0.333 to extrapolate to the current 1.5 lb/A application rate. Adjusting these values for % dry matter and the proposed 10% of crop treated results in anticipated cotton feedstuff residue values of 0.14 ppm (cottonseed), 0.87 ppm (cotton gin trash), and 0.043 ppm (cottonseed meal). Based on the use of these exposure data and a unit risk (Q_1* (mg/kg/day)$^{-1}$, of bromoxynil of 1.03×10^{-1}, the upper-bound human risk estimate for the general (U.S.) population represented by all sources of bromoxynil exposure, including use on up to 10% of the U.S. treated acreage is approximately 2×10^{-6}.

2. *Drinking water*. There is no Maximum Concentration Level or Health Advisory Level established for bromoxynil under the Safe Drinking Water Act. Based on field dissipation studies demonstrating a short half-life of bromoxynil in the environment (average half-life of 3–7 days), bromoxynil residues will degrade in soil before residues can move downward into ground water. Therefore, no significant potential exists for bromoxynil residues to be present in drinking water from ground water. Likewise, contamination of drinking water supplies from bromoxynil movement through agricultural surface runoff is considered highly unlikely due to relatively low application rates and rapid degradation rates in soil. As demonstrated by available monitoring data, normal dilution and degradation processes will greatly reduce concentrations in surface water during movement from agricultural ditches near fields into streams of adequate size for use as drinking water. It is the conclusion of Rhone-Poulenc that the potential bromoxynil exposure derived from any use through drinking water is insignificant and does not significantly increase the aggregate risk assessment above that estimated to occur through food exposure alone.

3. *Non-dietary exposure*. The potential for non-occupational exposure to bromxynil among the general public is insignificant. There are no residential lawn or garden uses for bromoxynil products where the general population might be exposed via inhalation or dermal routes. Turfgrass use is restricted to non-residential areas. Exposure to bromoxynil following application to non-residential turfgrass is not likely to be significant in either time or duration. This use will therefore not significantly add to the aggregate exposure.

D. Cumulative Effects

There are no reliable data suggesting that any toxic effect that might be caused by bromoxynil would be cumulative with those of any other compound. Further, bromoxynil does not appear to produce a toxic metabolite that is produced by other substances. Therefore, consideration of potential cumulative effects is not appropriate at this time.

E. Safety Determination

1. *U.S. population*. Using the present RfD for bromoxynil of 0.015 mg/kg/day, it has been determined that aggregate chronic exposure to bromoxynil from all uses, including cotton, represents <1% of the RfD for all population sub-groups. A unit risk, Q_1* (mg/kg/day)$^{-1}$, of bromoxynil of 1.03×10^{-1} in human equivalents, has been calculated based on mouse liver tumors. It is the opinion of Rhone-Poulenc that the bromoxynil data are not suitable for quantitative risk assessment. A threshold safety factor approach is more appropriate and is

commonly used for single sex, single species carcinogens such as bromoxynil that are thought to work through secondary mechanisms. Nevertheless, the risk assessments filed with this petition have been performed using quantitative risk assessment methodology. Accordingly, the upper-bound risk estimate for the general U.S. population represented by all sources of bromoxynil exposure, including use of bromoxynil on up to 10% of the U.S. treated acreage is approximately 2×10^{-6}.

2. *Infants and children*. To estimate acute dietary risk for systemic effects other than developmental from food sources, an MOE of 270 was calculated using 1–day dietary exposure for infants (the most highly exposed population group) and a NOEL of 8 mg/kg/day derived from a 13–week oral toxicity study in dogs. It is concluded that reliable data support use of the standard hundredfold margin of exposure/safety factor in assessing the risk to children. The general U.S. population and all population sub-groups are estimated to be exposed at a level less than 1 percent of the bromoxynil RfD of 0.015 mg/kg/day. Both chronic and acute assessments show no appreciable threshold risks to children and the non-threshold cancer risk is no greater than negligible. Therefore, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to bromoxynil.

Two multi-generation rodent reproduction studies demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development. Maternal and developmental NOELs and LOELs were comparable indicating no increase susceptibility of developing organisms. No evidence of endocrine effects were noted in any study. It is therefore concluded that bromoxynil poses no additional risk for infants and children and no additional uncertainty factor is warranted.

F. International Tolerances

There are no Codex tolerances established for bromoxynil residues, therefore international compatibility is not considered to be an issue at this time.

[FR Doc. 97–30812 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5927–7]

Proposed Settlement Pursuant to Section 122(g) of the Comprehensive Environmental Response, Compensation, and Liability Act, Regarding the Sealand Restoration Superfund Site, Lisbon, New York

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed administrative settlement and opportunity for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9622(i), the U.S. Environmental Protection Agency (EPA), Region II, announces a proposed administrative *de minimis* settlement pursuant to section 122(g)(4) of CERCLA, 42 U.S.C. 9622(g)(4), relating to the Sealand Restoration Superfund Site (Site). The Site is located on Pray Road in the Town of Lisbon, St. Lawrence County, New York. This document is being published pursuant to section 122(i) of CERCLA to inform the public of the proposed settlement and give it the opportunity to comment. EPA will consider any comments received during the comment period and may withdraw or withhold consent to the proposed settlement if comments disclose facts or considerations which indicate that the proposed settlement is inappropriate, improper, or inadequate.

The proposed *de minimis* settlement between EPA and Westpoint Stevens Inc., on behalf of former Cluett, Peabody & Co. (Respondent) has been memorialized in an Administrative Order on Consent (Index Number CERCLA–97–0215). This Order will become effective after the close of the public comment period, unless comments received disclose facts or considerations which indicate the Agreement is inappropriate, improper, or inadequate, and EPA, in accordance with section 122(i)(3) of CERCLA, modifies or withdraws its consent to the Agreement. Under the Order, the Respondent will be obligated to make payments to the Hazardous Substance Superfund in reimbursement of EPA's response costs relating to the Site, plus a premium, based on documented volumes of substances in EPA's records associated with the Site, totaling $47,676.

Pursuant to CERCLA section 122(h)(1), the Order may not be issued without the prior written approval of the Attorney General or her designee. In accordance with that requirement, the Attorney General or her designee has approved the proposed administrative order in writing.

DATES: Comments must be provided on or before December 26, 1997.

ADDRESSES: Comments should be addressed to the U.S. Environmental Protection Agency, Office of Regional Counsel, New York/Caribbean Superfund Branch, 17th Floor, 290 Broadway, New York, New York 10007–1866, and should refer to: ''Sealand Restoration Superfund Site, U.S. EPA Index No. CERCLA–97–0215''. For a copy of the settlement document, contact the individual listed below.

FOR FURTHER INFORMATION CONTACT: Elizabeth Davis, Assistant Regional Counsel, New York/Caribbean Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007. Telephone: (212) 637–3165.

Dated: November 4, 1997.

William J. Muszynski,

Acting Regional Administrator.

[FR Doc. 97–31137 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–P

COUNCIL ON ENVIRONMENTAL QUALITY

Notice of Meeting; Postponement

SUMMARY: The Council on Environmental Quality (CEQ) is postponing a public meeting it had previously scheduled for December 2, 1997, to discuss development of a memorandum of understanding on coordinating environmental response actions with natural resource restoration under the Comprehensive Environmental Response, Compensation, and Liability Act and other laws. 62 FR 51660 (October 2, 1997). CEQ intends to reschedule the meeting for late January or early February, 1998. CEQ will soon publish another **Federal Register** notice identifying the time, place, and agenda for the meeting.

FOR FURTHER INFORMATION CONTACT: Mary Morton at (202) 208–3302.

Bradley M. Campbell,

Associate Director.

[FR Doc. 97–31031 Filed 11–25–97; 8:45 am]

BILLING CODE 3125–01–M

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 96–45; DA 97–2392]

Universal Service

AGENCY: Federal Communications Commission.

ACTION: Notice.

FOR FURTHER INFORMATION CONTACT: Diane Law, Common Carrier Bureau, Accounting and Audits Division, Universal Service Branch, (202) 418–7400, or via E-mail to ''dlaw@fcc.gov''.

SUPPLEMENTARY INFORMATION:

Released: November 13, 1997.

In this Public Notice, the Accounting and Audits Division announces the proposed universal service contribution factors for the first quarter of 1998.

In the *Universal Service Order* released on May 8, 1997, the Commission established new federal universal service support mechanisms consistent with the Telecommunications Act of 1934, as amended. (*See* Federal-State Joint Board on Universal Service, CC Docket No. 96–45, *Report and Order,* FCC 97–157 (62 FR 32862, June 17, 1997)). The Commission required all telecommunications carriers that provide interstate telecommunications services, providers of interstate telecommunications, and payphone service providers to contribute to the federal universal service support mechanisms. The Commission found that contributions for the schools, libraries, and rural health care programs would be based on interstate, intrastate, and international end-user telecommunications revenues. The Commission also found that contributions for the high cost, rural, and insular and low-income programs would be based on interstate and international end-user telecommunications revenues.

On July 18, 1997, the Commission released an Order directing the National Exchange Carrier Association (NECA) to create an independently functioning not-for-profit subsidiary, the Universal Service Administrative Company (USAC), through which it will administer temporarily certain aspects of the federal universal service support mechanisms. The Commission also directed NECA to create two independent, not-for-profit entities, Schools and Libraries Corporation and Rural Health Care Corporation, to administer certain aspects of the schools, libraries, and rural health care programs of the federal support mechanisms. The Commission instructed USAC, Schools and Libraries Corporation, and Rural Health Care Corporation to submit projections of demand and administrative expenses for their respective programs for the first quarter of 1998 to the Commission at least sixty days before the start of the first quarter of 1998. USAC also must compile total interstate, intrastate, and international end-user telecommunications revenues and submit that information to the Commission. The Commission stated that it would publish these figures and the proposed quarterly contribution factors in a Public Notice. (*See* Changes to the Board of Directors of the National Exchange Carrier Association, Inc., Federal-State Joint Board on Universal Service, *Report and Order and Second Order on Reconsideration,* FCC 97–253 (62 FR 41294, August 1, 1997)).

On October 31, 1997, USAC, Schools and Libraries Corporation, and Rural Health Care Corporation submitted projections of demand and administrative expenses for their respective programs for the first quarter of 1998. Those figures are as follows:

Program	Program demand (million)	Administrative expenses	Interest income	Total program costs (millions)
Schools and Libraries Program	$299.1	$2.7 million	($1.8 million)	$300.0
Rural Health Care Program	98.4	2.2 million	(605,000)	100.0
High Cost Program	434.0	1.1 million	(2.8 million)	432.3
Low Income Program	135.7	600,000	(900,000)	136.0
Totals	967.2	6.6 million	(6.1 million)	968.3

Based on information contained in the Universal Service Worksheets, FCC Form 457, USAC submitted the following information regarding end-user telecommunications revenues on November 13, 1997:

Total Interstate and International End-User Telecommunications Revenues from January 1, 1997–June 30, 1997: $35.001 billion;

Total Interstate, Intrastate, and International End-User Telecommunications Revenues from January 1, 1997—June 30, 1997: $89.827 billion.

To calculate the proposed quarterly contribution factors, the Bureau divided the combined total demand projections by the appropriate six-month contribution base. Based on USAC's recommendation, to account for possible uncollectible contributions and possible errors in the projections of demand and administrative expense, the Accounting and Audits Division decreased the contribution base totals submitted by USAC by two percent. Based on the figures submitted by USAC, Schools and Libraries Corporation, and Rural Health Care Corporation, the proposed contribution factors for the first quarter of 1998 are as follows:

Contribution factor for interstate and international end-user telecommunications revenues: 0.0166. This figure was calculated by dividing $568 million total projected demand for the high cost and low income programs by $34,301 million interstate and international end-user telecommunications revenues. $34,301 million is 98 percent of the reported $35.001 billion interstate and international end-user telecommunications revenues contribution base.

Contribution factor for interstate, intrastate, and international end-user telecommunications revenues: 0.0045. This figure was calculated by dividing $400 million total projected demand for the schools, libraries, and rural health care programs by $88,030 million interstate, intrastate, and international end-user telecommunications revenues. $88,030 million is 98 percent of the reported $89.827 billion interstate, intrastate, and international end-user telecommunications revenues contribution base.

If the Commission takes no action regarding the proposed contribution factors by November 28, 1997, the proposed contribution factors will be deemed approved by the Commission. Until November 28, 1997, the Commission reserves the right to modify

these contribution factors and set the projections of demand and administrative expenses at amounts that the Bureau determines will serve the public interest. Once the proposed contribution factors are deemed approved by the Commission or are modified and approved in a subsequent Public Notice, USAC shall use the approved contribution factors to calculate and bill first quarter universal service contributions. USAC will send all contributors a quarterly bill for the federal universal service support mechanisms in December of 1997. Contributors must submit their first quarter universal service contribution to USAC within thirty days of the date listed on their quarterly bill. Payments must be sent to the address specified on the quarterly bill.

Federal Communications Commission.

Timothy A. Peterson,

Deputy Division Chief, Common Carrier Bureau.

[FR Doc. 97–31116 Filed 11–24–97; 10:00 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collections Approved by Office of Management and Budget

November 20, 1997.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collections pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number. For further information contact Shoko B. Hair, Federal Communications Commission, (202) 418–1379.

Federal Communications Commission

OMB Control No.: 3060–0803.

Expiration Date: 05/31/98.

Title: Tariff Review Plan Revisions.

Form No.: N/A.

Respondents: Business or other for-profit.

Estimated Annual Burden: 16 respondents (estimated annual responses: 71); 25 hours per response (avg.); 1776 total annual burden hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: $0.

Frequency of Response: One-time requirement.

Description: In the Tariff Review Plan (TRP) Revision, the Commission initiates the necessary revisions to the TRPs under which incumbent price cap local exchange carriers (LECs) should make their access filing to take effect on January 1, 1998. This filing is necessary so that incumbent price cap LECs can adjust their rates in response to the *First Report and Order* (rel. May 16, 1997) and the *Second Order on Reconsideration* (rel. October 9, 1997) in CC Docket No. 96–262. Sections 201, 202, 203, 204 and 205 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 201, 202, 203, 204 and 205, require that common carriers establish just and reasonable charges, practices and regulations for the telecommunications services provided. The tariff schedules containing those charges, practices and regulations must be filed with the FCC, and the FCC is required to determine whether such schedules are just, reasonable, and not unduly discriminatory. The Commission is granted broad authority to require the submission of data showing the value of the property used to provide these services. 47 U.S.C. Section 213. Pursuant to its statutory mandate to assure just, reasonable, and nondiscriminatory charges for interstate telephone service, the FCC has adopted specific rules regarding the determination of the range of rates charged by local exchange carriers (LECs) to interexchange carriers (IXCs) transporting long distance calls. The IXCs use local networks of LECs to originate or terminate long distance calls. 47 CFR Part 69. The TRP material submitted by the Local Exchange Carrier is used by the FCC to determine whether its interstate access rates are just and reasonable as required by the Communications Act of 1934, as amended. Obligation to respond: mandatory. Contact Shoko Hair (202–418–1379) for copies of the TRP Revision displaying the OMB control number and expiration date and required PRA statements.

OMB Control No.: 3060–0804.

Expiration Date: 05/31/98.

Title: Universal Service—Health Care Providers Universal Service Program.

Form No.: FCC Forms 465, 466, 467, and 468.

Respondents: Business or other for profit.

Estimated Annual Burden: 15,400 respondents; 2.5 hours per response (avg.); 117,000 total annual burden hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: $0.

Frequency of Response: On occasion.

Description: The Telecommunications Act of 1996 (1996 Act) directed the Commission to initiate a rulemaking to reform our system of universal service by preserving and advancing universal service markets toward competition, and to benefit everyone. Congress placed on the Commission the duty to implement these principles in a manner consistent with the pro-competition purposes of the Act. To fulfill that mandate, on March 8, 1996, the Commission adopted a Notice of Proposed Rulemaking (NPRM) in CC Docket No. 96–45 implementing the Congressional directives set out in section 254 of the Communications Act of 1934, as amended by the 1996 Act. On May 8, 1997, the Commission adopted rules providing support for all telecommunications services, limited distance charges, and Internet access for all eligible health care providers. In an effort to implement these requirements and obligations the Commission has received OMB approval for the following forms to administer the health care providers universal service program: *FCC Form 465* ''Description of Services Requested and Certification.'' All health care providers requesting services eligible for universal service support must file a ''Description of Services and Certification'' form with the Administrator.

Filing this form is the first step a health care providers must take to participate in the universal service program. The Administrator will then post a description of the services sought on a website for all potential competing service providers to see and respond to as if they were requests for proposals (RFPs). 47 CFR 54.603(b)(2), 47 CFR 54.615(c). *FCC Form 466* ''Services Ordered and Certification.'' All health care providers ordering services that are eligible for universal service support must file a ''Services Ordered and Certification'' form with the Administrator. 47 CFR 54.603(b)(4). Form 466, ''Services Ordered and Certification,'' will be used to ensure health care providers have selected the most cost-effective method of providing the requested services as set forth in 47 CFR 54.603(b)(4). FCC Form 466 is also the means by which an applicant informs the Administrator that it has entered a contract with a telecommunications service provider for services that are supported under the universal services support program. The administrator must receive this form before it can commit universal service funds to support the services for which the applicant has contracted. *FCC Form 467* ''Receipt of Service Confirmation.''

All health care providers that are receiving supported telecommunications service must file this form with the Administrator. The data in the report will be used to ensure that health care providers are receiving the services they have contracted for with telecommunications service providers so that universal service support may be appropriate to the telecommunications service provider pursuant to 47 CFR 54.611. *FCC Form 468* ''Telecommunications Service Providers Support.'' All health care providers ordering services eligible for universal service support must file this form. The data in the report will be used to ensure that health care providers have calculated the amount of universal service support as set forth in 47 CFR 54.609(b). Telecommunications carriers must complete Form 468 by indicating the rural and urban rates for the services they have provided and the amount of the discount for which they must be reimbursed, and return it to the health care provider. The health care provider must attach it to Form 466 and file both forms with the administrator. These forms are used to administer the health care providers universal service program. The information is used primarily to determine eligibility. Obligation to respond: required to obtain or retain benefits. A Public Notice will be issued when the forms are available for public use.

OMB Control No.: 3060–0790.

Expiration Date: 11/31/2000.

Title: Availability of Inside Wiring Information—Section 68.110(c).

Form No.: N/A.

Respondents: Business or other for profit.

Estimated Annual Burden: 1200 respondents; 1 hours per response (avg.); 1200 total annual burden hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: $5000.

Frequency of Response: On occasion.

Description: Title II of the Communications Act of 1934, as amended, 47 U.S.C. Section 201 et al provides the statutory authority for the Commission to promulgate the rules and regulations contained in Part 68 of the FCC Rules, 47 CFR Part 68. Requirements in Part 68 are necessary to prevent the degradation of the telephone network. In CC Docket No. 88–57, Order on Reconsideration, Second Report and Order and Second Further Notice of Proposed Rulemaking (Order on Reconsideration) (released 6/17/97), the Commission amends Part 68 to require telephone companies to provide building owners with all available information regarding carrier-installed wiring on the customer's side of the demarcation point, including copies of existing schematic diagrams and service records, shall be provided by the telephone company upon request of the building owner or agent thereof. The telephone company may charge the building owner a reasonable fee for this service, which shall not exceed the cost involved in locating and copying the documents. In the alternative, the telephone company may make these documents available for review and copying by the building owner. In this case, the telephone company may charge a reasonable fee, which shall not exceed the cost involved in making the documents available, and may also require the building owner to pay a deposit to guarantee the documents' return. The FCC is requiring the disclosure of drawings and schematics of existing carrier-installed wiring for duplication by building owners or their agents for a reasonable fee to be determined by the carrier. Building owners will be able to contract with a installer of their choice for maintenance and installation service, or elect to contract with the telephone company to modify existing wiring or assist with the installation of additional inside wiring. See 47 CFR 68.110. Obligation to respond: Required to obtain or retain benefits.

Public reporting burden for the collections of information is as noted above. Send comments regarding the burden estimate or any other aspect of the collections of information, including suggestions for reducing the burden to Performance Evaluation and Records Management, Washington, D.C. 20554.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 97–31301 Filed 11–25–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 97–2430; CC Docket No. 90–571]

Notice of Telecommunications Relay Services (TRS) Applications for State Certification Accepted

Released: November 20, 1997.

Notice is hereby given that the state listed below has applied to the Commission for State Telecommunications Relay Service (TRS) Certification. Current state certifications expire July 25, 1998. Applications for certification, covering the five year period of July 26, 1998 to July 25, 2003, must demonstrate that the state TRS program complies with the Commission's rules for the provision of TRS, pursuant to Title IV of the Americans with Disabilities Act (ADA), 47 U.S.C. § 225. These rules are codified at 47 CFR §§ 64.601–605.

Copies of applications for certification are available for public inspection at the Commission's Common Carrier Bureau, Network Services Division, Room 235, 2000 M Street, N.W., Washington, D.C., Monday through Thursday, 8:30 AM to 3:00 PM (closed 12:30 to 1:30 PM) and the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C., daily, from 9:00 AM to 4:30 PM. Interested persons may file comments *on or before December 12, 1997.* Comments should reference the relevant state file number of the state application that is being commented upon. One original and five copies of all comments must be sent to William F. Caton, Acting Secretary, Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554. Two copies also should be sent to the Network Services Division, Common Carrier Bureau, 2000 M Street, N.W., Room 235, Washington, D.C. 20554.

A number of state TRS programs currently holding FCC certification have failed to apply for recertification. Applications received after October 1, 1997, for which no extension has been requested before October 1, 1997, must be accompanied by a petition explaining the circumstances of the late-filing and requesting acceptance of the late-filed application.

File No: TRS–97–39.

Applicant: Public Utilities Commission of Ohio, State of Ohio.

For further information, contact Al McCloud, (202) 418–2499, amccloud@fcc.gov, or Andy Firth, (202) 418–2224 (TTY), afirth@fcc.gov, at the Network Services Division, Common Carrier Bureau, Federal Communications Commission.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–30971 Filed 11–25–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of information collection to be submitted to OMB for review and

approval under the Paperwork Reduction Act of 1995.

SUMMARY: In accordance with requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the FDIC hereby gives notice that it plans to submit to the Office of Management and Budget (OMB) a request for OMB review and approval of the information collection system described below.

Type of Review: Renewal of a currently approved collection.

Title: Dispute Resolution Neutrals Questionnaire.

Form Number: 8000/01.

OMB Number: 3064–0107.

Annual Burden:

Estimated annual number of respondents: 100.

Estimated time per response: 0.5 hours.

Average annual burden hours: 50 hours.

Expiration Date of OMB Clearance: November 30, 1997.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, D.C. 20503.

FDIC Contact: Tamara R. Manly, (202) 898–7453, Office of the Executive Secretary, Room F–4022, Federal Deposit Insurance Corporation, 550 17th Street N.W., Washington, D.C. 20429.

Comments: Comments on this collection of information are welcome and should be submitted on or before December 26, 1997 to both the OMB reviewer and the FDIC contact listed above.

ADDRESSES: Information about this submission, including copies of the proposed collection of information, may be obtained by calling or writing the FDIC contact listed above.

SUPPLEMENTARY INFORMATION: The FDIC's Roster of Dispute Resolution Neutrals is part of its Alternative Dispute Resolution (ADR) program. Parties wishing to be considered for inclusion on the Roster must submit a completed questionnaire containing biological and demographic data. The information obtained from respondent is used to evaluate the candidate's qualifications to serve as neutrals in cases involving ADR.

Dated: November 21, 1997.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 97–31088 Filed 11–25–97; 8:45 am]

BILLING CODE 6714–01–M

FEDERAL HOUSING FINANCE BOARD

[No: 97–70]

Pilot Procedures and Pilot Proposal Initial Submission Guidelines

Whereas, the Federal Housing Finance Board (Finance Board) considers it appropriate to adopt a policy that provides procedures for processing and analyzing pilot programs proposed by the Federal Home Loan Banks;

Now therefore be it resolved that, the Finance Board hereby adopts the Pilot Procedures and Pilot Proposal Initial Submission Guidelines attached hereto.

Dated: November 12, 1997.

By the Board of Directors of the Federal Housing Finance Board.

Bruce A. Morrison,

Chairman.

The text of the Pilot Procedures and Pilot Proposal Initial Submission Guidelines follows:

Policy and Procedures For Pilot Proposals That Support Housing and Community Investment

Purpose: To establish procedures to be followed by staff of the Federal Housing Finance Board (Finance Board) in the processing and analysis of proposed Federal Home Loan Bank (Bank) pilot programs through which the Banks would make other investments that support housing and community development. These procedures shall apply also to the processing and analysis of proposed amendments to existing pilot programs. In establishing these procedures, it is the Finance Board's intent that the pilot review process proceed in an efficient, expeditious fashion at all stages.

Introduction: The Federal Home Loan Bank Act (Bank Act) provides that certain assets of each Bank not required for advances to members, may be invested in certain specified securities and investments. The Finance Board has implemented the investment provisions of the Bank Act through its regulations and the Financial Management Policy (FMP). Under Section 934.1 of the Finance Board's regulations and Section II.B.12 of the FMP, certain Bank investments that support housing and community development, and that are not specifically authorized under the FMP or otherwise, may be submitted to the Finance Board for approval. This policy establishes general procedures to be followed by Finance Board staff in reviewing pilot proposals or pilot amendment proposals (Proposal) for compliance with the statutory, regulatory, and FMP requirements.

References: 12 U.S.C. Sections 1431(g), 1431(h), and 1436(a); 12 CFR Section 934.1, of the Finance Board regulations; and Section II.B.12 of the FMP.

Procedures for Review of Proposals

I. Receipt of Proposal. Copies of a Proposal shall be distributed to Finance Board Directors and appropriate Finance Board staff.

II. Review of Proposal. The Office of Policy and the Office of General Counsel shall review the Proposal to ensure that it is complete and to determine whether there is evidence of a market for the proposal and whether it prima facie satisfies the FMP requirements (detailed below) and responds to the Finance Board's Pilot Proposal Submission Guidelines (Attachment).

III. FMP Requirements. Section II of the FMP specifies certain types of assets as permissible investments to the extent they are specifically authorized under 12 U.S.C. 1431(g), 1431(h), or 1436(a), or to the extent a Bank has determined that they are securities in which fiduciary or trust funds may be invested under the laws of the State in which the Bank is located. Other investments that support housing and community development are permitted, provided that the Bank:

A. Ensures the appropriate levels of expertise, establishes policies, procedures, and controls, and provides for any reserves required to effectively limit and manage risk exposure and preserve the Bank's and the Federal Home Loan Bank System's triple-A rating;

B. Ensures that the Bank's involvement in such investment activity assists in providing housing and community development financing that is not generally available, or that is available at lower levels or under less attractive terms;

C. Ensures that such investment activity promotes (or at the very least, does not detract from) the cooperative nature of the System;

D. Provides a complete description of the contemplated investment activity (including a comprehensive analysis of how the above three requirements are fulfilled) to the Finance Board; and

E. Receives written confirmation from the Finance Board, prior to entering into such investments, that the above investment eligibility standards and requirements have been satisfied.

IV. The Office of Policy and the Office of General Counsel shall identify any policy or legal issues or questions, identify and discuss with the Office of Supervision the management of any potential risks involved in the Proposal, discuss the Proposal with other staff as

necessary, call Bank personnel to clarify any uncertain or unclear aspects, and discuss issues or questions with the Director of the Office of Policy and the General Counsel, as appropriate.

V. If the Office of Policy and the Office of General Counsel deem the Proposal incomplete, staff shall contact the Bank and afford Bank officials the opportunity to submit the necessary additional information.

VI. If the Proposal is deemed complete by the Office of Policy and the Office of General Counsel but is not believed to meet the requirements of the FMP, the Director of the Office of Policy shall notify the Bank, either formally or informally, and afford the Bank the opportunity either to withdraw, modify, or insist upon the Proposal, as structured, being published for comment.

VII. If the Office of Policy and the Office of General Counsel determine that the Proposal is complete and appears to address the requirements of the FMP and all issues or questions are satisfactorily resolved, the Office of Policy and the Office of General Counsel shall draft a Notice for publication in the **Federal Register**. The Notice shall be a summary of the Proposal that is sufficiently detailed to allow meaningful comments from interested parties through a comment period. However, it need not contain the staff's analysis of whether or how the proposal meets the FMP requirements. Publication of a Notice does not imply any level of approval or support of the Proposal by the Finance Board. The Board of Directors of the Finance Board will not review and render a decision on the Proposal until after public comments received on the Proposal are reviewed and analyzed by staff, as is discussed below.

VIII. Prior to publication, the Office of Policy shall provide the Bank a copy of the section of the Notice that describes the Proposal and solicit the Bank's comments on the accuracy and completeness of the section.

IX. The Notice must be approved by the Director of the Office of Policy and the Office of General Counsel, with copies provided to the Directors of the Office of Supervision and the Office of Public Affairs, prior to going to the Executive Secretariat and then to the Managing Director for signature.

X. After publication of the Notice in the **Federal Register**, the Office of Policy and the Office of General Counsel shall respond to calls from the general public concerning the Proposal. The Office of Policy may answer questions about the program but requests for written information should be referred to the Office of General Counsel.

XI. The Office of Policy and the Office of General Counsel shall analyze comments received and discuss them with other Finance Board staff as necessary.

XII. To the extent necessary and appropriate, the Office of Policy or the Office of General Counsel shall contact the Bank and request a response to the issues or questions raised by commenters.

XIII. Following publication of the Notice, the Bank shall submit to the Finance Board proposed policies and procedures to address risks inherent in its proposed pilot program (e.g., credit risk, market risk, interest rate risk, and other risks).

XIV. Prior to Finance Board consideration, the Office of Policy and the Office of General Counsel shall review the proposed policies and procedures submitted by the Bank; the Bank's identification of, and plans for, managing risk; and the adequacy of expertise and number of staff planned by the Bank for its proposed pilot program. If necessary, staff may request additional information, clarification, etc.

XV. Following review and analysis of the Proposal, public comments received, and the above three factors, the Office of Policy and the Office of General Counsel, in consultation with the Office of Supervision, shall make a determination as to whether to recommend approval or disapproval to the Board of Directors of the Finance Board. The following shall result from this determination:

A. A briefing shall be held for Finance Board Directors regarding the Proposal and staff's recommendation.

B. A Board package shall be prepared for the Proposal and include the staff's recommendation and a summary of public comments.

C. Finance Board staff shall present the Proposal and their recommendation to the Board of Directors of the Finance Board.

XVI. The Board of Directors of the Finance Board will take action on the Proposal. If approved, the Board resolution approving the Proposal shall indicate that the approval is subject to the pilot program passing a safety and soundness examination conducted by the Office of Supervision.

XVII. The Office of Policy shall prepare a letter for signature by the Chairman or Managing Director to inform the Bank of the Finance Board's decision on the Proposal.

XVIII. If the Board of Directors has approved the Proposal, program implementation shall be contingent upon confirmation by the Office of Supervision that the appropriate program policies, procedures, and controls have been implemented by the FHLBank.

Pilot Proposal Initial Submission Guidelines

The following criteria should be addressed and included in a Bank's pilot proposal or pilot amendment proposal (Proposal) submitted to the Finance Board for approval.

1. *Board Resolution:* A resolution from the Bank's board of directors approving the Proposal and authorizing its submission to the Finance Board.

2. *Description of Proposal:* A complete description and discussion of the Proposal, including each of the following:

a. Overall goals and objectives
b. Pilot size and basis for determination
c. Pilot operations
d. Profitability goals and timeline
e. The marketplace: Potential competitors (size, sophistication, typical staffing, expertise, etc.) typical margins, historical loss experience, and whether marketplace is expanding or contracting and why.
f. Discuss which components of the program the Bank will have to create, hire, etc. This could include personnel, management, policies, procedures, hardware, software, facilities, etc.
g. How the Proposal would benefit membership
h. Expected benefits for the end user of the pilot product
i. Identification and management of potential risks
j. Explanation/basis for loan loss or risk reserves anticipated

3. *Compliance Authorization Criteria:* Explanation of how the Proposal meets the requirements of Section II B.12 of the Finance Board's Financial Management Policy. Please provide specific responses for each subpart. This should also include a legal opinion that the proposed activity may be legally authorized by the Finance Board.

4. *Pilot Documentation, Support and Reporting:* Discussion of anticipated program documentation, support, and reporting, including each of the following:

a. Evidence of a market for the pilot product. This could include letters of support from anticipated participants, market surveys, etc., and should include anticipated participants' estimates of the dollar volume of their participation within the first three years of the program.

b. Examples of required documentation between the Bank, members and other related counterparties, as well as any legal agreements drafted for the pilot.

c. The management structure for operating the pilot program. Identify the management, staff and directors who will be assigned to oversee and operate the pilot and discuss their expertise. Their resumes should be included with the Proposal. Discuss what additional personnel will need to be hired.

d. A listing, description, and examples of management reports necessary to adequately monitor ongoing pilot activities.

5. *Measurement of Pilot Success:* A discussion of criteria the Bank intends to utilize to measure the success of the program, such as:

a. When the Bank anticipates reviewing the program and making a decision on whether to seek permanent or other status for the pilot.

b. The existence of a sunset provision.

c. The factors or conditions that might trigger a decision to terminate the pilot.

[FR Doc. 97–30964 Filed 11–25–97; 8:45 am]

BILLING CODE 6725–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984.

Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, N.W., Room 692. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, by December 8, 1997.

Agreement No.: 202–008900–063.

Title: The ''8900'' Lines Agreement.

Parties:

The National Shipping Company of Saudi Arabia
United Arab Shipping Company (S.A.G.)
DSR-Senator Lines
A.P. Moller-Maersk Line
Sea-Land Service, Inc.
P&O Nedlloyd Limited

Synopsis: The proposed modification to Article 14 of the Agreement authorizes any party or any group of parties to enter into individual service contracts and deletes the current prohibition on such contracts. The modification also expands and clarifies current guidelines applicable to service contracts.

Agreement No.: 217–011595.

Title: TBS/Oceanica Space Charter Agreement.

Parties:

TBS North America Liner, Ltda. (''TBS'')
Comercial Maritima Oceanica Ltd. (''Oceanica'')

Synopsis: The proposed Agreement authorizes Oceanica to charter space to TBS on a maximum of six vessels it will operate from United States ports, and U.S. inland and coastal points served via such ports, to ports and points in Central America, South America and the Caribbean Sea. It also authorizes the parties to agree on transshipment arrangements and to cooperate with respect to terminals and equipment.

Dated: November 20, 1997.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 97–30978 Filed 11–25–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

[Docket No. 97–22]

Bermuda Container Line Ltd. v. SHG International Sales Inc. FX Coughlin Co., and Clark Building Systems, Inc., Notice of Filing of Complaint and Assignment

Notice is given that a complaint filed by Bermuda Container Line, Ltd., (''Complainant'') against Respondents SHG International Sales Inc. (''SHG''), FX Coughlin Co. (''Coughlin''), and Clark Building Systems, Inc. (''Clark'') was served November 20, 1997. Complainant alleges that (1) Respondent SHG violated sections 8 and 23 or, alternatively, section 19, and section 10(a)(1) of the Shipping Act of 1984 (''the Act''), 46 U.S.C. app. §§ 1707 and 1721 or 1718, and 1709(a)(1), by failing to file a non-vessel operating common carrier (''NVO'') tariff or bond or performing freight forwarding services without a forwarder license, and by concealing the identity of the shipper with respect to a shipment from Clark, PA to Bermuda, entering into a credit agreement with no intention of paying the freight and misrepresenting itself as the shipper; (2) Respondent Coughlin violated section 19 of the Act and 46 CFR §§ 510.21(c), (e) and (f), by falsely certifying it had processed the shipment's Bill of Lading (''BL'') when it knew or should have known that the BLs designated shipper (SHG) could not be a shipper, seeking a commission from Complainant by misrepresentation and permitting SHG to use Coughlin's forwarding license; and (3) Respondent Clark violated section 10(a)(1) of the Act by delivering cargo to Complainant when it knew or should have known that SHG had no tariff or NVO bond on file with the Commission and failing to inform Complainant of the facts or to pay the shipment's freight.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by November 20, 1998, and the final decision of the Commission shall be issued by March 22, 1999.

Joseph C. Polking,

Secretary.

[FR Doc. 97–31032 Filed 11–25–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 10, 1997.

A. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Wallace Company, Limited Partnership, Cheyenne, Wyoming; to

acquire voting shares of Farmers State Bankshares, Inc., Cheyenne, Wyoming, and thereby indirectly acquire Wyoming Bank & Trust, Cheyenne, Wyoming.

Board of Governors of the Federal Reserve System, November 20, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–30967 Filed 11–25–97; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, December 1, 1997.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: November 21, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–31151 Filed 11–21–97; 4:09 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

Performance Review Board; Membership; Senior Executive Service

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: Notice is hereby given of the names of the members of the Performance Review Board.

FOR FURTHER INFORMATION CONTACT: Gail T. Lovelace, Director of Human Resources, General Services Administration, 1800 F Street, N.W., Washington, DC 20405, (202) 501–0398.

SUPPLEMENTARY INFORMATION: Section 4313(c) (1) through (5) of Title 5 U.S.C. requires each agency to establish in accordance with regulations prescribed by the Office of Personnel Management, one or more Performance Review Board(s). The Board(s) shall review the performance rating of each senior executive's performance by the supervisor, along with any recommendation to the appointing authority relative to the performance of the senior executive.

Members of the Review Board are:

1. Thurman M. Davis, Sr. (Chairperson), Deputy Administrator.
2. Martha N. Johnson, Chief of Staff.
3. Dennis J. Fisher, Commissioner, Federal Technology Service.
4. Robert A. Peck, Commissioner, Public Buildings Service.
5. Frank P. Pugliese, Commissioner, Federal Supply Service.
6. G. Martin Wagner, Associate Administrator for Governmentwide Policy.

Dated: November 20, 1997.

Gail T. Lovelace,

Director of Human Resources.

[FR Doc. 97–31038 Filed 11–25–97; 8:45 am]

BILLING CODE 6820–BR–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0472]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for filing a petition for administrative stay of action.

DATES: Submit written comments on the collection of information by January 26, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502 (3) and 5 CFR 1320.3 (c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506 (c) (2) (A) of the PRA (44 U.S.C. 3506 (c) (2) (A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Petition For Administrative Stay of Action—21 CFR Part 10.35 (OMB Control Number 0910—0194)—Reinstatement

Section 10.35 (21 CFR 10.35), issued under the authority of section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may file a petition for an administrative stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Such a petition must: (1) Identify the decision involved; (2) state the action requested—including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. The information provided in the petition is used by the agency to determine whether the requested stay should be granted.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.35	7	1	7	100	700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible for processing the filing of petitions for administrative stays of action estimate that seven such petitions are received by the agency annually, with each requiring approximately 100 hours of preparation time.

Dated: November 19, 1997

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30982 Filed 11–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0396]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by December 26, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reports of Corrections and Removals for Manufacturers, Importers, and Distributors of Medical Devices (21 CFR 806.10 and 806.20).

In a final rule published in the **Federal Register** of May 19, 1997 (62 FR 27183), FDA issued regulations requiring that manufacturers, importers, and distributors of medical devices report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act (the act) that could present a risk to health. The collection of this information is required by section 519(f) of the act (21 U.S.C. 360i(f)). These regulations will help FDA to protect the public health by ensuring that the agency has current and complete information regarding those actions taken to reduce risks to health caused by devices. Reports of such actions will improve the agency's ability to evaluate device-related problems and to take prompt action against potentially dangerous devices.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20	440	1	440	10	4,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the final rule (62 FR 27183), the agency requested comments on the information collection provision of the new regulation. The 60-day comment period closed July 18, 1997. The agency received four comments. Comments received in response to the information collection provisions stated that: (1) The U.S. designated agent provisions should be reinstated; (2) the definition of risk to health is confusing and contradictory, and it raises the threshold of reports of corrective and removal actions to that of a voluntary recall, and as such will de facto result in the automatic classification of these reports as recalls; (3) FDA has underestimated the reporting burden; and (4) the recordkeeping requirements place undue burden on industry.

FDA disagrees with these comments. As discussed in the May 1997 final rule requiring reports of corrections and removals, FDA published a final rule staying the U.S. designated agent provisions of the medical device reporting (MDR) rule in the **Federal Register** of July 23, 1996 (61 FR 38346). FDA stayed those provisions in response to serious concerns on the part of regulated industry that the agency had not adequately considered the costs to and administrative burden on foreign firms. The same concerns apply to the U.S. designated agent provision included in the proposed rule to require reports of corrections and removals (59 FR 13828, March 23, 1994). FDA omitted that provision in the final rule (62 FR 27183) to allow the agency to continue to consider industry's concerns. The agency has not announced its decision on whether it will reinstate U.S. designated agent provisions in MDR or the corrections and removals rule, but intends to do so in the future.

FDA does not believe that the definition of ''risk to health'' in the corrections and removals rule is confusing or contradictory. The agency and manufacturers have used this same definition successfully under part 7 (21 CFR part 7), the voluntary recall rule, for over 20 years. Moreover, by using the definition of ''risk to health'' that appears in the voluntary recall rule, the agency believes that it has established an appropriate threshold for requiring reports of removals and corrections. The definition the agency adopted in the final rule is narrower than the one that appeared in the proposed rule and eliminates the burden on manufacturers of having to report corrections of minor or very remote health risks. Adoption of this definition does not affect recall procedures under part 7, which remain voluntary.

The agency does not believe that the reporting burden for reports of corrections and removals has been underestimated. The agency revised the reporting and recordkeeping burden estimate in the final rule upward based on a review of voluntary reporting data and industry complaint files. The comments did not submit any specific data as to what they believe to be the true costs of the rule.

The agency disagrees with the comment that recordkeeping requirements place an undue burden on industry. The statute requires manufacturers to keep records of corrections and removals that do not meet the requirements for reporting. The regulation implements this statutory requirement. FDA believes that the recordkeeping requirement of the corrections and removals rule carries out the statutory mandate and is appropriately tailored to the agency's mission of protecting the public health. The statute and the regulation require reporting only of events, corrections, and removals that are initiated to address a public-health risk. FDA believes that it has limited reporting requirements to information necessary to carry out its mission of protecting the public health.

Dated: November 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–31063 Filed 11–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–59]

Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: December 26, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: November 20, 1997.

David S. Cristy,

Director, Information Resources, Management Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Application for Homeownership Assistance Under Section 235 of the National Housing Act.

Office: Housing.

OMB Approval Number: 2502–0190.

Description of the Need for the Information and its Proposed Use: The information collection will be used to determine a homeowner's eligibility for and amount of financial assistance to be provided under Section 235, Homeowners Assistance Payments Program.

Form Number: HUD–93100.

Respondents: Individuals or Households and Business or Other For-Profit.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
HUD–93100	21,000		1		25		250

Total Estimated Burden Hours: 5,250.

Status: Reinstatement, with changes.

Contact: Diane Lobasso, HUD, (202) 708–2700 x2191; Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: November 20, 1997.

[FR Doc. 97–31071 Filed 11–25–97; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–60]

Submission of OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: December 26, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30 days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: November 20, 1997.

David S. Cristy,

Director, Information Resources Management Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Description of materials.

Office: Housing.

OMB Approval Number: 2502–0192.

Description of the Need for the Information and Its Proposed Use: Form HUD–92005 is needed so that builders and sponsors can describe the materials for the construction and other improvements to the single family property. This form and the drawings define the scope and limits of the proposed construction. This information is also used by HUD to estimate the value for FHA mortgage insurance to determine if the construction meets regulatory requirements.

Form Number: HUD–92005.

Respondents: Business or Other For-Profit and the Federal Government.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
HUD–92005	2,500		20		.5		25,000

Total Estimated Burden Hours: 25,000.

Status: Reinstatement, with changes.

Contact: Kenneth L. Crandall, HUD, (202) 708–6396 X5626; Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: November 20, 1997.

[FR Doc. 97–31072 Filed 11–25–97; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF THE INTERIOR

Geological Survey

Application Notice Describing the Areas of Interest and Establishing the Closing Date for Receipt of Applications Under the National Earthquake Hazards Reduction Program (NEHRP) for Fiscal Year (FY) 1999

AGENCY: Department of the Interior, U.S. Geological Survey.

ACTION: Notice.

SUMMARY: Applications are invited for research projects under the NEHRP.

The purpose of this program is to support research in earthquake hazards prediction; to provide earth-science data and information essential to determine seismic hazards present in the United States; and information essential to mitigate earthquake damage.

Applications may be submitted by educational institutions, private firms, private foundations, individuals, and agencies of state and local governments.

The NEHRP supports research related to the following general areas of interest:

I. Evaluating National and Regional Hazard and Risk. National and regional hazard and risk maps are critical to effective risk reduction strategies.

II. Evaluating Urban Hazard and Risk. The strong ground shaking and resulting catastrophic losses in the 1994 Northridge earthquake reinforced the need for the U.S. Geological Survey to concentrate its efforts where the risks are highest, that is, in the nation's urban areas.

III. Understanding Earthquake Processes. The effectiveness of risk-mitigation strategies and disaster response are limited by our meager understanding of the tectonic processes that cause earthquakes and generate the strong shaking and ground failure that devastates the built environment.

IV. Providing Real-time Hazard Assessment. Effective earthquake hazard evaluation and response to damaging events depend on timely, accurate information. Short, intermediate, and long-term earthquake forecasts in regions of high earthquake potential can all lead to mitigation activities that reduce the losses in subsequent earthquakes.

V. Providing Geologic Hazards Information Services. Computer technology has evolved rapidly in recent years to the point that new powerful tools are accessible both to the providers and the users of geologic hazards information.

DATES: The closing date for receipt of applications will be on or about April 1, 1998. The actual closing date will be specified in Announcement No. 1434–HQ–99–PA–00061.

ADDRESSES: The program announcement is expected to be available on or about February 2, 1998. You may obtain a copy of Announcement No. 1434–HQ–99–PA–00061 from the USGS Contracts and Grants Information Site at http://www.usgs.gov/contracts/nehrp/ or by writing Brian Heath, U.S. Geological Survey, Office of Acquisition and Federal Assistance—Mail Stop 205A, 12201 Sunrise Valley Drive, Reston, Virginia 20192, or by fax (703–648–7901).

FOR FURTHER INFORMATION CONTACT: John Sims, Earthquake Hazards Reduction Program—U.S. Geological Survey, Mail Stop 905, 12201 Sunrise Valley Drive, Reston, Virginia 20192. Telephone: (703) 648–6722.

SUPPLEMENTARY INFORMATION: Authority for this program is contained in the Earthquake Hazards Reduction Act of 1977. Pub. L. 95–124 (42 U.S.C. 7701, *et seq.*). The Office of Management and Budget Catalog of Federal Domestic Assistance number is 15.807.

Tim Calkins,

Acting Associate Chief, Operations.

[FR Doc. 97–30897 Filed 11–25–97; 8:45 am]

BILLING CODE 4310–31–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[4310–CA065–1492]

Notice of Availability

November 20, 1997.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that the Record of Decision for the Soledad Mountain Gold Mine, Kern County, California, is available.

ADDRESSES: Written requests for copies of the Record of Decision should be addressed to Bureau of Land Management, Ridgecrest Resource Area, 300 S. Richmond Road, Ridgecrest, California 93555, Attention: Ahmed Mohsen, EIS Coordinator.

FOR FURTHER INFORMATION CONTACT: Ahmed Mohsen-EIS Coordinator (760) 384–5421.

Russell Miles,

Acting Area Manager.

[FR Doc. 97–31042 Filed 11–25–97; 8:45 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Minerals Management Service, DOI.

ACTION: Notice of information collection solicitation.

SUMMARY: Under the Paperwork Reduction Act of 1995, the Minerals Management Service (MMS) is soliciting comments on an information collection, Oil Transportation Allowance (OMB Control Number 1010–0061); this information collection pertains to Indian leases only.

FORMS: MMS–4110, Oil Transportation Allowance Report

DATES: Written comments should be received on or before January 26, 1998.

ADDRESSES: Comments sent via the U.S. Postal Service should be sent to Minerals Management Service, Royalty Management Program, Rules and Publications Staff, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165; courier address is Building 85, Room A613, Denver Federal Center, Denver, Colorado 80225; e:Mail address is David—Guzy@mms.gov.

FOR FURTHER INFORMATION CONTACT: Dennis C. Jones, Rules and Publications Staff, phone (303) 231–3046, FAX (303) 231–3385, e-Mail Dennis—C—Jones@mms.gov.

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act of 1995, Section 3506 (c)(2)(A), we are notifying you, members of the public and affected agencies, of this collection of information and are inviting your comments. Is this information collection necessary for us to properly do our job? Have we accurately estimated the industry burden for responding to this collection? Can we enhance the quality, utility, and clarity of the information we collect? Can we lessen the burden of this information collection on the respondents by using automated collection techniques or other forms of information technology?

The Secretary of the Interior (Secretary) is responsible for the collection of royalties from lessees who produce minerals from leased Indian lands. The Secretary is required by various laws to manage the production of mineral resources on Indian lands, to collect the royalties due, and to distribute the funds in accordance with those laws. The product valuation and allowance determination process is essential to assure that the public and/or the Indians receive payment on the proper value of the minerals being removed.

MMS performs the royalty management functions for the Secretary. When a company or an individual enters into a contract (a lease) to explore, develop, produce, and dispose of oil from Indian lands, that company or individual agrees to pay the United States or Indian tribe or allottee a share (royalty) of the value received from production from the leased lands. Royalty rates are specified in the lease agreement. In order to determine whether the amount of royalty tendered represents the proper royalty due, it is first necessary to establish the proper value of the oil that is being sold or otherwise disposed of in some other manner, as well as the proper costs associated with allowable deductions.

In some circumstances, lessees are authorized to deduct from royalty payments the reasonable actual cost of transporting the royalty portion of the oil from the lease to a delivery point remote from the lease. Transportation allowances are a part of the product valuation process which MMS uses to determine if the lessee is reporting and paying the proper royalty amount.

Before any deduction may be taken, the lessee must submit page one of the Oil Transportation Allowance Report, Form MMS–4110, declaring the amount of reasonable actual transportation costs to be deducted from royalty. We estimate that 3 respondents will each submit an average of 7 allowance data lines for a total of 21 data lines annually. We estimate that each data line will require ¼ hour to prepare, a total of 5.25 burden hours. Authorization to deduct a transportation allowance continues for 12 months, or until the contract is changed or terminated. At that time, the lessee must resubmit page one of Form MMS–4110. We estimate that recordkeeping for these transportation allowances will require 1/2 hour per respondent annually.

Dated: November 20, 1997.

Joan Killgore,

Acting Associate Director for Royalty Management.

[FR Doc. 97–31081 Filed 11–25–97; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service, Interior

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Minerals Management Service, DOI.

ACTION: Notice of information collection solicitation.

SUMMARY: Under the Paperwork Reduction Act of 1995, the Minerals Management Service (MMS) is soliciting comments on an information collection, Coal Transportation and Washing Allowance (OMB Control Number 1010–0074); this information collection pertains to Indian leases only.

FORMS: MMS–4292, Coal Washing Allowance Report and MMS–4293, Coal Transportation Allowance Report.

DATES: Written comments should be received on or before January 26, 1998.

ADDRESSES: Comments sent via the U.S. Postal Service should be sent to Minerals Management Service, Royalty Management Program, Rules and Publications Staff, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165; courier address is Building 85, Room A613, Denver Federal Center, Denver, Colorado 80225; e:Mail address is David__Guzy@mms.gov.

FOR FURTHER INFORMATION CONTACT: Dennis C. Jones, Rules and Publications Staff, phone (303) 231–3046, FAX (303) 231–3385, e-Mail Dennis__C__Jones@mms.gov.

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act of 1995, Section 3506(c)(2)(A), we are notifying you, members of the public and affected agencies, of this collection of information and are inviting your comments. In this information collection necessary for us to properly do our job? Have we accurately estimated the industry burden for responding to this collection? Can we enhance the quality, utility, and clarity of the information we collect? Can we lessen the burden of this information collection on the respondents by using automated collection techniques or other forms of information technology?

The Secretary of the Interior is responsible for the collection of royalties from lessees who produce minerals from leased Indian lands. The Secretary is required by various laws to manage the production of mineral resources on Indian lands, to collect the royalties due, and to distribute the funds in accordance with those laws. The product valuation process is essential to assure that the public and/or the Indians receive payment on the full value of the minerals being removed.

MMS performs these royalty management functions for the Secretary. When a company or an individual enters into a contract (a lease) to develop, mine, and dispose of coal deposits from Indian lands, that company or individual (the lessee) agrees to pay the United States, Indian tribe, or allottee (the lessor) a share (royalty) of the gross proceeds received from the sale of production from leased lands. Royalty rates are specified in the lease agreement. In order to determine whether the amount of royalty tendered represents the proper royalty due, it is necessary to establish the value of the coal being sold or otherwise disposed of in some other manner, as well as the proper costs associated with allowable deductions.

In some circumstances, lessees are authorized to deduct certain costs in the calculation of royalties due. An allowance may be granted from royalties to compensate lessees for the reasonable actual cost of washing the royalty portion of coal. Also, when the sales point is not in the immediate vicinity of a lease or mine area, an allowance may be granted to compensate lessees for the reasonable actual cost of transporting the royalty portion of coal to a sales point not on the lease or mine area.

Before any deductions are taken, the lessee with an arm's-length contract must submit page one of the Coal Washing Allowance Report, Form MMS–4292, or the Coal Transportation Allowance Report, Form MMS–4293. The allowances will be based on reasonable actual costs reported by the lessees and are subject to later audit. We estimate that one lessee will submit two reports annually and that each submission will require ½ hour to prepare, a total of 1 burden hour.

Lessees with a non-arm's-length contract must also submit Form MMS–4292 or Form MMS–4293. All applicable pages of the allowance application forms should be submitted. The allowances will be based on reasonable actual costs reported by the lessees and are subject to later audit. We do not anticipate any lessee with a non-arm's-length contract submitting allowance reports.

In those instances when Indian royalty coal is washed, transported, or sold under non-arm's-length conditions, it is necessary for MMS to obtain other data, and in some cases, appropriate sales contracts, to accurately determine if the value of coal and the gross proceeds for royalty calculation purposes have been correctly computed by the lessee. Coal sales contracts for Indian lands are required to be submitted only upon request by MMS. We estimate that four lessees may be requested to submit sales contracts and that each submission will take 3 hours to prepare, a total of 12 burden hours.

Authorization to deduct coal transportation and washing allowances continues for 12 months, or until the contract is changed or terminated. We estimate that recordkeeping for these allowances will require 1 hour per respondent annually (5 respondents × 1 hour = 5 burden hours). Therefore, the total annual burden hour estimate for this information collection is 18 burden hours (1+12+5=18).

Dated: November 20, 1997.

Joan Killgore,

Acting Associate Director for Royalty Management.

[FR Doc. 97–31082 Filed 11–25–97; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Request for Determination of Valid Existing Rights Within the Wayne National Forest

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of decision.

SUMMARY: This notice announces the decision of the Office of Surface Mining Reclamation and Enforcement (OSM) on a request by Edward and Madeiline Blaire and Buckingham Coal Company, Inc. (Buckingham) for a determination of valid existing rights (VER) under section 522(e) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA). OSM has determined that the requesters do possess VER to mine coal by surface methods on 25.2 acres of federal lands within the Wayne National Forest in Perry County, Ohio. This decision is based on the ''takings standard,'' which requires OSM to evaluate whether a determination that the requester does not have VER would result in a compensable taking of a property interest under the Fifth Amendment to the U.S. Constitution.

FOR FURTHER INFORMATION CONTACT: Peter Michael, Office of Surface Mining Reclamation and Enforcement, Appalachian Regional Coordinating Center, Room 218, Three Parkway Center, Pittsburgh, PA 15220. Telephone: (412) 937–2867. E-mail address: pmichael@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on VER Requirements for National Forest Lands

Section 522(e) of SMCRA (30 U.S.C. 1272(e)) prohibits surface coal mining operations on certain lands unless a person has VER to conduct such operations or unless the operation was in existence on August 3, 1977, the date of enactment of SMCRA. Section 522(e)(2) in relevant part, applies the prohibition to federal lands within the boundaries of any national forest unless the Secretary of the Interior finds that (1) there are no significant recreational, timber, economic, or other values that may be incompatible with surface coal mining operations and (2) the surface operations and impacts are incident to an underground coal mine.

Under section 523 of the Act and 30 CFR 740.11, the state definition of VER applies to all federal lands in states with regulatory programs approved under section 503 of SMCRA. However, under 30 CFR 745.13, the Secretary has exclusive authority to determine VER for surface coal mining and reclamation operations on federal lands within the boundaries of the areas specified in paragraphs (e)(1) and (e)(2) of section 522 of the Act. OSM reaffirmed these basic principles in the preamble to the suspension notice concerning VER published on November 20, 1986 (51 FR 41954). However, to be consistent with a previous federal court decision concerning OSM's March 13, 1979 definition of VER, the preamble included the caveat that, in states with an all-permits standard for VER, OSM would apply the standard as if it contained a good-faith component. In other words, if the state program requires that a person obtain all necessary permits prior to August 3, 1977, to qualify for VER, OSM will apply the standard as if it recognizes that a person also has VER in situations where that person has made a good faith effort to obtain all necessary permits by that date.

The approved Ohio program relies primarily upon the all-permits standard. Ohio Revised Code 1501:13–3–02(A)(1)(a). However, the United States District Court for the Southern District of Ohio has prohibited OSM from using the state program definition or the policy set forth in the November 20, 1986 suspension notice. *Belville Mining Co.* v. *Lujan*, No. C–1–89–790 (S.D. Ohio July 22, 1991), *modified*, Sept. 21, 1992. In separate litigation, the same court applied a takings standard to a VER determination. *Sunday Creek Coal Co.* v. *Hodel*, No. C12–88–0416 (S.D. Ohio 1988).

In the *Belville* litigation, OSM made a commitment to the court to apply a takings standard in determining whether a person possesses VER to conduct surface coal mining operations on federal lands within the court's jurisdiction, including the Wayne National Forest, until a new federal rule defining VER is in place. Therefore, in the Southern District of Ohio, under the takings standard, a person has VER if, as of the date of the lands come under the protection of section 522(e) of SMCRA, application of the prohibitions of section 522(e) would result in a compensable taking of property under the Fifth Amendment to the U.S. Constitution.

II. Request for VER Determination

On August 14, 1995, James F. Graham of Buckingham requested that OSM determine whether the company has VER to remove the No. 6 coal seam, using block cut, contour, and area mining methods, from 25.2 acres of federal lands within the authorized boundaries of the Wayne National Forest in Perry County, Ohio. Buckingham previously submitted an application for a permit to conduct surface mining and reclamation operations on this parcel and an adjoining 10.7 acres of land in private ownership to the Ohio Department of Natural Resources (ODNR), Division of Reclamation on March 8, 1995. Of the 35.9 acres in the permit application, Buckingham proposes to mine a total of 12.6 acres of coal. The federal government owns the surface overlying 9.8 of these acres.

The lands included in the request lie along the eastern edge of a 134-acre parcel for which the United States of America purchased the surface rights from Daniel C. Jenkins, Jr. and other interested parties on April 24, 1967, and the Blaires on May 1, 1967. The U.S. Department of Agriculture, Forest Service (USFS) currently manages the land as part of the Wayne National Forest. The Blaires own the mineral estate and Mr. Graham is the lessee of all coal within that estate.

The property extends from north to south along an ephemeral tributary of Pine Run and is about 1.8 miles northeast of the city of Shawnee, Ohio. Its southern limit is adjacent to County

Route 43. The center of the property lies on the boundary between Sections 11 and 14 on the New Straightsville, Ohio USGS Quadrangle.

The proposed permit area, including the federal lands, has been affected by past surface and underground mining of the No. 6 coal seam. Two unreclaimed highwalls and an impoundment remain on 5.1 acres at the southern end of the property. The coal which the requester proposes to surface mine comprises a line of barrier pillars in an abandoned underground mine beneath the Pine Run tributary. The requester estimates that the extractable coal reserves total 88,200 tons.

On August 28, 1995, OSM notified the USFS that it had received a request for a VER determination from Buckingham and requested that the USFS provide a title opinion and any related information concerning Buckingham's property right to mine coal by the methods proposed. By letter dated April 24, 1996, the USFS submitted a report from the U.S. Department of Agriculture's General Counsel that concluded that the Blaires do have the property right to remove the coal by surface mining methods. (A person must possess the right to conduct the proposed activity under state property law before OSM can issue a positive VER determination under SMCRA.)

In a notice published in the March 1, 1996 **Federal Register** (61 FR 8074), OSM provided opportunity for public comment on the Buckingham request. In response to a request for a public hearing from the Buckeye Forest Council, OSM reopened the public comment period by notice published in the July 16, 1996 **Federal Register** (61 FR 37078). The public hearing took place at the Ohio University Inn in Athens, Ohio on August 8, 1996. The comment period closed on August 16, 1996.

On September 16, 1996, OSM requested additional information from Buckingham. Buckingham forwarded supplemental information on September 17 and October 3, 1996. The October 3 submittal also added the Blaires as persons requesting the VER determination.

On May 27, 1997, OSM again requested that Buckingham and the Blaires provide additional information relating to the economic viability of the proposed surface mining operation and other potential uses for the property. On August 7, 1997, Buckingham and the Blaires supplied information responsive to the request after OSM agreed to treat the information as presumptively confidential and protected commercial or financial information within the limitations of the Freedom of Information Act.

III. The Applicable Standard

Pursuant to OSM's commitment to the court in the Southern District of Ohio, as set forth in the portion of this notice entitled ''Background on VER Requirements for National Forest Lands,'' OSM evaluated Buckingham's request in accordance with judicial case law involving takings and the Attorney General's Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings, issued June 30, 1988. *See* 56 FR 33165 (July 18, 1991). Specifically, OSM relied upon a three-part regulatory takings analysis commonly used by the courts in deciding whether governmental action has effected a compensable taking of private property. This analysis includes a determination of: (1) The economic impact of the proposed government policy or action on the property interest involved, (2) the extent to which the action or regulation interferes with any reasonable, investment-backed expectations of the owner of the property interest, and (3) the character of the government action. Under the standard for compensable takings, OSM will not find that the Blaires have VER unless OSM makes either of two sets of findings. First, OSM could find that the Blaires have demonstrated that, as of August 3, 1977, application of the prohibition would preclude all economic use of the property. In the alternative, OSM could find that prohibition would not substantially advance a legitimate public purpose of SMCRA. Under the latter option, OSM would also have to find that the Blaires have demonstrated either that prohibition of surface coal mining would significantly diminish the property's value, or that prohibition would substantially interfere with the Blaires' investment-backed expectations. If the Blaires have VER to surface mine the 25.2 acres, then the lease to Buckingham would also convey VER to Buckingham.

IV. Application of the Standard

This matter involves a situation where governmental regulation has the potential to result in a taking of private property. The rights of property owners are not absolute and government may, within limits, regulate the use of property. But, the United States Supreme Court has long held that regulation that affects the value, use, or transfer of property may constitute a taking if it goes too far. *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393 (1922). In making the VER determination, OSM must decide whether prohibiting surface coal mining on the property would cause economic impacts on the property or interfere with reasonable, investment-backed expections of the persons with an interest in the property to the extent that justice and fairness would require that the public, rather than the private property owners, pay for the public use of the property. *Armstrong* v. *United States*, 364 U.S. 40, 49 (1959).

When regulation goes too far in infringing on private property rights is not precisely definable. The Supreme Court has consistently ''eschewed any 'set formula' for determining how far is too far, preferring to 'engage in * * * essentially ad hoc, factual inquiries.' '' *Lucas* v. *South Carolina Coastal Council*, 505 U.S. 1003, 1015 (1992), *quoting Penn Central Transportation Co*, v. *New York City*, 438 U.S. 104, 124 (1978). To aid in this determination, however, the Court has identified the three factors referenced in Part III above as having ''particular significance.'' *Connolly* v. *Pension Benefit Guaranty Corp.*, 475 U.S. 211, 224–25 (1986).

A. Protected Property Interest

In *Lucas*, the Supreme Court recognized what it characterized as a ''logically antecedent inquiry'' into a takings claimant's title prior to the inquiry into whether the government has interfered with rights inherent in that title in a manner that rises to the level of a Fifth Amendment taking. *Id.* at 1027. Thus, OSM starts with this inquiry.

The Court notes in *Lucas* that its takings jurisprudence ''has traditionally has been guided by the understandings of our citizens regarding the content of, and the State's power over the 'bundle of rights' that they acquire when they obtain title to property.'' *Id.* at 1027. Thus, the Court continues, some regulation of rights should be expected. ''In the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings,'' the possibility of significant impacts should be anticipated. *Id.* at 1027–28. But, the Court indicated that interests in land have greater expectations of protection. *Id.* at 1028. Further, the Court suggested that an ''owner's reasonable expectations'' may be critical to a takings determination. *Id.* at 1016 n. 7. These expectations are those that ''have been shaped by the State's law of property—i.e., whether and to what degree the State's law has accorded legal recognition and protection to the particular interest in land with respect to which the takings claimant alleges a diminution (or elimination of) value.'' *Id.* at 1016 n. 7.

In this case, the critical property interest is the mineral estate held by the Blaires. This is an interest in land historically accorded recognition and protection by the courts of Ohio, as well as all other states. This is not the type of interest that might normally be expected to be subject to deprivation without compensation. Thus, the Blaires possess title to an interest subject to Fifth Amendment protection.

B. Economic Impact of the Prohibition

Evaluation of the economic impact of a government action on a property interest involves determination of the economic and property interest or interests affected, the degree of the economic impact on the property interests, the character and present use of the property, the duration of the proposed governmental action, and whether the proposed government action carries benefits to the private property owner that offset or mitigate any adverse economic impact.

With respect to the property interest affected, OSM considers the relevant unit of property for analysis to be the land for which VER is requested and all other contiguous units of property under the same ownership and/or same use. *See* 56 FR 33161 (July 18, 1991). In this case, the relevant unit of property is the 134-acre tract of property for which the Blaires own the mineral estate.

The VER determination requested by the Blaires and Buckingham includes only 25.2 acres of this unit. The economic interest in this coal has been split, since the Blaires have leased the right to mine the coal at issue to Buckingham in return for a one dollar royalty per ton of the coal mined. Hence, the Blaires' place the value of their interest in the coal at $88,200, based on an estimated 88,200 tons of recoverable coal. OSM's analysis confirms the requesters' estimate of the recoverable coal reserves. Administrative Record No. 206 (hereinafter, ''A.R. ____''). Furthermore, OSM's evaluation of information provided by Buckingham concerning coal quality and overburden ratios confirms the proposed operation is economically viable, which means that the Blaires' royalty interest has economic value. (A.R. 219.)

With respect to Buckingham's interest, the company contends that the coal is a necessary and integral part of a larger operation. Specifically, the company states that it needs the low-sulfur coal from this property to blend with higher-sulfur coal from its other mines to meet contractual supply obligations with a local utility. Buckingham further contends that it will suffer losses amounting to approximately 3.5 million dollars if it cannot mine the coal in question. This contention is based upon the assumption Buckingham will be unable to market the coal from its other reserves if it cannot blend this coal with the coal from the national forest tract.

OSM's analysis, however, finds that Buckingham may have other options with far less dramatic financial implications. (A.R. 220.) For example, obtaining low-sulfur coal from another source could reduce the projected financial impact by 90% or more. Alternatively, Buckingham might be able to renegotiate its supply contract and acquire sulfur dioxide emission allowances to package with its higher sulfur coat, which would reduce the potential losses by 67–90 percent. Under either option, OSM agrees that the company likely would sustain some lost profit potential if it cannot develop the proposed mine. However, it is not clear from the record what the loss in market value of the leased coal would be, as distinguished from lost profits in Buckingham's business dealings.[1]

Analysis of the economic impact of a prohibition on surface mining involves a number of factors. First, there cannot be a compensable taking unless there is a diminution in the value of the requesters' property rights. Thus, if the coal could be extracted by some other method, there may be no taking issue. If this is not possible, any value allegedly taken must be compared to other value in the property that has accrued or will accrue to the owners. If a prohibition would affect merely one strand of a bundle of property rights and would not be significant, there may be no taking. Thus, it must be determined whether the property proposed surface coal mining.

With respect to alternative methods of mining, the requesters claim that the absence of competent rock above the coal seam precludes underground mining. The requesters also dismiss auger mining as a viable alternative, because they contend that method is not suitable for the removal of pillars from abandoned underground mine workings.

After a technical review, OSM finds that underground mining is not feasible for this site because of stress relief fracturing, roof stability and water inflow problems. (A.R. 206.) In addition, because of the need to establish a face-up to perform auger mining and due to the irregular shape of the remaining block of coal and the fact that entries have been cut through it in the past so that it is not solid, OSM agrees that auger mining is an unviable option for mining the coal.

Since alternative methods of mining are not possible here, other benefits derived from the property or other potential uses for the property are relevant. The 134-acre tract for which the Blaires own the mineral interest has previously been underground and/or surface mined. Maps in OSM's mine map repository indicate this mining was completed prior to 1940, which predates the current owners' acquisition of the property. Thus, the bulk of the use of the coal interest in this property has already been derived from the property by the Blaires' predecessors in interest. Prohibition of mining the remainder of the coal, then, would only deprive the Blaires of the use of the unmined pillars of coal.

OSM's investigation indicate there may be other recoverable coal from the No. 6 seam within the 134-acre tract. (A.R. 222). The maps in OSM's mine map repository show barrier pillars along Pine Run which, if still existing, may be surface mineable. The record provides no further information on the value of that coal. In addition, the 1961 New Straightsville USGS topographic quadrangle indicates that surface mining has already occurred along both sides of the run. In any event, any remaining coal could not be surface mined absent a VER determination. Underground extraction of the remainder of the workings appears infeasible because of mine-stability and safety considerations, as well as the low percentage of coal remaining. (A.R. 222.)

Published geologic maps and cross sections for Ohio indicate the potential existence of other seams below the No. 6 coal seam. However, there has been little interest in mining these seams to date and ODNR has no records of marketable coal beneath the No. 6 seam in Perry County. (A.R. 222.) An ODNR geologist advised that the occurrence of these coal beds is spotty and, where present, the quality of the coal can change significantly between locations. (A.R. 222.) Thus, there is no data to indicate any value in lower coal seams in which the Blaires may have an interest.

Other potential uses of the mineral estate include oil and gas production. The Blaires receive royalties from two wells operating since 1987 on the 134-acre tract of land. Another well drilled on the property proved economically unproductive. The wells tap the Clinton

[1] In any case, as noted below, OSM did not base its decision on the economic impacts of prohibition of mining on Buckingham's current property interests, but rather on the property interests that existed on August 3, 1977.

sandstone, which is the most productive oil and gas deposit in the region. Income from the two economically productive wells has been modest. Based on the state's regulatory restrictions on spacing of oil and gas wells and information provided by the Blaires concerning performance of the existing wells, OSM determined that the Blaires could potentially develop two or three additional wells on the property, the value of which, with the existing wells, would likely be approximately the same as the value of the coal royalties the Blaires expect to receive from their coal interest. (A.R. 221.) Other deposits may exist, but their presence and recoverability are entirely speculative.

Clay also exists on the property, with the shallowest deposit located immediately underneath the No. 6 coal seam. However, the market for clay is limited (Perry County produced less than 18,000 tons in the last two years combined) and its value is low, generally about one-fifth that of coal. (A.R. 222.) Most clay mining occurs in conjunction with coal mining and is secondary to the coal mining. In addition, the requesters state that the type of clay on the property is not in demand, so no market exists. Therefore, OSM finds that the record (including available market and geologic information) indicates that the clay on the property is not economically recoverable and that clay mining does not constitute a reasonable alternative use of the property.

Based on the record before it and on the analysis in this decision, OSM finds that application of the 552(e)(2) prohibition to the Blaires property (the mineral estate of the 134-acre parcel) would not deny the Blaires all economic use of the property in question. In particular, OSM finds that predecessors in interest to the Blaires have already made reasonable economic use of the coal rights on the 134 acres, because the record shows that the coal on this property has already been underground and surface mined. Further, OSM finds that the Blaires are making economic use of the oil and gas rights they hold in the 134 acres by means of two operating oil and gas wells and available information indicates the Blaires could potentially operate as many as three more wells on their property.

However, because the remaining coal on the Blaires property can only be mined by surface methods, OSM also concludes that a negative VER determination would preclude recovery of the remaining coal, and therefore would cause diminution in the value of the Blaires' property.

C. Interference With Reasonable, Investment-Backed Expectations

This element of the standard taking analysis requires an evaluation of (1) the owner's demonstrated expectations for use of the property, (2) whether the expectations are reasonable and investment-backed, and (3) the degree to which the government action interferes with these expectations.

The Blaires cite the acquisition of the property with an expectation of mining, contending that the coal was the principal value of the mineral estate. Buckingham points to its investment of resources in preparation of a permit application, as well as significant additional investments in an integrated mining operation that it claims relies upon access to the high sulfur coal under the national forest tract. Buckingham invested significant resources (several million dollars) in both acquiring the contract to be served by the integrated operation, and in establishing the mining operation.[2]

While the Blaires may have had expectations of exploiting the mineral interest when they acquired the property, it appears their acquisition was by inheritance and, consequently involved no investment. Presumably, the purchase they cite was the original purchase by the predecessor in interest. OSM does not consider this an investment by the Blaires, and therefore concludes that the record does not demonstrate that the Blaires have investment-backed expectations.

D. Character of the Government Action

This element of the takings analysis requires an evaluation of (1) the intended purpose of the enabling statute, (2) whether the action will substantially advance a legitimate public purpose, and (3) the degree to which the regulated activity contributes to a harm that the governmental action is designed to address.

The public purpose in this matter is Congress' intent to protest federal lands in national forests from the harmful affects of surface coal mining operations. The prohibition, specified in section 522(e)(2) of SMCRA, is based on Congress' determination that federal lands in the national forests are places that are generally incompatible with surface coal mining operations. *See* S. Rep. No. 95–128, at 55 (1977). Congress was concerned that mining might destroy the land's potential for other equally or more desirable land uses. *Id.* For purposes of this takings analysis, OSM will assess the degree to which the mining of this specific property would contribute to the harm Congress proposed to address by prohibiting mining. This determination, then, must address the intended uses, purposes and values of this particular national forest land.

The United States acquired the surface rights to this parcel pursuant to the Weeks Forestry Act of 1911, 16 U.S.C. § 515. The Weeks Act authorized the Secretary of Agriculture to ''purchase such forested, cut-over, or denuded lands within the watersheds of navigable streams as in his judgment may be necessary to the regulation of the flow of navigable streams or for the production of timber.'' *Id.* Thus, the principal purposes for acquiring land for the national forests under this Act were to provide watershed control and to ensure a national timber supply. But, over time, the uses, purposes and values of the national forests have expanded. In the Multiple-Use Sustained-Yield Act of 1960, Congress expressed its policy ''that the national forests are established and shall be administered for outdoor recreation, range, timber, watershed, and wildlife and fish purposes.'' 16 U.S.C. § 528. The Secretary of Agriculture was further ''directed to develop and administer the renewable surface resources of the national forests for multiple use and sustained yield of the several products and services obtained therefrom.'' 16 U.S.C. § 529. Accordingly, the current purpose of national forest lands is to provide a diversified, multiple use of the forest resources. Pursuant to the Forest and Rangeland Renewable Resources Planning Act of 1974, as amended by the National Forest Management Act, national forest administrators are required to prepare forest management plans. 16 U.S.C. § 1604. The Wayne National Forest has such a plan. This plan provides guidance on the uses, purposes and values of lands within the forest. The tract at issue here is included in Management Area 3.3, which has a designated management goal of providing (1) high-quality hardwoods on a sustained-yield basis; (2) wildlife habitat diversity, favoring species that require mature and overmature hardwoods; and (3) dispersed recreational activities, such as hiking, horseback riding and hunting. Forest areas managed for these purposes are intended to be in blocks of 1,000 acres or larger. Provision is made for mineral exploration and extraction.

More general statements in the forest plan recognize the existence of considerable private mineral ownership

[2] OSM did not base its decision on evaluation of the investment-backed expectations of Buckingham, because Buckingham did not hold the coal rights on August 3, 1977.

on federal lands within the national forest. The plan does not specifically address surface coal mining, but it does refer to the possibility of surface mining and recognizes that mineral extraction will occur throughout the forest. With respect to minerals, the forest management goal provides that the USFS administer private mineral rights so that all activities and operations are prudently consistent with the best private management practices.

The persons requesting the VER determination claim that the proposed surface coal mining operation would not adversely impact these uses, purposes and values. They state that the land in its current condition has no significant recreational, timber, or economic values incompatible with the proposed surface mining. They point out that the USFS has not developed the land for recreation. There are no camp sites, picnic sites or hiking trails. Further, it is noted that the tract is not contiguous with any other USFS property and only approximately twenty acres of relatively undisturbed timber is at issue. They also assert that development of the property as a resource is limited by the topography, soil conditions, shape of the area and timber quality. Finally, the requesters contend that the proposed mining and reclamation would improve the land in some respects by eliminating highwalls and subsidence depressions resulting from previous surface and underground mining operations.

OSM's examination of the property confirms that the requesters have accurately portrayed the condition of the property. In particular, the size of the subject property and its isolated location render it of limited current use and value for the purposes specified by the USFS. As indicated, the size of the property is small for the intended uses and the USFS has not developed the property. Also, it is approximately three-fourths of a mile from any other national forest tract, with properties owned by a number of other persons separating the forest tracts, making consolidation in the near future unlikely. In addition, the quality of the timber does not appear to be consistent with the purposes delineated for the property. It has been characterized as low to medium quality by the USFS. (A.R. 223.) Further, the property exhibits scars of previous mining that would benefit from reclamation, as claimed.

Finally, the USFS has not asserted that any governmental interest in the national forest would be significantly impacted by the proposed mining. (A.R. 223.) Rather, the USFS has confirmed that the proposed operation likely would have no significant impact on the current uses, purposes and values of this land. In addition, the USFS has provided input to the state regulatory authority concerning the proposed reclamation plan for the site and has stated that the agency will work closely with the state to ensure that reclamation fully returns the land to its planned use under the USFS management plan for this area. (A.R. 112.) Thus, OSM finds that mining the subject tract would have no significant impact on the current uses, purposes and values of the national forest.

V. Summary and Disposition of Comments

As discussed in Part II of this notice, OSM solicited public comments and held a public hearing on the request for a VER determination. Approximately 175 people attended the public hearing and OSM received approximately 150 comments. With two exceptions, all commenters opposed a positive VER determination. Most of the comments are addressed in the foregoing analysis of this matter. The following, however, are more specific responses to the comments made.

A number of commenters argued that OSM should rely upon the good-faith all-permits standard rather than the takings standard in making the VER determination. As discussed in Part I of this notice, as a result of litigation, OSM must use the takings standard when making VER determinations in the Southern District of Ohio.

One commenter proposed delaying a decision on the request until OSM adopts a final federal rule defining VER. OSM finds no support in law or regulation for this course of action. The agency has an obligation to execute its responsibilities with due diligence.

Several commenters questioned the propriety of Buckingham requesting the VER determination, since it did not own the coal in question. As noted in Part II of this notice, the owners of the mineral estate (the Blaires) subsequently joined Buckingham in requesting the VER determination. OSM notes, however, that Buckingham, as the lessee of the coal, also possesses an interest in the coal and is appropriately a part of the determination.

Some commenters emphasized SMCRA's expressed intent to protect public lands and urged OSM to accord preference to the public interest over the private interests when conducting the takings analysis. As discussed in Parts III and IV of this notice, OSM has conducted its takings analysis in accordance with its understanding of applicable takings jurisprudence.

Many commenters expressed concern about Buckingham's ability to reclaim the site and avoid adverse impacts to soil, water, wildlife habitats and ecosystems. While these concerns are not pertinent to the VER determination process, the regulatory authority must address them as part of its review of the permit application. Under both SMCRA and the Ohio program, the regulatory authority may not approve a permit application unless it finds that reclamation in accordance with the requirements of the approved program is feasible and that the operation has been designed to ensure compliance with these requirements. In addition, the USFS has provided input to the state concerning the proposed reclamation plan for the operation, and has stated that it does not anticipate that the proposed surface coal mining operation would significantly affect the current use of value of the affected lands for national forest purposes.

A few commenters also expressed concern that a positive VER determination in this case could establish an adverse precedent for allowing surface coal mining in the national forests. Since all takings analyses are fact-specific and limited to the unique circumstances of each case, OSM does not consider this case to have precedential value of the nature feared by the commenters.

VI. Conclusion

OSM deems the Blaires' interest to be key to this VER determination. If the Blaires had VER on August 3, 1977, they could transfer it under the lease to Buckingham. Conversely, if the Blaires did not possess VER as of that date, then VER could not be created by transferring one small portion of the coal rights to Buckingham.

As of August 3, 1977, if OSM applied the section 522(e)(2) prohibition to the Blaires' property, the Blaires would be deprived of the right to conduct surface coal mining on federal lands portion of the proposed permit area, which would mean that they could not recover approximately 88,200 tons of coal. This deprivation is slight, because the majority of the coal on the entire 134-acre parcel has already been exploited by predecessors of the Blaires. In addition, the Blaires also have a remaining use of their mineral estate in the form of oil and gas production. The value of the remaining oil and gas interest is probably about equivalent to the value of the coal interest. Thus, OSM finds that (1) most of the economic use of the Blaires' coal interest has already been made by previous exploitation; (2) the Blaires retain

substantial remaining use of their mineral property interests in the form of oil and gas production; (3) prohibition of the proposed surface coal mining would cause a diminution in value of the Blaires' property; and (4) the Blaires have no reasonable, investment-backed expectations of surface mining this land.

Finally, the agency finds that mining of this national forest tract would not contribute significantly to the harm Congress addressed through the prohibition of mining on federal lands within national forests. Because of its small size, isolated location relative to other national forest lands, and previously mined condition, the tract is of limited current use for the designated national forest purposes. The proposed surface coal mining operation would have only minimal short-term impacts on the current use and value of the land. There are no anticipated adverse long-term impacts. Thus, mining the tract would have no significant impact on the forest and reclamation will restore the land to the planned uses under the management plan. Therefore, OSM concludes that the record does not demonstrate that prohibition of surface coal mining of the property in question would substantially advance the section 522(e) prohibition.

OSM also finds that, because most of the coal on this property has already been mined, the use of that part of the Blaires' property interest has already occurred. Therefore, a prohibition on surface mining the remaining coal would not totally abrogate a property interest historically viewed as an essential stick in the bundle of property rights. However, because prohibition would diminish the value of the Blaires' property and would not substantially advance a legitimate public purpose of SMCRA, OSM finds that application of the statutory prohibition on surface mining the Blaires' property would constitute a compensable taking of the Blaires' property interests under the Fifth Amendment to the U.S. Constitution. Therefore, OSM finds that the Blaires have VER for the lands in question and that Buckingham acquired VER for the same lands by virtue of its lease of the Blaires' coal rights.

VII. Appeals

Any person who is or may be adversely affected by this decision may appeal to the Interior Board of Land Appeals under 43 CFR 4.1390 *et seq.* (1988). Notice of intent to appeal must be filed within 30 days from the date of publication of this notice of decision in a local newspaper with circulation in Perry County, Ohio.

Dated: November 19, 1997.

John A. Holbrook, II,

Acting Regional Director, Appalachian Regional Coordinating Center.

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INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA–372 (Enforcement Proceeding)]

In the Matter of Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing Same; Notice of Commission Determination to Deny Motion of YBM Magnex, Inc. to be Substituted for Complainant Crucible Materials Corporation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''the Commission'') determined to deny as moot the September 25, 1997, motion of YBM Magnex, Inc. (''YBM'') to substitute YBM for complainant Crucible Materials Corporation (''Crucible'') in the above-referenced enforcement proceeding.

FOR FURTHER INFORMATION CONTACT: Jay H. Reiziss, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–205–3116.

SUPPLEMENTARY INFORMATION: On May 16, 1996, the Commission instituted a formal enforcement proceeding based on an enforcement complaint filed by Crucible Materials Corporation (''Crucible'') alleging that respondents San Huan New Materials High Tech, Inc. (''San Huan''), Ningbo Konit Industries, Inc. (''Ningbo''), and Tridus International, Inc. (''Tridus'') (collectively ''respondents'') had violated the Commission's October 11, 1995, consent order wherein those respondents agreed not to sell for importation, import, or sell after importation magnets which infringe any of claims 1–3 of Crucible's U.S. Letters Patent 4,588,439 (''the '439 patent'') by importing or selling magnets that infringed the claims in issue of the '439 patent. On December 24, 1996, following an evidentiary hearing, the presiding administrative law judge (''ALJ'') issued a recommended determination (''RD'') finding that respondents had violated the consent order on 33 different days and recommending that the Commission impose a civil penalty of $1,625,000 on respondents. The Commission adopted the bulk of the RD's findings on violation on April 8, 1997, and issued an opinion explaining that determination on April 15, 1997, finding that respondents violated the consent order on 31 days between October 11, 1995, and October 10, 1996. On September 26, 1997, the Commission issued its final determination in the enforcement proceeding, imposing a $1.55 million civil penalty on respondents, revoking the consent order and issuing an exclusion order directed to foreign respondents San Huan and Ningbo and a cease and desist order directed to domestic respondent Tridus, denying Crucible's request for attorneys' fees and its petition for reconsideration of the Commission's prior determination regarding the application of the Federal Circuit decision in *Maxwell* v. *J. Baker, Inc.* 86 F.3d 1098, 29 U.S.P.Q.2d 1001 (Fed. Cir.), *reh'g denied, suggestion of reh'g in banc declined (1996), cert. denied,* 117 S. Ct. 1244 (1997), and denying respondents' request that the Commission require the domestic industry to submit periodic reports regarding its status as a domestic industry. Thus, there are no outstanding issues in this investigation.

On September 25, 1997, YBM moved to be substituted as the complainant in this investigation in place of Crucible in light of the fact that YBM had acquired the '439 patent from Crucible. On October 6, 1997, respondents and the Commission investigative attorney filed replies to YBM's motion opposing it as moot in light of the fact that the Commission concluded this investigation on September 26, 1997.

Because the Commission concluded this investigation on September 26, 1997, the Commission determined to deny YBM's motion as moot. The Commission noted, however, that it would have granted YBM's motion had this proceeding still been ongoing.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and section 210.75 of the Commission's Rules of Practice and Procedure (19 CFR § 210.75).

By order of the Commission.

Issued: November 20, 1997.

Donna R. Koehnke,

Secretary.

[FR Doc. 97–31091 Filed 11–25–97; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–370 (Sanctions Proceeding)]

In the Matter of Certain Salinomycin Biomass and Preparations Containing Same; Notice of Postponement of Commission Hearing

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to postpone indefinitely a public hearing in the above-captioned proceeding while the Commission considers a joint motion by the private parties to terminate the proceeding.

FOR FURTHER INFORMATION CONTACT: Jean H. Jackson, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202–205–3104. General information concerning the Commission may also be obtained by accessing its Internet server *(http://www.usitc.gov or ftp://ftp.usitc.gov).*

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 6, 1995, based on a complaint filed by Kaken Pharmaceutical Co. Inc. (Kaken). On November 6, 1995, the ALJ issued his final initial determination (ID) in this investigation, finding no violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, by respondents Hoechst Aktiengesellschaft, Hoechst Veterinar GmbH, and Hoechst-Roussel Agri-Vet Co. (collectively, Hoechst). His determination was based on his findings that the patent at issue was invalid for failure to disclose the best mode of operation and unenforceable due to inequitable conduct during prosecution of the patent. The ALJ's ID was not reviewed by the Commission and was ultimately upheld on appeal to the U.S. Court of Appeals for the Federal Circuit, *Kaken Pharmaceutical Co.* v. *USITC,* Appeal Nos. 96–1300,-1302, nonprecedential opinion dated March 31, 1997.

On January 19, 1996, Hoechst filed a motion for sanctions against Kaken, which the Commission referred to the presiding ALJ for issuance of a recommended determination (RD). Hoechst's motion alleged, *inter alia,* that Kaken committed sanctionable conduct by filing a complaint totally lacking in merit. On May 14, 1997, the ALJ issued his RD in which he recommended that the Commission impose on Kaken and its attorneys joint and several liability for an amount of money equal to double the entire attorneys fees and costs of the Hoechst respondents incurred in both the section 337 investigation on the merits and in the proceedings on sanctions. All parties filed comments on the RD. On August 8, 1997, Kaken and its attorneys requested an opportunity for oral argument before the Commission. On October 24, 1997, the Commission granted the motion for oral argument and set a hearing date for December 10, 1997. 62 FR 58746 (Oct. 30, 1997).

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337 and Commission rule 210.25, 19 CFR § 210.25.

Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

By order of the Commission.

Issued: November 21, 1997.

Donna R. Koehnke,

Secretary.

[FR Doc. 97–31092 Filed 11–25–97; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated July 21, 1997, and published in the **Federal Register** on August 26, 1997 (62 FR 45271), Bridgeway Trading Corporation, 7401 Metro Blvd., Suite 480, Minneapolis, Minnesota 55439, made application by renewal to the Drug Enforcement Administration to be registered as an importer of marihuana (7360), a basic class of controlled substance listed in Schedule I.

The firm plans to import marihuana seed which will be rendered non-viable and used as bird feed.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Bridgeway Trading Corporation to import marihuana is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. Therefore, pursuant to Section 1008(a) of the Controlled Substances Import and Export Act and in accordance with Title 21, Code of Federal Regulations, Section 1301.34, the above firm is granted registration as an importer of the basic class of controlled substance listed above.

Dated: November 14, 1997.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 97–31098 Filed 11–25–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,817]

AMEX Manufacturing Incorporated, El Paso, Texas, Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 15, 1997 in response to a worker petition which was filed August 18, 1997 on behalf of workers at AMEX Manufacturing Incorporated located in El Paso, Texas (TA–W–33,817).

The petitioning group of workers are covered under an existing Trade Adjustment Assistance certification (TA–W–32,431). Consequently, further investigation in this case would service no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 10th day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31057 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,715]

Brandon Apparel Group, Incorporated Columbus, WI; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of October 21, 1997, petitioners requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers of the subject firm. The denial notice was signed on September 11, 1997, and published in

the **Federal Register** on October 14, 1997 (62 FR 53347).

The petitioner presents evidence that Department's collection of information regarding company sales and imports was incomplete for the time period relevant to the investigation.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C. this 31st day of October 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31051 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Acting Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Acting Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 1997.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Acting Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 1997.

The petitions filed in this case are available for inspection at the Office of the Acting Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C., this 3rd day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

APPENDIX

[Petitions Instituted on 11/3/97]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,946	Chevron U.S.A. Production (Comp)	Houston, TX	10/22/07	Crude Oil and Natural Gas.
33,947	H.K. Co (Comp)	New York, NY	10/07/97	Lace Fabric.
33,948	W.S. Wormser (Wrks)	Bradford, TN	10/17/97	Sleepwear-Childrens'.
33,949	Metro Plastics Tech. (Comp)	Columbus, IN	10/16/97	Injection Molding Components.
33,950	Mario Casuals, Inc. (UNITE)	New York, NY	10/16/97	Better Ladies' Wear.
33,951	Robinson Manufacturing (Wrks)	Linden, NJ	10/15/97	Gym Shirts, Casuals Shorts.
33,952	Amesbury Group, Inc (UAW)	Amesbury, MA	10/14/97	EMI Shielding Gaskets.
33,953	Royal Craft Trimmings (Wrks)	New York, NY	10/14/97	Beaded Ornaments and Trimmings.
33,954	Color-Clings, Inc (Comp)	Plymouth, MN	10/13/97	Static Cling Window Decorations.
33,955	Koh-I-Noor, Inc (Comp)	Bloomsbury, NJ	10/13/97	Pens.
33,956	Veratec Lewisburg Int'l (UPIU)	Lewisburg, PA	10/10/97	Non Woven Roll Goods.
33,957	Tubed Products, Inc (Comp)	Freehold, NJ	10/03/97	Plastic Squeeze Tubes.
33,958	Henchel Manufacturing (Wrks)	Potosi, MO	09/30/97	Leather Ball Caps.
33,959	Electra-Sound, Inc (Wrks)	Parma, OH	10/15/97	Engine Control Modules.
33,960	Wilhold (Wrks)	Sunbury, PA	10/20/97	Hair Care Products.
33,961	Teledyne Fluid Systems (UAW)	Independence, OH	10/17/97	Molds & Dyes for Auto Industry.
33,962	Fonda Group (UPIU)	Three Rivers, MI	10/16/97	Paper Plates and Cups.
33,963	Lenworth Aminco, Inc (Wrks)	Meadville, PA	10/16/97	Steel Racking/Shelving.
33,964	International Flavors (Comp)	Union Beach, NJ	10/21/97	Aroma Chemicals.
33,965	Tri America (Wrks)	El Paso, TX	10/24/97	Jeans.
33,966	Cason Manufacturing Co (Comp)	Stephenville, TX	10/24/97	Skirts and Pants.
33,967	Fedco Corp (USWA)	Buffalo, NY	10/23/97	Automobile Heater Cores.
33,968	Pendleton Woolen Mills (UNITE)	Milwaukie, OR	10/23/97	Men's Woolen Shirts.
33,969	Champion Aviation Prod. (Wrks)	Weatherly, PA	10/22/97	Incandescent Displays for Aircrafts.
33,970	GE Control Products (Wrks)	Carroll, IA	10/20/97	Range Minute Timers, Motors.
33,971	Buster Brown Apparel, Inc (Comp)	Chattanooga, TN	10/03/97	Children's Socks.
33,972	Banner Packaging (Wrks)	Shelbyville, TN	10/14/97	Poultry Bags, Diaper Bags.
33,973	A.O. Smith Corp (IBEW)	Upper Sandusky, OH ..	10/23/97	Fractional Horsepower Electric Motors.
33,974	Lightalarms Electronics (IBEW)	Baldwin, NY	10/21/97	Emergency Lighting.
33,975	Marion Power Shovel Co (USWA)	Marion, OH	10/24/97	Large Shovels, Draglines and Repair Parts.
33,976	Trade Apparel, Inc (Wrks)	El Paso, TX	10/17/97	Jeams—Cutting, Sewing, and Laundry.

[FR Doc. 97–31047 Filed 11–25–97; 8:45 am]
BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,477; TA–W–33,477B]

Cone Mills Corporation; Haynes Plant, Henrietta, North Carolina and Cliffside Plant, Cliffside, North Carolina; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Notice of Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on June 17, 1997, applicable to workers of Cone Mills Corporation, Haynes Florence Plant located in Henrietta, North Carolina. The notice was published in the **Federal Register** on July 18, 1997 (62 FR 38579). The worker certification was subsequently amended to correctly identify the plant to read Haynes Plant instead of Haynes Florence Plant and to include workers of the Florence Plant in Forest City, North Carolina (TA–W–33,477A). The notice of amended certification was published in the **Federal Register** on July 18, 1997 (62 FR 38584).

At the request of petitioners, the Department reviewed the certification for workers of the subject firm. The workers produce denim. Findings on review show that workers separations have occurred at the subject firm's Cliffside Plant, in Cliffside, North Carolina.

The intent of the Department's certification is to include all workers of Cone Mills Corporation who were affected by increased imports. Accordingly, the Department is amending the worker certification to include the workers of the Cliffside Plant of Cone Mills Corporation, Cliffside, North Carolina.

The amended notice applicable to TA–W–33,477 is hereby issued as follows:

''All workers of Cone Mills Corporation, Haynes Plant, Henrietta, North Carolina (TA–W–33,477) and Cliffside Plant, Cliffside, North Carolina (TA–W–33,477B), who became totally or partially separated from employment on or after April 8, 1996 through June 17, 1999, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, D.C. this 31st day of October 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31055 Filed 11–25–97; 8:45 am]
BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Acting Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Acting Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 1997.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Acting Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 1997.

The petitions filed in this case are available for inspection at the Office of the Acting Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, DC 20210.

Signed at Washington, D.C. this 27th day of October, 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

Appendix

[Petitions Instituted on 10/27/97]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,916	Delphi Energy and Engine (Co.)	Anaheim, CA	10/04/97	Automotive Batteries.
33,917	International Paper Co (UPIU)	Erie, PA	10/08/97	Paper Products.
33,918	Aeroquip Corp. (UAW)	Spring Arbor, MI	10/07/97	Automobile Glove Boxes.
33,919	Brooklyn Foil, Inc (Wkrs)	Brooklyn, NY	10/07/97	Tin/Lead Alloy Foil and Sheets.
33,920	Tarrytown Garment Co (UNITE)	Tarrytown, NY	10/08/97	Ladies' Bathing Suits.
33,921	Tru Stitch Footwear (UFCW)	Bombay, NY	10/06/97	Soft Moccasin and Boot Style Slippers.
33,922	Anitec Image Corp (ICWU)	Binghamton, NY	10/10/97	Graphic Arts Film Paper & Chemicals.
33,923	Timberline Lumber, Inc (Wkrs)	Kalespell, MT	10/01/97	Lumber Studs.
33,924	International Wire (Co.)	Bremen, IN	10/06/97	Wire.
33,925	Apparel Brands, Inc (Co.)	Wrightsville, GA	10/08/97	Men's & Ladies' Uniform Pants & Shorts.
33,926	Robinson Manufacturing (Wkrs)	Parsons, TN	10/09/97	Sports Apparel.
33,927	Oneita Industrial (Co.)	Fayette, AL	10/07/97	Tee Shirts.
33,928	Grainger Knitwear (Wkrs)	Rutledge, TN	10/08/97	Tee Shirts.
33,929	Micro Stamping Corp (Co.)	Somerset, NJ	10/08/97	Lead Frames, Medical Device.
33,930	Frolic Footwear (Wkrs)	Walnut Ridge, AR	09/29/97	Shoes.
33,931	Stroh Brewery (IAM)	St. Paul, MN	10/08/97	Beer.
33,932	Racal Datacom, Inc (Wkrs)	Sunrise, FL	10/05/97	PC Boards, Chassis.
33,933	University Technical Serv (Wkrs)	Canton, NY	10/06/97	Electric Power.
33,934	Delphi Energy & Engine (Co.)	Olathe, KS	10/08/97	Automotive Batteries.
33,935	Reef Gear Manufacturing (Wkrs)	East China, MI	10/10/97	Transmissions Gears.
33,936	Jennmar Corporation (Wkrs)	Knoxville, TN	10/13/97	Coal Mine Roof Products.

Appendix—Continued

[Petitions Instituted on 10/27/97]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,937	O.R. Technology (Co.)	Campbell, CA	10/14/97	Floppy Disk Drive.
33,938	Lees Manufacturing Co (Co)	Cannon Falls, MN	10/09/97	Children's Sleepwear and Sportswear.
33,939	KD Industries (Co.)	Blountsville, AL	10/09/97	Children's Sleepwear & Sportswear.
33,940	Liberty Childrenswear Co (Co.)	Snead AL	10/17/97	Children's Sportswear.
33,941	Maine Yankee Atomic Power (UWUA)	Wiscasset, ME	10/21/97	Electric Power.
33,942	Woodgrain Millwork, Inc (Wkrs)	Lakeview, OR	10/14/97	Moulding.
33,943	Carolyn of Virginia, Inc (Co.)	Bristol, VA	09/15/97	Ladies' Apparel.
33,944	Kysor Michigan Fleet (UAW)	Scottsburg, IN	10/16/97	Auxiliary Fuel Tanks.
33,945	General Motors Corp (UAW)	Danville, IL	10/22/97	Automobile Iron Castings.

[FR Doc. 97–31045 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–m

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33, 404]

Devoe & Raynolds Company, Louisville, Kentucky; Notice of Negative Determination on Reconsideration

On July 18, 1997, the Department issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of the subject firm. The petitioner presented new evidence regarding company imports of paint. The notice was published in the **Federal Register** on August 1, 1997 (62 FR 41424).

The Department initially denied TAA to workers of Devoe & Raynolds Company, Louisville, Kentucky because the ''contributed importantly'' group eligibility requirement of Section 222(3) of the Trade Act of 1974, as amended, was not met. The workers at the subject firm produced latex and alkyd paints. The layoffs at the Louisville plant were attributed to the corporate decision to consolidate operations with that of the parent company's domestic plants in Texas, Ohio, Pennsylvania, and Florida. The parent company did not import paint from foreign sources.

New findings on reconsideration show that the parent company of Devoe & Raynolds, ICI Paints, operating in the U.S. as Glidden, had a corporate-wide sales increase from 1995 to 1996. Other new findings reveal that the company did import paint from its foreign production facility. Company imports, however, were negligible, accounting for less that 1 percent of corporate-wide sales in 1995 and 1996.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Devoe & Raynolds Company, Louisville, Kentucky.

Signed at Washington, DC, this 31st day of October 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31054 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility to Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Acting Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Acting Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 1997.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Acting Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 8, 1997.

The petitions filed in this case are available for inspection at the Office of the Acting Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C., this 10th day of November, 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

APPENDIX

[Petitions Instituted on 11/10/97]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,977	Falcon Industries (Co.)	Graham, TX	10/23/97	T-Shirts, Athletic Shirts.
33,978	Howden Fan (USWA)	Buffalo, NY	10/23/97	Commercial Fans and Blowers.
33,979	Cytec Industries (USWA)	Linden, NJ	10/28/97	Surfactants and Docusates.
33,980	Lockheed Martin (IUPPE)	Liverpool, NY	10/31/97	Electronic Defense Equipment.
33,981	Shenandoah Knitting Mills (Wkrs)	Edinburg, VA	10/29/97	Sweaters.
33,982	Gary Peterson Logging (Co.)	Cascade, ID	10/21/97	Logging.
33,983	Standard Keil TAP Rite (Co.)	Allenwood, NJ	10/31/97	Refrigerator Doors, Hinges, Latches.

APPENDIX—Continued

[Petitions Instituted on 11/10/97]

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,984	Hartsville Garment (Co.)	Hartsville, TN	10/30/97	Men's & Ladies' Shirts and Blouses.
33,985	Gardin Logging (Wkrs)	Winlock, WA	10/24/97	Cedar Logs.
33,986	Texas Instruments (Co.)	Central Lake, MI	10/27/97	Thermal Motor Over Load Devices.
33,987	Dublin Garment Co., Inc (Co.)	Dublin, VA	10/27/97	Uniform Shirts and Pants.
33,988	EIF Atochem North America (Wkrs)	Tonawanda, NY	10/27/97	Peroxide.
33,989	Allegheny Ludlum Steel (USWA)	Pittsburgh, PA	10/07/97	Silicon Steel.
33,990	Extex, Inc (Co.)	St. Elmo, IL	10/27/97	Crude Oil.
33,991	Jetricks (Wkrs)	Selmer, TN	10/21/97	Children's Clothing.
33,992	Claridge Products (Wkrs)	Harrison, AR	10/23/97	Chalkboard, Bulletin Board.
33,993	Nye Tex Manufacturing (Wkrs)	Dallas, TX	10/31/97	Office Products.
33,994	Wilroy, Inc (UNITE)	Secaucus, NJ	10/29/97	Children's Clothing.
33,995	Eaton Corporation (Wkrs)	Athens, AL	10/21/97	Thermostats for Appliances.
33,996	Brownsvile Products (Wkrs)	Brownsville, TX	10/29/97	Parts for Airbags.

[FR Doc. 97–31048 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,782]

General Motors Corporation, Delphi Chassis (Livonia Plant), Livonia, Michigan; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 2, 1997 in response to a worker petition which was filed on behalf of workers at General Motors Corporation, Delphi Chassis, Livonia Plant, Livonia, Michigan.

The petitioners have requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose; and the investigation has been terminated.

Signed at Washington, D.C. this 10th day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31049 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,718 and TA–W–33,718C]

Glenn Enterprises, Incorporated; McCoy Manufacturing, #3, Caledonia, Mississippi and Vernon Manufacturing Company, Vernon, Alabama; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Trade Adjustment Assistance on September 24, 1997, applicable to all workers of McCoy Manufacturing #3, located in Caledonia, Mississippi. The notice was published in the **Federal Register** on October 14, 1997 (62 FR 53348).

At the request of the company, the Department reviewed the certification for workers of the subject firm. The workers were engaged in employment related to the production of men's dress and casual pants and shorts for its parent company, Glenn Enterprises, Incorporated, Sulligent, Alabama. New information received from the company shows that worker separations occurred at Vernon Manufacturing Company, Vernon, Alabama when it closed on April 11, 1997. The workers produced men's dress pants for Glenn Enterprises, Incorporated.

Accordingly, the Department is amending the certification to cover the workers of Vernon Manufacturing Company, Vernon, Alabama.

The intent of the Department's certification is to include all workers of Glenn Enterprises, Incorporated who were adversely affected by increased imports.

The amended notice applicable to TA–W–33,718 is hereby issued as follows:

''All workers of Glenn Enterprises, Incorporated, McCoy Manufacturing #3, Caledonia, Mississippi (TA–W–33,718) and Vernon Manufacturing Company, Vernon, Alabama (TA–W–33,718C) who became totally or partially separated from employment on or after July 25, 1996 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington D.C. this 31st day of October, 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31052 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,519]

Hayes Wheels International, Incorporated, Romulus, Michigan; Notice of Negative Determination Regarding Application for Reconsideration

By application of July 11, 1997, the United Automobile-Aerospace-Agricultural Implement Workers of America (UAW) requested administrative reconsideration of the Department's negative determination regarding worker eligibility to apply for trade adjustment assistance, applicable to workers of the subject firm. The denial notice was signed on June 13, 1997 and will be published in the **Federal Register.**

Pursuant to CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The request for reconsideration claims that the workers are facing a plant closing and job loss as the result of Hayes Wheels International, Inc. moving work and awarding new work to their Europe, Mexico, Venezuela plants.

In order for the Department to issue a worker group certification, all of the group eligibility requirements of Section 222 of the Trade Act must be met. Review of the investigation findings show that criterion (3) was not met.

Sales and production at the subject firm increased from 1995 to 1996 and from January through September 1997 over the corresponding 1996 period. The company is in the process of shifting work performed at the subject firm to two other domestic corporate facilities. The decision to close the facility down is attributed to corporate excess capacity and an outmoded manufacturing facility. The investigation further revealed that although the company imported wheels, the quantity was not significant and was not the contributing factor in the terminations at the subject firm.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, D.C. this 17th day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31059 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,513; TA–W–33,513X]

Levi Strauss and Company; Goodyear Cutting Facility and El Paso Field Headquarters 1440 Goodyear, El Paso, Texas; San Benito, Texas, Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on August 7, 1997, applicable to workers of Levi Strauss and Company, located in El Paso, Texas. The notice was published in the **Federal Register** on September 17, 1997 (62 FR 48888). The certification was subsequently amended to include the subject firm workers at the El Paso Field Headquarters in El Paso, Texas. The amendment was issued on September 14, 1997 and published in the **Federal Register** on September 30, 1997 (62 FR 51155).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. New information received by the State shows that worker separations have occurred at the San Benito, Texas plant of Levi Strauss and Company. The workers in San Benito are engaged in employment related to the production of men's, women's and youth's denim jeans and jackets. Based on this new information, the Department is amending the certification to cover the subject firms' workers at the San Benito, Texas plant.

The intent of the Department's certification is to include all workers of Levi Strauss and Company who were adversely affected by increased imports of men's, women's and youth's denim jeans and jackets.

The amended notice applicable to TA–W–22,513 is hereby issued as follows:

''All workers of Levi Strauss and Company, Goodyear Cutting Facility and El Paso Field Headquarters, El Paso, Texas (TA–W–33,513) and San Benito, Texas (TA–W–33,513X) who were engaged in employment related to the production of men's, women's and youth's denim jeans and jackets who became totally or partially separated from employment on or after May 13, 1996 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington D.C. this 10th day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31050 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–31,704 and TA–W–31,704A]

Parker & Parsley Petroleum USA, Incorporated, A/K/A Pioneer Natural Resources USA, Inc., Midland, Texas and Various Locations in Texas (except Midland); Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Notice of Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on February 2, 1996, applicable to all workers of Parker & Parsley Petroleum USA, Incorporated located in Midland, Texas. The notice was published in the **Federal Register** on February 21, 1996 (61 FR 6660). The certification was amended on February 12, 1996, to include workers at the Parker & Parsley operations at various locations in Texas. The notice of amendment was published in the **Federal Register** on February 23, 1996 (61 FR 7023).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers of Parker & Parsley Petroleum are engaged in employment related to the production of crude oil and natural gas. New information provided by the company shows that some of the workers of Parker & Parsley have had their wages reported to the Unemployment Insurance tax account of Pioneer Natural Resources USA, Inc.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports. Accordingly, the Department is amending the certification to include workers of Pioneer Natural Resources USA, Inc.

The amended notice applicable to TA–W–31,704 is hereby issued as follows:

All workers of Parker & Parsley Petroleum USA, Incorporated, also know as Pioneer Natural Resources USA, Inc., Midland, Texas (TA–W–31,704), operating at various

locations in Texas except Midland (TA–W–31,704A), who became totally or partially separated from employment on or after June 30, 1994 through February 12, 1998, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C., this 31st day of October 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31053 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,431]

Shaneco Manufacturing Company a/k/a Amex Manufacturing Incorporated, El Paso, Texas; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Notice of Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on June 11, 1996, applicable to workers of Shaneco Manufacturing Company located in El Paso, Texas. The notice was published in the **Federal Register** on July 3, 1996 (61 FR 34875).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers at the subject firm produce miscellaneous sewn articles. Findings on review show that some of the workers have had their wages reported to the Unemployment Insurance tax account of Amex Manufacturing Incorporated. The intent of the Department's certification is to include all workers of Shaneco Manufacturing Company who were affected by increased imports. Accordingly, the Department is amending the worker certification to include the workers of Amex Manufacturing Incorporated.

The amended notice applicable to TA–W–32,431 is hereby issued as follows:

All workers of Shaneco Manufacturing Company, also known as Amex Manufacturing Incorporated, El Paso, Texas, who became totally or partially separated from employment on or after May 23, 1995 through June 11, 1998, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C. this 10th day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31062 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,725]

Stanwood Mills, Incorporated, Slatington, Pennsylvania; Notice of Revised Determination on Reopening

In response to a letter of October 28, 1997, from a company official requesting administrative reconsideration of the Department's denial of TAA for workers of the subject firm, the Department reopened its investigation for the former workers of Stanwood Mills, Incorporated.

The initial investigation resulted in a negative determination issued on October 14, 1997, because the ''contributed importantly'' test of the Group Eligibility Requirements of the Trade Act was not met for workers at the subject firm. The workers produce greige goods. The denial notice will soon be published in the **Federal Register**.

The Department has new information showing that during the time period relevant to the investigation, a customer of Stanwood Mills, Incorporated increased import purchases of greige goods, while reducing purchases from the subject firm.

Conclusion

After careful consideration of the new facts obtained on reopening, it is concluded that increased imports of articles like or directly competitive with greige goods produced by the subject firm contributed importantly to the decline in sales and to the total or partial separation of workers of the subject firm. In accordance with the provisions of the Trade Act of 1974, I make the following revised determination:

''All workers of Stanwood Mills, Incorporated, Slatington, Pennsylvania who became totally or partially separated from employment on or after July 30, 1996, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed in Washington, D.C. this 17th day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31061 Filed 11–25–97; 8:45 am]

BILLING CODE 4810–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,353]

Technotrim, Incorporated Greencastle, Indiana; Notice of Negative Determination Regarding Application for Reconsideration

By application dated June 6, 1997, the peer counselor for TechnoTrim's dislocated worker group, hereafter referred to as the petitioners, requested administrative reconsideration of the Department's negative determination regarding worker eligibility to apply for trade adjustment assistance. The denial notice applicable to workers of the subject firm located in Greencastle, Indiana, was signed on May 20, 1997, and will soon be published in the **Federal Register.**

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

Findings of the investigation showed that workers of TechnoTrim, Incorporated were engaged in employment related to the Production of automobile set covers. The petitioners assert that workers of the subject firm produced seat covers for pick-up trucks, not automobiles. The Department's reference to automobile seat covers in the final determination is intended to include light trucks.

The petitioners assert that production at the subject firm was shifted to Hyperion for 90 days so that the sewing machines could be shipped from Greencastle, Indiana to Mexico. The petitioners add that Hyperion is not a TechnoTrim plant but another domestic facility located in Lewisburg, Tennessee. The petitioners assert that the office equipment at Greencastle was

also shipped to Mexico. Transfer of production from the subject firm to another domestic facility, whether or not corporate affiliated, and the shift of equipment to Mexico are not a basis for a worker group certification under the Trade Act of 1974, as amended.

In order to issue a worker group certification, the Department must be able to show that increased imports of articles like or directly competitive with the products produced at the workers' firm contributed importantly to the worker separations.

The Department's denial of TAA for workers of the subject firm was based on the fact that the ''contributed importantly'' test of the Group Eligibility requirements of Section 222 of the Trade Act of 1974, as amended, was not met. The ''contributed importantly'' test is generally demonstrated through a survey of the workers' firm's customers. The Department of Labor surveyed the major declining customers of the subject firm regarding their purchases of automobile seat covers. None of the respondents increased their import purchases of seat covers while decreasing their purchases form TechnoTrim, Incorporated. The company reports that it does not import seat covers from foreign sources.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, D.C. this 31st day of October 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31058 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,880]

United Technologies Automotive, Incorporated, Steering Wheels Division (Currently Known as Breed Technologies, Incorporated) Niles, Michigan; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 30, 1997, applicable to all workers of United Technologies Automotive, Incorporated, Steering Wheels Division, Niles, Michigan. The notice was published in the **Federal Register** on February 13, 1997 (62 FR 6806).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of molded steering wheels and airbag covers. The company reports that in July, 1997 the Niles, Michigan location of United Technologies became known as Breed Technologies, Incorporated. The Niles, Michigan workers have their wages reported under a separate unemployment insurance (UI) tax account, ''United Technologies, Incorporated on Behalf of Breed Technologies, Incorporated''.

The company also reports that worker separations are expected to occur at the Niles, Michigan facility when it closes at the end of October, 1997. Accordingly, the Department is amending the certification to reflect this matter.

The intent of the Department's certification is to include all workers of United Technologies Automotive, Incorporated, Steering Wheels Division adversely affected by increased imports.

The amended notice applicable to TA–W–32,880 is hereby issued as follows:

''All workers of United Technologies, Incorporated, Steering Wheels Division, currently known as Breed Technologies, Niles, Michigan who became totally or partially separated from employment on or after October 15, 1995, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, D.C. this 12th day of November, 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31060 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33, 799]

West Virginia Shoe Company, Marlinton, West Virginia; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Acting Director of the Office of Trade Adjustment Assistance for workers at West Virginia Shoe Company, Marlinton, West Virginia. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–33, 799; West Virginia Shoe Company, Marlinton, West Virginia (November 6, 1997)

Signed at Washington, D.C. this 6th day of November, 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31046 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–01766]

Seminole Tribe of Florida, Hollywood, Florida; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (P.L. 103–182) concerning transitional adjustment assistance, hereinafter called (NAFTA–TAA), and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2273), an investigation was initiated on May 27, 1997 in response to a petition filed on behalf of workers at Seminole Tribe of Florida located in Hollywood, Florida.

The sole petitioner was not employed by the subject firm cited, therefore, the petition is not valid. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 7th day of November 1997.

Grant D. Beale,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 97–31056 Filed 11–25–97; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (97–164)]

NASA Advisory Council, Advisory Committee on the International Space Station (ACISS); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Advisory Committee on the International Space Station.

DATES: Tuesday, December 9, 1997, from 9:00 a.m. until 5:00 p.m.; and Wednesday, December 10, 1997 from 11:00 a.m. until 12:00 p.m.

ADDRESSES: Lyndon B. Johnson Space Center, Building 1, Room 966, Houston, TX 77058–3696.

FOR FURTHER INFORMATION CONTACT: Mr. W. Michael Hawes, Code ML, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–0242.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to seating capacity of the room, from 9:00 a.m. until 5:00 p.m. on Tuesday, December 9, 1997. The meeting will reconvene at 11:00 a.m. until 12:00 p.m. on Wednesday, December 10, 1997. The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—ISS Status
—On-Orbit Maintenance
—Contingency Planning for the Assembly Sequence
—PrePlanned Program Improvement
—Space Station Utilization Advisory Subcommittee Report
—Cost Assessment and Validation Task Force Report
—Outreach Task Group Report

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: November 19, 1997.

Alan M. Ladwig,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 97–31097 Filed 11–25–97; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Advanced Scientific Computing; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Advanced Scientific Computing (#1185).

Date and Time: December 15–16, 1997, 8:30 am to 5:00 pm.

Place: Embassy Suites Hotel, 1881 Curtis Street, Denver, CO 80202.

Type of Meeting: Closed.

For Further Information Contact: Dr. John Van Rosendale, Program Director, New Technologies Program, Suite 1122, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 306–1962.

Purpose of Meeting: To provide recommendations and advice concerning proposals submitted to NSF for financial support.

Agenda: Panel review of the New Technologies Program proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and person information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31121 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Astronomical Sciences (1186); Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub L. 92–463, as amended), the National Science Foundation announces that the Special Emphasis Panel in Astronomical Sciences (1186) will be holding panel meetings for the purpose of reviewing proposals submitted to the Galactic Astronomy Program in the area of Astronomical Sciences. In order to review the large volume of proposals, panel meetings will be held on December 16 and 17, 1997, (3). All meetings will be closed to the public and will be held at the National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia, from 8:30 AM to 5:00 PM each day.

For Further Information Contact: Dr. Vernon L. Pankonin, Program Director, Galactic Astronomy, Division of Astronomical Sciences, National Science Foundation, Room 1030, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 306–1826.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 USC 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31119 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Civil and Mechanical Systems; Notice of Meeting

In accordance with the Federal Advisory Committee Act Public Law 92–463, as amended, the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Civil and Mechanical Systems (1205).

Date and Time: December 12, 1997; 8:30 a.m. to 5:00 p.m.

Place: Best Western Key Bridge Hotel, 1850 North Fort Meyer Dr., Arlington, Virginia 22209. 703/522–0400.

Contact Person: Dr. Sunil Saigal, Program Director, Mechanics and Materials Programs, Division of Civil and Mechanical Systems, Room 545, NSF, 4401 Wilson Blvd., Arlington, VA 22230. 703/306–1363, x 5069.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government Sunshine Act.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31124 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Cross Disciplinary Activities; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Cross Disciplinary Activities (1193).

Date & Time: December 15; 8:30 am–5:00 pm.

Place: Room 1060 and 1020, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Type of Meeting: Closed.

For Further Information Contact: Steve Mahaney, Program Director, CISE/OCDA, National Science Foundation, 4201 Wilson Blvd., Room 1160, Arlington, VA 22230. Telephone: (703) 306–1980.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate CISE Research Infrastructure proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in The Sunshine Act.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31120 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Mathematical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Mathematical Sciences (1204).

Date and Time: December 13, 1997.

Place: O'Hare Airport Hilton, Chicago, Illinois.

Type of Meeting: Closed.

Contact Meeting: Lloyd Douglas, Infrastructure Program, Program Officer, Room 1025 National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 306–1874.

Purpose of Meeting: To provide advice and recommendations concerning applications submitted to NSF for financial support.

Agenda: To review and evaluate proposals concerning the Mathematical Sciences Postdoctoral Research Fellowship Program, as part of the selection processes for awards.

Reason For Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31125 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Mathematical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Mathematical Sciences (1204).

Date and Time: December 18 to 20, 1997.

Place: Room 1020 National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Lloyd Douglas, Infrastructure Program, Program Officer, room 1025 National Science Foundation, 4201 Wilson Boulevard, Arlington VA 22230. Telephone: (703) 306–1874.

Purpose of Meeting: To provide advice and recommendations concerning applications submitted to NSF for financial support.

Agenda: To review and evaluate proposals concerning the Interdisciplinary Grants in the Mathematical Sciences Program, as part of the selection process for awards.

Reason For Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31126 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Physics; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and Time: Thursday, December 18, 1997; 8:00 a.m. to 5:00 p.m., Room 365.

Place: National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Type of Meeting: Closed.

For Further Information Contact: Dr. Bradley D. Keister, Program Director for Nuclear Physics, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1891.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate the Nuclear Faculty Early Career Development (CAREER) program proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31123 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Social, Behavioral, and Economic Sciences; Committee of Visitors; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory Committee for Social, Behavioral, and Economic Sciences, Committee of Visitors (1171).

Date and Time: December 11–12 1997; 9:00 a.m. to 5:00 p.m.

Place: Rm. 970, NSF, 4201 Wilson Boulevard, Arlington, VA.

Type of Meeting: Closed.

For Further Information Contact: Dr. Jonathan Leland, Program Director, Decision, Risk and Management Sciences Program National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 306–1757.

Purpose of Meeting: To carry out Committee of Visitors (COV) review, including examination of decisions on proposals, reviewer comments, and other privileged materials.

Agenda: To provide oversight review of the Decision, Risk and Management Sciences Program.

Reason for Closing: The meeting is closed to the public because the Committee is reviewing proposal actions that will include privileged intellectual property and personal

information that could harm individuals if they are disclosed. If discussions were open to the public, these matters that are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act would be improperly disclosed.

Dated: November 21, 1997.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 97–31122 Filed 11–25–97; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–302]

Florida Power Corporation; Crystal River Nuclear Generating Plant Unit 3; Exemption

I

Florida Power Corporation (the licensee) is the holder of Facility Operating License No. DPR–72, which authorizes operation of the Crystal River Nuclear Generating Plant Unit 3 (CR3). The license provides, among other things, that the licensee is subject to all rules, regulations, and orders of the Commission now or hereafter in effect.

The facility is of a pressurized water reactor type and is located in Citrus County, Florida.

II

In its letter dated September 5, 1997, the licensee requested an exemption from the Commission's regulations.

Title 10 of the *Code of Federal Regulations,* part 50, Appendix A, ''General Design Criteria for Nuclear Power Plants,'' Criterion 3, ''Fire Protection,'' specifies that ''Structures, systems, and components important to safety shall be designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.'' 10 CFR part 50, Appendix R sets forth the fire protection features required to satisfy certain provisions of General Design Criterion 3 of the Commission's regulations. Pursuant to 10 CFR part 50, Appendix R, Section III, Paragraph O, ''Oil Collection System for Reactor Coolant Pump,'' reactor coolant pumps (RCPs) shall be equipped with an oil collection system which ''* * * shall be capable of collecting lube oil from all potential pressurized and unpressurized leakage sites in the reactor coolant pump lube oil systems.''

In 1985, CR3 added remote oil addition lines (ROALs) to the original RCP oil fill lines to eliminate the need to shut down the reactor, and to reduce personnel radiation and heat stress exposure during periodic RCP oil additions. At that time, the licensee did not consider the ROALs to be a part of the RCP lube oil systems and as a result, did not provide a lube oil collection system to collect potential leakages. As part of its current Appendix R design review project, the licensee has now determined the ROALs to be a part of the RCP lube oil systems and therefore, would require a lube oil collection system.

The licensee states that the ROALs are of a rugged leak tight design. They are used only periodically using controlled plant procedures. In a hypothetical worst case spill, with ignition assumed, use of the ROALs does not impact post fire safe shutdown capability. As a result, the licensee believes that a lube oil collection system for the ROALs is not necessary to achieve the underlying purpose of the rule. Exemption from Appendix R, Paragraph O, requirements is required for the ROALs to have no lube oil collection system for collecting oil from potential leak sites.

III

Discussion

The licensee requests an exemption from the technical requirements relating to an oil collection system for the ROALs associated with the RCPs.

CR3 design includes four RCP motors which are located inside the D-Ring area. This area is separated from other fire areas by concrete barriers forming primary containment. Each group of two RCPs is separated from the other group by the reactor vessel and its concrete compartment. The walls of the reactor compartment are four feet thick concrete.

The RCP Motors have an upper oil reservoir for the thrust bearing containing 175 gallons of oil, and a lower bearing oil reservoir containing 15 gallons of oil. Both reservoirs are vented to the containment atmosphere to ensure that they would not be overpressurized during oil addition operations. The upper and lower oil reservoirs have oil fill lines at the motors which are contained by the RCP motor lube oil collection system. In 1985, ROALs were added to the original RCP oil fill lines to eliminate the need to shut down the reactor, and to reduce personnel radiation and heat stress exposure during periodic RCP oil additions. The RCP lube oil collection system provides collection coverage for the original oil fill lines and the ROAL connection at the RCP motor. High and low oil level control room annunciators, and digital local level indications are provided for both upper and lower lube oil reservoirs.

The ROALs are constructed of ½″ stainless steel tubing with 3000 psi pressure-rated swagelok unions. The ROALs transition to ½″ stainless steel flexible metal hose (3000 psi rating) with compression type fittings at the D-Ring penetrations and attachment to each RCP motor reservoir. Connections to the original RCP lube oil fill line are above the maximum oil level of the upper and lower reservoirs. The operating pressure of the ROALs is 30 psig or less.

Inside the RCP D-Ring, the ROALs travel over or along a main steam line, steam generator insulation, and RCP casing before attaching to the original oil fill lines. The main steam line and the steam generator are insulated with stainless steel encapsulated mineral wool. The RCP casing insulation is a non-absorbing mirror-type insulation. Outside the secondary shield wall, the ROALs do not travel over any hot main pipes or steam lines.

A portable oil metering pump skid, two portable tanks, and associated high pressure flexible hoses transport oil to containment during oil transfer operations. Connection of the pump discharges to the permanently mounted ROALs is via high pressure flexible hose with quick disconnect fittings. Each metering pump is provided with a relief valve located adjacent to the pump discharge and arranged to ensure that any oil discharge from the relief valve is captured and contained in a portable tank (suction supply). The oil supply tanks for each of the oil metering pumps meet the requirements of CR3's Administrative Instructions for the use of flammable or combustible liquids inside plant areas.

To minimize the potential for an oil fire due to a leak from the ROALs, the licensee proposes to implement several precautionary procedural actions during and following oil additions. They include requirements for monitoring oil transfers, communications between the control room and local operations personnel, walkdown and inspection of the ROALs and the areas around the oil pumping manifolds, and containment closeout inspection following refueling outages to assure the integrity of the ROALs.

IV

Evaluation

The Commission has completed its evaluation of the licensee's application.

The reactor lube oil collection system is required to prevent a major fire from occurring inside the reactor

containment as a result of a lube oil leak from the RCPs. The ROALs are a low pressure system. The 3000 psi minimum design pressure of the ROALs is significantly higher than the 30 psig line operating pressures. All piping components associated with the suction and discharge of the portable oil transfer pump skid are appropriately rated for the service conditions. The hose connections are flexible hoses, and therefore, are not subjected to mechanical vibration and thermal stresses.

Oil leakage from the ROALs is not expected to occur during oil transfer operations. The ROALs are used only periodically and operated using controlled procedures and processes. The controlled oil addition process includes determining the amount of oil to be added, performing a walk down before oil addition to check for leakage, and local and control room monitoring of the oil addition process. Following the addition of the proper amount of oil, the ROAL is drained either by gravity or by reversing the pump suction and discharge connections and pumping down the line. The upper and lower reservoirs contain only limited quantities of oil, 175 and 10 gallons, respectively. Based on the maximum oil addition allowed by procedures, the maximum potential oil spill will be only 12 gallons.

During power operation, damage to the ROALs would not occur because the reactor building access and work activities are limited during this time. Further, following refueling outages, containment close-out procedures require visual inspections to assure the integrity of the ROALs.

Inside the D-ring, the ROALs travel over or along hot components that are insulated with a non-absorbing material or encased mineral wool. The surface temperatures of the insulation are below the ignition temperature of the oil, such that the insulation would not be a potential ignition source. The construction of this insulation makes it less likely for potential leaking oil to soak the encased mineral wool. Any potential oil leak in this area would be reasonably expected to travel down the insulation to the floor. Further, there are spot-type heat detectors located in this general area which can provide early warning to the control room in the event of a fire.

Outside the secondary shield wall, the ROALs do not travel over any hot main coolant pipes or steam lines and any potential leak in this area would pool on the floor and have no opportunity for ignition.

The ROALs are routed through two fire areas in the reactor building (RB), elevations 95 and 119 feet, designated as RB–95–300 and RB–119–302. The licensee has administrative controls that are designed to control the type, amount, use and location of combustibles. Proper control of combustibles minimizes the possibility of starting, spreading, or contributing to a fire. The probability for a fire hazard in this area is minimal because of separation of redundant components, the surrounding concrete structure, minimal or no intervening combustibles in the area, high ROAL design pressure and low operating pressure, and the short duration and infrequency of oil addition operations. However, the licensee has evaluated a worst case lube oil fire for these fire areas that contain ROALs and concluded that it is bounded by the CR3's existing Fire Hazards Analysis and Appendix R fire study.

In 1985, when the ROALs were originally installed, they were functionally leak tested with no visible leakage detected. During the last 12 years of performance there has been no indication of any leakage from the ROALs.

Fire detection and manual fire suppression equipment is available in the vicinity of the lube oil fill lines. In the event of a fire, it is expected that a detector will alarm while the fire is in its incipient stages. Operators would then take appropriate action to mitigate the consequences of the fire. This provides further assurance that a worst-case postulated fire would not damage safe shutdown equipment.

Based on the design features of the ROALs and associated lube oil collection systems, and the licensee's proposed compensatory actions, there is reasonable assurance that the RCP lube oil system will not lead to a major fire hazard. In addition, based on the present level of fire protection provided for the RCPs, if a fire were to occur in the area, there is reasonable assurance that the fire will be detected and mitigated. Therefore, the staff finds the ROALs without an oil collection system acceptable.

The underlying purpose of 10 CFR part 50, Appendix R, Section III.O, is to ensure that lube oil from all potential pressurized and unpressurized leakage sites in the reactor coolant pump lube oil systems would be collected and not become a fire hazard such that ''the capability to achieve and maintain safe shutdown conditions during and after any postulated fire in the plant'' will be ensured. On the basis of its review and evaluation of the licensee's exemption request, the staff concludes that the addition of an oil collection system for the ROALs is not necessary to achieve the underlying purpose of the rule. Therefore, an exemption from the requirement for providing a lube oil collection system for the RCP Motor ROALs is acceptable.

V

For the foregoing reasons, the NRC staff has concluded that pursuant to 10 CFR 50.12(a) an exemption permitting the licensee's proposed use of ROALs without an oil collection system is authorized by law, will not present an undue risk to public health and safety and is consistent with the common defense and security. The NRC staff has determined that there are special circumstances present, as specified in 10 CFR 50.12(a)(2)(ii), in that application of 10 CFR part 50, Appendix R, Section III.O, is not necessary in order to achieve the underlying purpose of this regulation.

Accordingly, the Commission hereby grants an exemption from the technical requirements of 10 CFR part 50, Appendix R, Section III.O to the extent that the ROALs need not be provided with an oil collection system.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (62 FR 59752).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 19th day of November 1997.

For the Nuclear Regulatory Commission.

Samuel J. Collins,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 97–31085 Filed 11–25–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Number 40–6622]

Pathfinder Mines Corporation

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Amendment of Source Material License SUA–442 to change three reclamation milestone dates.

SUMMARY: Notice is hereby given that the U.S. Nuclear Regulatory Commission has amended Pathfinder Mines Corporation's (PMC's) Source Material License SUA–442 to change three reclamation milestone dates. This amendment was requested by PMC in

its letter dated September 11, 1997, and the receipt of the request by NRC was noticed in the **Federal Register** on October 6, 1997.

The license amendment modifies License Condition 50 to change completion dates for three site-reclamation milestones. The new dates approved by the NRC extend completion of placement of the interim cover over tailings pile by two years, and completion of placement of the final radon barrier and placement of the erosion protection cover by three years. PMC attributes the delays to a substantial volume of water still remaining to be evaporated from the tailings system, before an interim cover could be placed. Based on the review of PMC's submittal, the NRC staff concludes that the delays are attributable to factors beyond the control of PMC, the proposed work is scheduled to be completed as expeditiously as practicable, and the added risk to the public health and safety is not significant.

An environmental assessment is not required since this action is categorically excluded under 10 CFR 51.22(c)(11), and an environmental report from the licensee is not required by 10 CFR 51.60(b)(2).

SUPPLEMENTARY INFORMATION: PMC's amended license, and the NRC staff's technical evaluation of the amendment request are being made available for public inspection at the Commission's Public Document Room at 2120 L Street, NW. (Lower Level), Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Mohammad W. Haque, Uranium Recovery Branch, Division of Waste Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone (301) 415–6640.

Dated at Rockville, Maryland, this 19th day of November, 1997.

Joseph J. Holonich,

Chief, Uranium Recovery Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 97–31086 Filed 11–25–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Application for a License To Export Special Nuclear Material

Pursuant to 10 CFR 110.70(b) ''Public notice of receipt of an application'', please take notice that the Nuclear Regulatory Commission has received the following application for an export license. Copies of the application are on file in the Nuclear Regulatory Commission's Public Document Room located at 2120 L Street, N.W., Washington, D.C.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requester or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; and the Executive Secretary, U.S. Department of State, Washington, D.C. 20520.

The information concerning the application follows.

NRC EXPORT LICENSE APPLICATION

Name of applicant, date of application, date received, application No.	Description of material		End use	Country of origin
	Material type	Total quantity		
Transnuclear, Inc., October 27, 1997, October 29, 1997, XSNM03012.	High-enriched Uranium (93.3%)	26.738 kg ...	Fabrication of target material for production of medical isotopes.	Canada.

Dated this 12th day of November 1997 at Rockville, Maryland.

For the Nuclear Regulatory Commission.

Ronald D. Hauber,

Director, Division of Nonproliferation, Exports and Multilateral Relations, Office of International Programs.

[FR Doc. 97–30968 Filed 11–25–97; 8:45 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards Subcommittee Meeting on Planning and Procedures

The ACRS Subcommittee on Planning and Procedures will hold a meeting on December 3, 1997, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c) (2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, December 3, 1997—10:00 a.m. until 11:30 a.m.

The Subcommittee will discuss proposed ACRS activities and related matters. It may also discuss the qualifications of candidates for appointment to the ACRS. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the pubic, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff person named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

Further information regarding topics to be discussed, the scheduling of sessions open to the pubic, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements, and the time allotted therefor can be obtained by contacting the cognizant ACRS staff person, Dr. John T. Larkins (telephone: 301/415–7360) between 7:30 a.m. and 4:15 p.m. (EST). Persons planning to attend this

meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any changes in schedule, etc., that may have occurred.

Dated: November 12, 1997.

Sam Duraiswamy,

Chief, Nuclear Reactors Branch.

[FR Doc. 97–30969 Filed 11–25–97; 8:45 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards Meeting of the ACRS Subcommittee on Plant Operations

The ACRS Subcommittee on Plant Operations will hold a meeting on December 2, 1997, in Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, December 2, 1997—8:30 a.m. until the conclusion of business

The Subcommittee will review the staff's Safety Evaluation Report on the BWR Owners' Group Utility Resolution Guidance to address emergency core cooling system suction strainer blockage. The Subcommittee will also review the results of licensee responses to NRC Bulletins to address strainer blockage, research associated with debris generation and transport, and proposed actions to provide closure to these issues. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic Recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by containing the cognizant ACRS staff engineer, Mr. Amarjit Singh (telephone 301/415–6899) between 7:30 a.m. and 4:15 p.m. (EST). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: November 13, 1997.

Sam Duraiswamy,

Chief, Nuclear Reactors Branch.

[FR Doc. 97–30970 Filed 11–25–97; 8:45 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22897; File No. 812–10760]

Western Reserve Life Assurance Co. of Ohio, et al.; Notice of Application

November 19, 1997.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of application for an order under Section 26(b) of the Investment Company Act of 1940 (''1940 Act'') approving the proposed substitution of securities.

SUMMARY OF APPLICATION: Applicants request an order approving the substitution of securities issued by certain registered management investment companies and held by the Accounts to support individual flexible premium deferred variable annuity contracts and individual flexible premium variable life insurance policies issued by Western Reserve.

APPLICANTS: Western Reserve Life Assurance Co. of Ohio (''Western Reserve''), WRL Series Annuity Account (''Annuity Account'') and WRL Series Life Account (''Life Account'') (the Life Account and the Annuity Account together, the ''Accounts'').

FILING DATES: The application was filed on August 15, 1997, and an amended and restated application was filed on October 22, 1997.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving Applicants with a copy of the request, in person or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 15, 1997, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, c/o Thomas E. Pierpan, Esquire, Western Reserve Life Assurance Co. Of Ohio, 201 Highland Avenue, Largo, Florida 33770–2597.

FOR FURTHER INFORMATION CONTACT: Michael Koffler, Attorney, or Mark Amorosi, Branch Chief, Office of Insurance Products (Division of Investment Management), at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the SEC's Public Reference Branch, 450 Fifth St., N.W., Washington, D.C. 20549 (tel. (202) 942–8090).

Applicants' Representations

1. Western Reserve, a stock life insurance company, is principally engaged in the business of writing life insurance policies and annuity contracts and is authorized to do business in the District of Columbia and all states except New York. Western Reserve is a wholly-owned subsidiary of First AUSA Life Insurance Company which is a wholly-owned subsidiary of AEGON USA, Inc., which in turn is a wholly-owned indirect subsidiary of AEGON nv, a Netherlands corporation, which is a publicly traded international insurance group. Western Reserve is the sponsor and depositor of the Accounts.

2. Western Reserve issues individual flexible premium variable life insurance policies and individual flexible premium deferred variable annuity contracts (collectively, the ''Contracts'') through the Life Account and the Annuity Account respectively. Each of the Accounts is a separate account and is registered under the 1940 Act as a unit investment trust. Interests in the Accounts offered through the Contracts

have been registered under the Securities Act of 1933 (''1933 Act''). Each Account is comprised of sub-accounts established to receive and invest net purchase payments of the Contracts. Each sub-account invests exclusively in the shares of a specified portfolio of the WRL Series Fund, Inc. (the ''Fund'') and supports the Contracts.

3. The Fund is registered under the 1940 Act as an open-end management investment company. The Fund is a series investment company as defined by rule 18f–2 under the 1940 Act and is currently comprised of 21 investment portfolios (the ''Portfolios''). The Fund issues a separate series of shares of stock in connection with each Portfolio and has registered these shares under the 1933 Act. WRL Investment Management, Inc. (''WRL Management''), a direct wholly-owned subsidiary of Western Reserve, is the investment adviser to the Fund.

4. Applicants state that the following Portfolios of the Fund have not generated substantial Contract owner interest since their inception: the Short-to-Intermediate Government Portfolio, the C.A.S.E. Quality Growth Portfolio, the C.A.S.E. Growth & Income Portfolio, the Foreign Sector Portfolio and the US Sector Portfolio (collectively, the ''Replaced Portfolios''). In addition, the Replaced Portfolios are each relatively small in terms of assets compared to many other similar investment portfolios of open-end management investment companies available as investment vehicles for variable annuity and variable life insurance products. Applicants state that, as a result, the annual expense ratios of the Replaced Portfolios, absent any expense reimbursement, have been higher than the ratios of most similar, but larger portfolios. Moreover, the current expense reimbursement arrangements for the Replaced Portfolios are voluntary and there is no assurance these arrangements will continue in the future. Applicants also state that the performance of the Replaced Portfolios since their inception has been unremarkable given overall market performance during the relevant time periods.

5. For these reasons, Applicants propose that Western Reserve substitute shares of the Bond Portfolio for shares of the Short-to-Intermediate Government Portfolio; shares of the U.S. Equity Portfolio for shares of the US Sector Portfolio; shares of the Global Portfolio for shares of the Foreign Sector Portfolio; shares of the C.A.S.E. Growth Portfolio for shares of the C.A.S.E. Quality Growth Portfolio; and shares of the C.A.S.E. Growth Portfolio for shares of the C.A.S.E. Growth & Income Portfolio.

6. Applicants represent that the Portfolios proposed as substitutes for each of the Replaced Portfolios (the ''Substitute Portfolios'') are substantially larger than their Replaced Portfolio counterparts. Applicants also represent that each Substitute Portfolio also has lower expense ratios and (with the exception of the U.S. Equity Portfolio, which does not yet have a performance record of significant duration) has either outperformed or performed comparably, relative to the corresponding Replaced Portfolio.

7. Applicants state that, by supplements to the prospectuses for the Contracts of the Accounts, all owners and prospective owners of the Contracts were notified of Western Reserve's intention to take the necessary actions to substitute the Replaced Portfolios with the Substitute Portfolios. The supplements advised owners and prospective owners that they will be unable to allocate net purchase payments to, or transfer cash values to, the sub-accounts of the Accounts corresponding to each of the Replaced Portfolios after November 15, 1997. The supplements also advised owners and prospective owners that on the date of the proposed substitutions, the Substitute Portfolios will replace the Replaced Portfolios as the underlying investments for such sub-accounts. The supplements further apprised owners and prospective owners that from the date of the supplements until 30 days after the date of the proposed substitutions, owners will be permitted to make one transfer per affected sub-account of all the cash value under a Contract invested in such affected sub-account to other available subaccount(s), other than one of the other affected sub-accounts, without that transfer(s) counting as one of the 12 transfers permitted in a Contract year free of charge. In addition, the supplements informed owners and prospective owners that Western Reserve will not exercise any rights reserved by Western Reserve under any of the Contracts to impose additional restrictions on transfers until at least 30 days after the proposed substitutions.

8. Applicants state that at least 60 days before the date of the proposed substitutions, affected owners were provided with a prospectus for the Fund which includes complete current information concerning the Substitute Portfolios.

9. Applicants propose to have Western Reserve redeem shares of each Replaced Portfolio in cash and purchase with the proceeds shares of the relevant Substitute Portfolio. Applicants represent that redemption requests and purchase orders will be placed simultaneously so that Contract values will remain fully invested at all times.

10. Applicants state that the proposed substitutions will take place at relative net asset value with no change in the amount of any Contract owner's cash value or death benefit or in the dollar value of his or her investment in any of the Accounts. Applicants represent that Contract owners will not incur any fees or charges as a result of the proposed substitutions and that their rights and Western Reserve's obligations under the Contracts will not be altered in any way. All expenses incurred in connection with the proposed substitutions, including legal, accounting and other fees and expenses, will be paid by Western Reserve. In addition, Applicants represent that the proposed substitutions will not impose any tax liability on Contract owners. The proposed substitutions will not cause the Contract fees and charges currently paid by existing Contract owners to be greater after the proposed substitutions than before the proposed substitutions.

11. Within 5 days after the proposed substitutions, any owners who were affected by a substitution will be sent a written notice informing them that the substitutions were carried out and that they may make one transfer of all cash value under a Contract invested in each of the affected subaccounts to other subaccount(s) until 30 days after the substitution without that transfer counting as one of the 12 transfers permitted in a Contract year free of charge. the notice will also reiterate that Western Reserve will not exercise any rights reserved by Western Reserve under any of the Contracts to impose additional restrictions on transfers until at least 30 days after the proposed substitutions.

Applicants' Legal Analysis

1. Applicants request that the Commission issue an order pursuant to Section 26(b) of the 1940 Act approving the substitutions by Western Reserve of (1) shares of the Bond Portfolio for shares of the Short-to-Intermediate Government Portfolio; (2) shares of the U.S. Equity Portfolio for shares of the US Sector Portfolio; (3) shares of the Global Portfolio for shares of the Foreign Sector Portfolio; (4) shares of the C.A.S.E. Growth Portfolio for shares of the C.A.S.E. Quality Growth Portfolio; and (5) shares of the C.A.S.E. Growth Portfolio for shares of the C.A.S.E. Growth & Income Portfolio held by

corresponding sub-accounts of the Accounts.

2. Section 26(b) of the 1940 Act provides, in pertinent part, that ''[i]t shall be unlawful for any depositor or trustee of a registered unit investment trust holding the security of a single issuer to substitute another security for such security unless the Commission shall have approved such substitution.'' Section 26(b) of the 1940 Act also provides that the Commission shall issue an order approving such substitution if the evidence establishes that the substitution is consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the 1940 Act.

3. Applicants assert that the Contracts give Western Reserve the right, subject to Commission approval, to substitute shares of another open-end management investment company for shares of an open-end management investment company held by a sub-account of the relevant Account. Applicants also assert that the prospectuses for the Contracts and the Accounts contain appropriate disclosure of this right.

4. Applicants contend that the Substitute Portfolios will have lower or equal future expense ratios than the past expense ratios of the Replaced Portfolios. Each of the Substitute Portfolios is substantially larger than the corresponding Replaced Portfolio and each Substitute Portfolio (except the U.S. Equity Portfolio, which commenced operations on January 2, 1997) has had more favorable expense ratios over the last two years than the corresponding Replaced Portfolio.

5. As of November 15, 1997, the Replaced Portfolios will no longer be available for new investment, and most likely will experience the net redemption of their shares from that date forward. Therefore, Applicants assert that it is highly likely that in the near future each Replaced Portfolio's asset base will decrease and, accordingly, each Replaced Portfolio's expense ratio will increase.

6. Applicants state that each Substitute Portfolio has performed favorably over the past two years (except the U.S. Equity Portfolio, which commenced operations on January 2, 1997), and since its inception compared to the corresponding Replaced Portfolio. Applicants therefore anticipate that after the proposed substitutions, the Substitute Portfolios will provide Contract owners with more favorable or comparable investment results than would be the case if the proposed substitutions do not take place.

7. Applicants represent that each of the Substitute Portfolios is a suitable and appropriate investment vehicle for Contract owners and that each Substitute Portfolio has, or will have, substantially identical or similar investment objectives and policies to its corresponding Replaced Portfolio.

Conclusion

Applicants submit that, for all the reasons summarized above, the proposed substitutions are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Security.

[FR Doc. 97–31016 Filed 11–27–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22898]

Allied Capital Corporation (File No. 811–907) and Allied Capital Lending Corporation (File No. 811–2708); Notice of Proposed Deregistration

November 20, 1997.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of proposed deregistration under section 8(f) of the Investment Company Act of 1940 (the ''Act'').

SUMMARY OF NOTICE: The SEC proposes to declare by order on its own motion that the registrations of Allied Capital Corporation (''Allied'') and Allied Capital Lending Corporation (''Allied Lending'') under the Act have ceased to be in effect as of June 28, 1991, and November 12, 1993, respectively, the dates that each elected to be regulated as a business development company (''BDC'').

HEARING OR NOTIFICATION OF HEARING: An order will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving the relevant registrant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on December 15, 1997, and should be accompanied by proof of service on the registrant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, N.W., Washington, D.C. 20549. Allied and Allied Lending: 1666 K Street, N.W., 9th Floor, Washington, D.C. 20006–2803.

FOR FURTHER INFORMATION CONTACT: Elaine M. Boggs, Senior Counsel, at (202) 942–0572, or Mercer E. Bullard, Branch Chief, at (202) 942–0572, (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION:

Statement of Facts

1. Allied and Allied Lending, both Maryland corporations and closed-end investment companies registered under the Act, filed Notifications of Registration under the Act on September 29, 1959 and November 23, 1976, respectively. In January 1960, Allied began a public offering. Until November 23, 1993, Allied Lending was a wholly-owned subsidiary of Allied. Allied Lending filed a registration statement under the Act and the Securities Act of 1933 that became effective on November 16, 1993. Allied commenced an initial public offering of its shares on November 23, 1997.

2. Section 54(a) of the Act provides that any company that satisfies the definition of a BDC under sections 2(a)(48) (A) and (B) of the Act may elect to be subject to the provisions of sections 55 through 65 of the Act and be regulated as a BDC by filing with the SEC a notification of the election, if the company: (i) has a class of its equity securities registered under section 12 of the Securities Exchange Act of 1934 (the ''Exchange Act''); or (ii) has filed a registration statement pursuant to section 12 of the Exchange Act for a class of its equity securities. On June 28, 1991, and November 12, 1993, Allied and Allied Lending, respectively, each elected BDC status by filing a Form N–54A. Allied Lending filed a registration statement under the Exchange Act on November 12, 1993. Allied did not file a registration statement under the Exchange Act in reliance on the exemption provided by rule 12g–2 under the Exchange Act.

3. Section 8(a) of the Act, which requires registration of investment companies, does not apply to BDCs. After an existing registered investment company has filed an election to be regulated as a BDC, the SEC on its own motion will declare by order under section 8(f) that the company's registration under the Act has ceased to be in effect. The order will be effective retroactively, as of the date the SEC

received the company's election. See Investment Company Act Release No. 11703 (March 26, 1981).

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–31018 Filed 11–25–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–39338; File No. SR–CBOE–97–48]

Self-Regulatory Organizations; Chicago Board Options Exchange, Inc.; Order Approving Proposed Rule Change Relating to a Reduction in the Value of the Standard & Poor's 100 Stock Index and a Corresponding Increase in the Existing Position and Exercise Limits for the Option Traded on the Index

November 19, 1997.

I. Introduction

On September 19, 1997, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') submitted to the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to double current position and exercise limits in connection with a reduction by Standard & Poor's (''S&P'') of the value of its S&P 100 Stock Index (''Index'') option (''OEX'') to one-half of its present value by doubling the divisor used in calculating the Index.

The proposed rule change appeared in the **Federal Register** on October 10, 1997.[3] No comments were received on the proposed rule change. This order approves the CBOE's proposal.

II. Description of the Proposal

In March 1983, the CBOE began trading OEX options,[4] which are American-style, cash-settled options on the Index. The Exchange notes that the value of the OEX has doubled in value since mid-1995, such that the value of the Index stood at 928.20 as of August 7, 1997. As a result of the significant increase in the value of the underlying Index, the premium for OEX options also has increased. This has caused OEX options to trade at a level that may be uncomfortably high for retail investors, a large and important part of the market for OEX options.

As a result, pursuant to CBOE's request, S&P (the reporting authority and sole party responsible for maintaining the Index) has agreed to a ''two-for-one split'' of the Index. The change, which will be implemented immediately following the November expiration,[5] will result in a halving of the Index level, as well as a doubling of the number of OEX contracts outstanding, such that for each OEX contract held, the holder will receive two contracts at the reduced value, with a strike price of one-half of the original strike price.[6]

In addition to the above, the CBOE proposes to double the position limits applicable to the OEX from 25,000 to 50,000 contracts.[7] The CBOE also proposes to double the exercise limits applicable to OEX options from 15,000 to 30,000 contracts. The Exchange believes this increase in the position and exercise limits is justified because the reduction in the divisor would result in each contract overlying only one-half of the value of a current OEX contract. Consequently, the revised position and exercise limits would be equivalent to the current levels in terms of the value of the Index.

The CBOE announced the effective date of the change by way of an Exchange circular to its membership, which also described the changes to the strike prices and the position and exercise limits.[8]

The Exchange expects the proposed changes to attract additional customer business in OEX in those series in which retail customers are interested most in trading. The Exchange believes the proposed change will permit some retail investors to trade these options who otherwise have been priced out of the market due to the recent market surge. The Exchange further believes that OEX options provide an important opportunity for investors to hedge and speculate upon the market risk associated with the stocks comprising this broad-based, widely followed Index. By reducing the value of the Index, investors will be able to utilize this trading vehicle, while extending a smaller outlay of capital. The Exchange believes that this should attract additional investors and create a more active and liquid trading environment.

The Exchange believes that reducing the value of the Index does not raise manipulation concerns and will not cause adverse market impact because the Exchange will continue to employ the same surveillance procedures and has proposed an orderly procedure to achieve the Index split, including adequate prior notice to market participants.

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of Section 6(b) of the Act[9] and the rules and regulations thereunder applicable to a national securities exchange.[10] Specifically, because reducing the value of the Index will enhance the depth and liquidity of the market for both members and investors in general, the Commission believes that this rule change is consistent with and furthers the objectives of Section 6(b)(5) of the Act[11] in that it would remove impediments to and perfect the mechanism of a free and open market in a manner consistent with the protection of investors and the public interest.

By reducing the value of the Index, the Commission believes that a broader range of investors will be provided with a means to hedge their exposure to the market risk associated with the stocks underlying the Index. Similarly, the Commission believes that reducing the value of the Index may attract additional investors, thus creating a more active and liquid trading market in OEX.

The Commission also believes that CBOE's adjustments to its position and exercise limits are appropriate and consistent with the Act. In particular,

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 39192 (October 3, 1997) 62 FR 53040.

[4] *See* Securities Exchange Act Release No. 19264 (November 22, 1997) 47 FR 53981 (November 30, 1982).

[5] The Index is scheduled to be split on November 24, 1997. Telephone conversation between Timothy Thompson, Senior Attorney, CBOE, and Michael Walinskas, Senior Special Counsel, Division of Market Regulation, Commission, on November 10, 1997.

[6] The value of reduced-value Long-Term AnticiPation Securities (''LEAPS'') based on the Index will not be affected by the proposed change in the value of the Index. Therefore, reduced value OEX LEAPS, based on one-tenth of the value of the Index, will be based on one-fifth of the value of the Index after the value of the Index is reduced by one-half. *See* Letter from Timothy H. Thompson, Senior Attorney, CBOE, to Michael Walinskas, Division of Market Regulation, Commission, dated November 11, 1997.

[7] The Exchange has separately requested an increase in the position and exercise limits for OEX. *See* Securities Exchange Act Release No. 38525 (April 18, 1997) 62 FR 20046 (April 24, 1997) (noticing SR–CBOE–97–11).

[8] In this regard, the Commission notes that in a circular dated November 13, 1997, the CBOE provided notice to its members and member organizations of the S&P's intent to reduce the value of the Index by one-half and of the CBOE's intent to double the position and exercise limits for OEX.

[9] 15 U.S.C. 78f(b).

[10] In approving this rule, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78f(b)(5).

the Commission believes that the position and exercise limits are reasonable in light of the fact that the size of the OEX contract will be halved. Doubling the position and exercise limits, therefore, will permit market participants to maintain, after the split of the Index, their current level of investment in OEX options.

The Commission further believes that doubling the Index's divisor will not have an adverse market impact or make trading in OEX options susceptible to manipulation. After the split, the Index will continue to be comprised of the same stocks with the same weightings and will be calculated in the same manner, except for the proposed change in the divisor. The Commission notes that the CBOE's surveillance procedures also will remain the same.

Finally, the Commission notes that the Exchange provided notice of the proposed changes to the Index and the OEX contract to its membership through a circular.[12] The Commission believes that the CBOE provided adequate notice to market participants regarding this change to the Index value and the OEX contract prior to its implementation.

IV. Conclusion

For the foregoing reasons, the Commission finds that the CBOE's proposal is consistent with the requirements of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[13] that the proposed rule change (SR–CBOE–97–48) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–31019 Filed 11–25–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–39337; File No. SR–CHX–97–30]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Stock Exchange, Incorporated Codifying the Exchange's Clearing the Post Policy

November 19, 1997.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on October 23, 1997, the Chicago Stock Exchange, Incorporated (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to add interpretation and policy .02 to Rule 10 of Article XX relating to clearing the post. The text of the proposed rule change is as follows: Additions are italicized.

Article XX

Rule 10. Manner of Bidding and Offering.

No change in text.

* * * Interpretations and Policies

.02 Clearing the Post.

Policy. All orders received by floor brokers or originated by market makers on the floor of the Exchange must effectively clear the post before the orders may be routed to another market, either via the ITS System or through the use of alternative means.

Floor brokers who receive an order on the floor have a fiduciary responsibility to seek a best price executive for such order. This responsibility includes clearing of the Exchange's post prior to routing an order to another market so that other buying and selling interest at the post can be checked for a potential execution that may be as good as or better than the execution available in another market.

Market makers are required to provide depth and liquidity to the Exchange market, among other things. Exchange Rules require that all market maker transactions constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market. In so doing, market makers must adhere to traditional agency/auction market principles on the floor. Transactions by Exchange market makers on other exchanges which fail to clear the Exchange post do not constitute such a course of dealings.

Notwithstanding the above, it is understood that on occasion a customer will insist on special handling for a particular order that would preclude it from clearing the post on the Exchange floor. For example, a customer might request that a specific order be given a primary market execution. These situations must be documented and reported to the Exchange. Customer directives for special handling of all orders in a particular stock or all stocks, however, will not be considered as exceptions to the clearing the post policy.

All executions resulting from bids and offers reflected on Instinet terminals resident on the Exchange floor constitute ''orders'' which are ''communicated'' to the Exchange floor. Therefore, all orders resulting from interest reflected on Instinet terminals on the Exchange floor must be handled as any other order communicated to the floor. All such orders must be presented to the post during normal trading hours. All trades between Instinet and Exchange floor members are Exchange trades and must be executed on the Exchange.

Method of Clearing the Post. The Exchange's clearing the post policy requires the floor broker or market maker to be physically present at the post. A market maker, after requesting the specialist's market quote, must bid or offer the price and size of his intended interest at the post. A floor broker must clear the post by requesting a market quote from the specialist. If the specialist or any other member who has the post indicates an interest to trade at the price that was bid or offered by the market maker or the price of the floor broker's order (even though that order has not yet been bid or offered), then the trade may be consummated with the specialist (or whomever has the post) in accordance with existing Exchange priority, parity and precedence rules. If the specialist (or any other member who has the post) indicates interest to trade at that price but the member communicating the intended interest, including Instinet interest, determines not to consummate the trade with the specialist or such member, then, to preserve the Exchange's existing priority, parity and precedence rules, the trade may not be done with any other Exchange floor member. (See Article XXX, Rule 2.) If the trade is consummated with the specialist or other member who has the post, the specialist (or any customer represented by the specialist) is not required to pay any fees to the broker or market maker in connection with the execution of the order, unless such fee is expressly authorized by an Exchange Rule. If the specialist does not indicate an interest to trade, then the trade may be consummated with another Exchange

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[12] *See supra* note 8.

[13] 15 U.S.C. 78s(b)(2).

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

floor member on the Exchange floor with a resultant Exchange print.

Failure to clear the post may result in a ''trade-through'' or ''trading ahead'' of other floor interest. In addition, failure to properly clear the post may result in a violation of the Exchange's Just and Equitable Trade Principles Rile (Article VIII, Rule 7) and a market maker rule that requires all market maker transactions to constitute a course of dealing reasonably calculated to contribute to the maintenance of a fair and orderly market (Article XXXIV, Rule 1). Failure to properly clear the post may also subject the violator to a minor rule violation under the Exchange's Minor Rule Violation Plan.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to codify the Exchange's existing clearing the post policies in the CHX Guide. The clearing the post policy will become an interpretation and policy of CHX Article XX, Rule 10. The Exchange's clearing the post policies are currently contained in several Notices to Members which had been approved by the Commission.[2] These Notices to Members, and their corresponding Approval Orders explain the Exchange's clearing the post requirements. No substantive change is being made to the clearing the post policy at this time.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)(5) of the Act[3] in that it is designed to prevent fraudulent and manipulative acts and practices and to perfect the mechanism of a free and open market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes a stated policy, practice or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the Exchange pursuant to Section 19(b)(3)(A)[4] of the Act and subparagraph (e) of Rule 19b–4[5] thereunder. At any time within 60 days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington D.C. 20549. Copies of the submissions, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 522, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to File No. SR–CHX–97–30 and should be submitted by December 17, 1997.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–31017 Filed 11–25–97; 8:45 am]

BILLING CODE 8010–01–M

[2] Securities Exchange Act Release No. 33806 (March 23, 1994) 59 FR 15248 (Notice of Filing and Immediate Effectiveness of file No. SR–CHX–94–03); Securities Exchange Act Release No. 17766 (May 8, 1981) 46 FR 25745 (Order approving SR–MSE–81–3 and SR–MSE–81–5); and Securities Exchange Act Release No. 28638 (November 30, 1990) 55 FR 49731 (Order approving SR–MSE–90–7).

[3] 15 U.S.C. 78f(b)(5).

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(e).

[6] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 28895]

Airport Privatization Pilot Program: Application Procedures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of amendment to final application procedures; request for comments.

SUMMARY: Section 149 of the Federal Aviation Authorization Act of 1996 establishes an airport privatization pilot program, and authorizes the Department of Transportation to grant exemptions from certain Federal statutory and regulatory requirements for up to five airport privatization projects. On September 16, 1997, the FAA issued a notice of final procedures for application for an exemption under the program. The notice included a provision that air carriers that submitted a proposal for the private operation of an airport but were unsuccessful would not be counted as air carriers for the purpose of the requirement that certain aspects of the privatization application be approved by 65 percent of the air carriers at the airport. In this amendment to the procedures, the FAA is clarifying that the provision does not apply retroactively to requests for proposals issued prior to the issuance of the FAA procedures on September 16, 1997. With respect to future requests for proposals, the provision is suspended until the FAA undertakes further public process on this aspect of the procedures. A separate provision of the procedures, which states that an air carrier that is a *successful* bidder on a privatization proposal will not be considered an air carrier under the 65 percent rule, is not affected.

DATES: This policy amendment is effective on publication. Comments on the issue are due January 12, 1998.

ADDRESSES: Comments should be mailed, in quadruplicate, to: Federal Aviation Administration, Office of Chief Counsel, Attention: Rules Docket (AGC–200), Docket No. 28895, 800 Independence Avenue, SW., Washington, DC 20591. All comments must be marked: ''Docket No. 28895.'' Commenters wishing the FAA to acknowledge receipt of their comments must include a pre-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 28895.'' The postcard will be date stamped and mailed to the commenter. Comments on this Notice may be examined in room 915G on weekdays, except on Federal holidays, between 8:30 a.m. and 5 p.m..

FOR FURTHER INFORMATION CONTACT: Benedict D. Castellano Manager, (202–267–8728) or Kevin C. Willis (202–267–8741) Airport Safety and Compliance Branch, AAS–310, Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591.

SUPPLEMENTARY INFORMATION:

Introduction and Background

This notice of amendment to application procedures to be used by applicants for an airport privatization project and request for comments is being published pursuant to § 149 of the Federal Aviation Administration Authorization Act of 1996, Pub. L. No. 104–264 (October 9, 1996) (1996 Reauthorization Act), which adds a new § 47134 to Title 49 of the U.S. Code. Section 47134 authorizes the Secretary of Transportation, and through delegation, the FAA Administrator, to exempt a sponsor of a public use airport that has received Federal assistance, from certain Federal requirements in connection with the privatization of the airport by sale or lease to a private party. Specifically, the Administrator may exempt the sponsor from all or part of the requirements to use airport revenues for airport-related purposes, to pay back a portion of Federal grants upon the sale of an airport, and to return airport property deeded by the Federal Government upon transfer of the airport. The Administrator is also authorized to exempt the private purchaser or lessee from the requirement to use all airport revenues for airport-related purposes, to the extent necessary to permit the purchaser or lessee to earn compensation from the operations of the airport.

On September 16, 1997, the FAA issued a notice of procedures to be used in applications for exemption under the Airport Privatization Pilot Program (62 FR 48693). The FAA has identified one issue in that notice that requires clarification.

Specifically, 49 U.S.C. § 47134(b)(1)(i)(ii) limits the exemption to permit the use of funds by the public airport sponsor for non-airport purposes, to amounts approved by 65 percent of the air carriers serving the airport and 65 percent of the air carriers by total landed weight of air carriers from the preceding calendar year. The same approval is required for increases in air carrier fees that exceed the increase in the Consumer Price Index. In interpreting this requirement, the FAA stated that the air carriers included in the calculation of the 65 percent would not include otherwise qualified air carriers that submitted proposals or that participate in consortia that submitted proposals for the privatization of the subject airport. This position was based on the consideration that the vote of such a carrier, whether or not it is the successful proponent, could be based on its interests as a proponent rather than its interests as a user of the airport and would not further the congressional objective of the 65 percent approval requirement.

On September 17, 1997, counsel for several Allegheny County Airport Part 135 operators filed comments arguing that the FAA had exceeded its authority by disqualifying otherwise qualified air carriers that submitted proposals or that participate in consortia that submitted proposals for the privatization of the subject airport from exercising their voting rights expressly granted in 49 U.S.C. Section 47134. The comments requested that the FAA delete provisions in question.

The comments argue that Congress did not intend for air carriers to lose their voting rights in the privatization process. The statute provides no basis for carrier exclusion or limitation other than the creation of the two classes, number serving the airport and percentage of landed weight. The comments further argue that the disqualification provision was issued in final notice without an opportunity for public comment and review. As a result, this provision violates the Administrative Procedure Act. Additionally, its application, retroactively is unlawful and a denial of due process. In the case of Part 135 operators at Allegheny County Airport, the provision would exclude many of the air carriers from exercising their voting rights under the statute because many of the air carriers responded to the airport's RFP without notice that doing so would jeopardize their voting rights under the statute.

After consideration of counsel's arguments, the FAA has decided to amend its application procedures and suspend the effectiveness of one provision. First, air carrier exclusion from the 65 percent approval rule based upon participation as a bidder in the privatization process will not be applied retroactively, i.e., to a solicitation issued before September 16, 1997, the date of the final notice, on the basis that this provision was not proposed for public comment and review. To impose it retroactively on carriers that participated in a bidding process prior to publication of the final procedures would inappropriately exclude them from exercising their voting rights without the benefit of notice of the adverse consequences of their participation as a bidder. Second, the FAA suspends indefinitely the provision in Part VI Certification of Air Carrier Approval (62 FR 48707) excluding otherwise qualified air carriers who submitted unsuccessful proposals as a private operator from participating in the voting process.

This provision was not proposed by the FAA and was not suggested in the **Federal Register** comment process. Moreover, it is not obvious that an unsuccessful bidder would give more weight to its interests as an unsuccessful bidder than its interests as an air carrier in deciding how to cast its vote.

In contrast, the proposal to exclude successful air carrier bidders from participation in the voting process was proposed in a comment in the **Federal Register** process, and the September 17 comments do not oppose such an exclusion. Moreover, the potential conflict of interest for a successful bidder is clear.

The FAA is suspending the provision, rather than deleting it, because we believe that the issue deserves further public comment before a final decision is made. We are therefore, providing a 45-day comment period to permit interested persons to address specifically the issue of whether otherwise qualified air carriers should be disqualified from participating in the statutory voting process because of their participation as unsuccessful bidders in a privatization proposal.

Pending further action, the FAA will exclude from the air carrier voting process only otherwise qualified air carriers that have been selected as the private operator (either individually or as a participant in a consortium) by the public agency.

Issued in Washington, DC, on November 20, 1997.

Susan L. Kurland,

Associate Administrator for Airports.

[FR Doc. 97–31106 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

RTCA, Inc., Special Committee 186; Automatic Dependent Surveillance—Broadcast (ADS–B)

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for Special Committee 186 meeting to be held December 15–19, 1997, starting at 9:00 a.m. on Monday, December 15. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, N.W., Suite 1020, Washington, D.C. 20036.

The agenda will include: (1) Chairman's Introductory Remarks/ Review of Meeting Agenda; (2) Review and Approval of Minutes of the Previous Meeting; (3) Response to SICASP Paper Concerning the Use of ADS–B Information for Collision Avoidance; (4) Editorial Committee Report; (5) Review of work accomplished during the meeting on September 29–October 2, 1997, and continuation of the ballot review and approval of the ADS–B MASPS (Only written comments will be considered); (6) Other Business; (7) Date and Place of Next Meeting. (At the conclusion of the plenary meeting, the 1090 MHz MOPS drafting group will meet for the remainder of the week.)

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, N.W., Suite 1020, Washington, DC, 20036; (202) 833–9339 (phone); (202) 833–9434 (fax); or http://www.rtca.org (web site). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 18, 1997.

Janice L. Peters,

Designated Official.

[FR Doc. 97–31076 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent to Rule on Application (#98–04–C–00–MFR) to Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Rogue Valley International-Medford Airport, Submitted by Jackson County, Medford, Oregon

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at Rogue Valley International-Medford Airport under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before December 26, 1997.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: J. Wade Bryant, Manager; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 250; Renton, WA 98055–4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Bern E. Case, A.A.E., Airport Director, at the following address: 3650 Biddle Road, Medford, OR 97504.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Rogue Valley International-Medford Airport, under section 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Ms. Mary E. Vargas, (425) 227–2660; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 250; Renton, WA 98055–4056. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application (#98–04–C–00–MFR) to impose and use PFC revenue at Rogue Valley International-Medford Airport, under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On November 19, 1997, the FAA determined that the application to impose and use the revenue from a PFC submitted by Jackson County, Rogue Valley International-Medford Airport, Medford, Oregon, was substantially complete within the requirements of § 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than February 17, 1998.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: March 1, 1998.

Proposed charge expiration date: March 1, 2001.

Total requested for use approval: $1,540,000.00.

Brief description of proposed project: Security fencing; Master plan update/ terminal area study; Jet blast fence; GA parking apron immediately NW of main terminal.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: Air Taxi/ Commercial Operators when enplaning revenue passengers in limited, irregular, special service air taxi/commercial operations such as air ambulance services, student instruction, non-stop sightseeing flights that begin and end at the airport and are conducted within 25 mile radius of the airport.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue S.W., Suite 540, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Rogue Valley International-Medford Airport.

Issued in Renton, Washington, on November 19, 1997.

George K. Saito,

Acting Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 97–31077 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application (#98–01–C–00–SGU) To Impose a Passenger Facility Charge (PFC) and Use the Revenue From a PFC at St. George Municipal Airport, Submitted by the City of St. George, St. George, Utah

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at St. George Municipal Airport under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before December 26, 1997.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Alan Wiechmann, Manager; Denver Airports District Office, DEN–ADO; Federal Aviation Administration; 26805 E. 68th Avenue, Suite 224; Denver, CO 80249–6361.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Larry Bulloch, Public Works Director, at the following address: City of St. George, 175 E. 200 North, St. George, Utah 84770.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to St. George Municipal Airport, under section 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Schaffer, (303) 342–1258; Denver Airports District Office, DEN–ADO; Federal Aviation Administration; 26805 E. 68th Avenue, Suite 224; Denver, CO 80249–6361. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application (#98–01–C–00–SGU) to impose and use PFC revenue at St. George Municipal Airport, under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On November 19, 1997, the FAA determined that the application to impose and use the revenue from a PFC submitted by the City of St. George, St. George Municipal Airport, St. George, Utah, was substantially complete within the requirements of section 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than February 17, 1998.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: April 1, 1998.

Proposed charge expiration date: August 1, 2002.

Total requested for use approval: $538,575.00.

Brief description of proposed project: Additional terminal ramp lighting; Acquisition of handicap lift; Terminal ramp, midfield apron, taxiway and miscellaneous pavement rehabilitation; Asphalt overlay of existing runway and replacement of pavement markings; Terminal parking expansion.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: Unscheduled part 135 air taxi operators.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue S.W., Suite 540, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the St. George Municipal Airport.

Issued in Renton, Washington, on November 19, 1997.

George K. Saito,

Acting Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 97–31078 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–97–3140]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intentions to request extension of approval for three years of a currently approved information collection.

DATES: Comments should be submitted on or before January 26, 1998.

FOR FURTHER INFORMATION CONTACT: Walter Lockland, Chief, Division of Operations Support, Office of Ship Operations, Maritime Administration, MAR–613, Room 2123, 400 Seventh Street, S.W., Washington, D.C. 20590. Telephone (202) 366–5735 or fax (202) 366–3954. Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Position Reporting System for Vessels.

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0025.

Form Number: CG–4796–A (MA) (Rev. 8–88).

Expiration Date of Approval: May 31, 1998.

Summary of Collection of Information: This collection is used to gather information regarding the location of U.S.-flag and certain other U.S. citizen-owned vessels for the purpose of Search and Rescue in the saving of lives at sea; and for the marshaling of ships for national defense and safety purposes. This collection consists of vessels that transmit their positions electronically via radio message, and from this, location data is read into a database and is accessed only by the U.S. Coast Guard and MARAD to determine the location of a particular ship.

Need and Use of the Information: The collection is necessary for maintaining a current plot of U.S.-flag and U.S.-owned vessels in order to facilitate immediate marshaling of ships for national defense purposes, and for the purpose of maintaining a current plot for Search and Rescue purposes for safety of life at sea.

Description of Respondents: U.S.-flag and U.S. citizen-owned vessels which are required to respond under current statute and regulation.

Annual Responses: 20,800 responses.

Annual Burden: 3,328 hours.

Comments: Signed, written comments should refer to the docket number that appears at the top of this document and must be submitted to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, S.W., Washington, D.C. 20590–0001.

Specifically, address whether this information collection is necessary for proper performance of the function of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance quality, utility, and clarity of the information to be collected.

All comments received will be available for examination at the above address between 10 a.m. and 5 p.m., e.t. Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at http:/dms.dot.gov.

Dated: November 20, 1997.

By Order of the Maritime Administrator.

Joel C. Richard,

Secretary.

[FR Doc. 97–31093 Filed 11–25–97; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–493 (Sub-No. 3X)] [1]

Track Tech, Inc.—Abandonment Exemption—in Eddy County, ND

On November 6, 1997, Track Tech, Inc. filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon a line of railroad located generally between Hamar, ND (milepost 98.0), and Warwick, ND (milepost 103.92), a distance of 5.92 miles in Eddy County, ND. The line traverses U.S. Postal Service ZIP Codes 58380 and 58381.

The line does not contain any federally granted rights-of-way. Any documentation in the railroad's possession will be made available promptly to those requesting it. The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by February 24, 1998.

Any offer of financial assistance under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each offer of financial assistance must be accompanied by a $900 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 U.S.C. 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than December 16, 1997. Each trail use request must be accompanied by a $150 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–493 (Sub-No. 3X) and must be sent to: (1) Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001; and (2) T. Scott Bannister, 1300 Des Moines Building, 405 Sixth Avenue, Des Moines, IA 50309.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1545. [TDD for the hearing impaired is available at (202) 565–1695.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Decided: November 18, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–30906 Filed 11–25–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–493 (Sub-No. 4X)] [1]

Track Tech, Inc.—Abandonment Exemption—in Ward County, ND

On November 6, 1997, Track Tech, Inc. filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon a line of railroad located generally between Minot, ND (milepost 4.00), and Tatman, ND (milepost 16.70), a distance of 12.70 miles in Ward County, ND. The line traverses U.S. Postal Service ZIP Codes 58701 and 58702.

The line does not contain any federally granted rights-of-way. Any documentation in the railroad's possession will be made available promptly to those requesting it. The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by February 24, 1998.

Any offer of financial assistance under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each offer of financial assistance must be accompanied by a $900 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 U.S.C. 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than December 16, 1997.[2] Each trail use request must be accompanied by a $150 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–493 (Sub-No. 4X) and must be sent to: (1) Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001; and (2) T. Scott Bannister, 1300 Des Moines Building, 405 Sixth Avenue, Des Moines, IA 50309.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1545. [TDD for the hearing impaired is available at (202) 565–1695.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be available within 60 days of the filing of the petition. The deadline for submission of comments on

[1] Petitioner acquired this line and 5 others from Burlington Northern Railroad Company in November 1996. Petitioner is also seeking to abandon, or will seek to abandon, the other lines via exemption in STB Docket No. AB–493 (Sub-Nos. 1X, 2X, 4X, 5X, and 6X).

[1] Petitioner acquired this line and 5 others from Burlington Northern Railroad Company in November 1996. Petitioner is also seeking to abandon, or will seek to abandon, the other lines via exemption in STB Docket No. AB–493 (Sub-Nos. 1X, 2X, 3X, 5X, and 6X).

[2] The Minot Park District, Minot, ND, has requested issuance of a public use condition and a notice of interim trail use, it has also submitted a statement of willingness to assume financial responsibility for the right-of-way. This request will be handled in a subsequent decision.

the EA will generally be within 30 days of its service.

Decided: November 18, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–30907 Filed 11–25–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–493 (Sub-No. 6X)][1]

Track Tech, Inc.—Abandonment Exemption—in Lubbock County, TX

On November 6, 1997, Track Tech, Inc. filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon a line of railroad located generally between milepost 351.15 and milepost 357.40, a distance of 6.25 miles in Lubbock County, TX. The line traverses U.S. Postal Service ZIP Codes 79403 and 79404.

The line does not contain any federally granted rights-of-way. Any documentation in the railroad's possession will be made available promptly to those requesting it. The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by February 24, 1998.

Any offer of financial assistance under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each offer of financial assistance must be accompanied by a $900 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 U.S.C. 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than December 16, 1997. Each trail use request must be accompanied by a $150 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–493 (Sub-No. 6X) and must be sent to: (1) Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001; and (2) T. Scott Bannister, 1300 Des Moines Building, 405 Sixth Avenue, Des Moines, IA 50309.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1545. [TDD for the hearing impaired is available at (202) 565–1695.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Decided: November 18, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–30909 Filed 11–25–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–33 (Sub–No. 115X)]

Union Pacific Railroad Company—Abandonment Exemption—in Waukesha County, WI

Union Pacific Railroad Company (UP) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments and Discontinuances of Service and Trackage Rights* to abandon and discontinue service over a 1.40-mile line of railroad on the Waukesha Industrial Lead from milepost 18.16 to the end of UP's line at milepost 19.56 (Grand Avenue), near Waukesha, in Waukesha County, WI. The line traverses United States Postal Service Zip Codes 53186, 53187 and 53188.

UP has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic on the line can be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment— Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed. Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on December 26, 1997, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by December 8, 1997. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by December 16, 1997, with: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant's representative: Joseph D. Anthofer, General Attorney, Union Pacific Railroad Company, 1416 Dodge Street, Room 830, Omaha, NE 68179.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

[1] Petitioner acquired this line and 5 others from Burlington Northern Railroad Company in November 1996. Petitioner is also seeking to abandon, or will seek to abandon, the other lines via exemption in STB Docket No. AB–493 (Sub-Nos. 1X, 2X, 3X, 4X, and 5X).

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each offer of financial assistance must be accompanied by the filing fee, which is currently set at $900. *See* 49 CFR 1002.2(f)(25).

UP has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by December 1, 1997. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423) or by calling SEA, at (202) 565–1545. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), UP shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by UP's filing of a notice of consummation by November 26, 1998, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Decided: November 20, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary,

[FR Doc. 97–31089 Filed 11–25–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Information Collection; Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Submission for OMB review; comment request.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Office of the Comptroller of the Currency (OCC) hereby gives notice that it has sent to the Office of Management and Budget (OMB) for review an information collection titled (MA)-Real Estate Lending and Appraisals—12 CFR 34.

DATES: Comments regarding this information collection are welcome and should be submitted to the OMB Reviewer and the OCC. Comments are due on or before December 26, 1997.

ADDRESSES: A copy of the submission may be obtained by calling the OCC contact listed. Direct all written comments to the Communications Division, Attention: 1557–0190, Third Floor, Office of the Comptroller of the Currency, 250 E Street, SW, Washington, DC 20219. In addition, comments may be sent by facsimile transmission to (202) 874–5274, or by electronic mail to REGS.COMMENTS@OCC.TREAS.GOV.

SUPPLEMENTARY INFORMATION:

OMB Number: 1557–0190.

Form Number: Not applicable.

Type of Review: Renewal of OMB approval.

Title: (MA) Real Estate Lending and Appraisals.

Description: The collections of information contained in 12 CFR part 34 are as follows:

Subpart C establishes real estate appraisal requirements that a national bank must follow for all federally-related real estate transactions. These appraisal requirements provide protections for the bank, further public policy interests, and were issued pursuant to title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (12 U.S.C. 3331 *et seq.*).

Subpart D requires that a national bank adopt and maintain written policies for real estate lending transactions. These requirements ensure bank safety and soundness and were issued pursuant to section 304 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (12 U.S.C. 1828(o)).

Subpart E requires that a national bank file an application to extend the five-year holding period for Other Real Estate Owned (OREO) and file notice when it makes certain expenditures for OREO development or improvement projects. These requirements further bank safety and soundness and were issued pursuant to 12 U.S.C. 29.

Respondents: Businesses or other for-profit; individuals.

Number of Respondents: 2,800.

Total Annual Responses: 3,540.

Frequency of Response: Occasional.

Estimated Total Annual Burden: 240,160.

OCC Contact: Jessie Gates, (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW, Washington, DC 20219.

OMB Reviewer: Alexander Hunt, (202) 395–7340, Paperwork Reduction Project 1557–0190, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

The OCC may not conduct or sponsor, and respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number. Comments are invited on: (a) Whether the proposed revisions to the following collections of information are necessary for the proper performance of the OCC's functions, including whether the information has practical utility; (b) the accuracy of the OCC's estimate of the burden of the information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Date: November 13, 1997.

Karen Solomon,

Director, Legislative & Regulatory Activities Division.

[FR Doc. 97–30976 Filed 11–25–97; 8:45 am]

BILLING CODE 4810–33–P

Corrections

Federal Register

Vol. 62, No. 228

Wednesday, November 26, 1997

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 97-5]

Martha Hernandez, M.D.; Reprimand and Continuation of Registrations with Restriction

Correction

In notice document 97–29972 beginning on page 61145, in the issue of Friday, November 14, 1997, make the following corrections:

1. On page 61146, in the second column, in the first complete paragraph, in the last line, ''January 1995.'' should read ''January 1994.''

2. On page 61148, in the first column, in the first complete paragraph, in the tenth line from the bottom, ''was to due'' should read ''was not due''.

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-39223; File No. SR-SCCP-97-04]

Self-Regulatory Organizations; Stock Clearing Corporation of Philadelphia; Notice of Filing of Proposed Rule Change Relating to Revision and Limitation of Clearing Services

Correction

In notice document 97–27278 beginning on page 53681, in the issue of Wednesday, October 15, 1997, make the following correction:

On page 53681, in the third column, the File No. should be as set forth above.

BILLING CODE 1505-01-D

Federal Register

Wednesday
November 26, 1997

Part II

Department of Education

34 CFR Part 97
Protection of Human Subjects; Final Rule

DEPARTMENT OF EDUCATION

34 CFR Part 97

RIN 1880–AA75

Protection of Human Subjects

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the Department's regulations governing the protection of human research subjects to add special protections for children who are involved as subjects of research. These amendments to the Department's regulations are needed to secure additional protections for children who are involved as subjects of research. The regulations will, for research involving children as subjects, remove exemptions for certain kinds of research, modify the informed consent provisions, and further limit the risks to which children may be made vulnerable. These amendments will make the Department's policy regarding the protection of children as research subjects consistent with the regulations of the Department of Health and Human Services and the Federal Policy for the Protection of Children as practiced by other research agencies of the Federal government.

EFFECTIVE DATE: These regulations take effect December 26, 1997.

FOR FURTHER INFORMATION CONTACT: Kent H. Hannaman, U.S. Department of Education, 600 Independence Avenue, SW., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651. *Telephone:* (202) 708–5207. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION: The Secretary adopts for the Department of Education regulations that are already in effect for research supported or conducted by the Department of Health and Human Services (DHHS), Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research (Subpart D). These regulations contain provisions specifically designed to protect children who are involved in research as subjects. Children are involved as subjects of important research that will benefit the Nation's children. Balancing the importance of this research with the needs of children, the Secretary is adding these protections because the research activities supported by the Department often include children, and the Department has a particular interest in protecting the welfare of children.

The Common Rule, in which the Department of Education is a participant, currently only includes Subpart A of the DHHS rule. To ensure that the protections in Subpart D apply to research subjects who are children, the Secretary adopts Subpart D, applying it to research programs of the Department.

On May 22, 1997, the Secretary proposed to add Subpart D through a notice of proposed rulemaking (NPRM) published in the **Federal Register** (62 FR 28156–28159). In the preamble to that NPRM, the Secretary discussed the current government-wide and Department of Education policy, the additional protections provided by these regulations, the additional costs and administrative burdens, alternative policy mechanisms, and additional protections for children as education research subjects other than the protections in these regulations.

There are no differences between the proposed regulations and these final regulations.

Analysis of Public Comment

In response to the Secretary's invitation in the NPRM, three parties submitted comments on the proposed regulations. Two commenters were from associations representing affected communities, and one commenter was an individual at an institution of higher education. Two of the commenters expressed support for the protections and the consistency of these protections with policies of other Federal agencies. An analysis of the other comments follow.

Comment: One commenter expressed concern over whether the regulations were sufficiently clear about the need to provide potential research subjects with specific information about their involvement in proposed research activities.

Discussion: The Secretary agrees that potential research subjects must have appropriate information about a specific research activity in order to give informed consent to participate. Subpart A of the existing regulations protecting human research subjects requires, as part of the provisions concerning informed consent, that potential research subjects be given information including the purpose of the particular research activity, the specific procedures to be followed, and the risks and benefits to the subject. Because existing regulations cover this subject, Subpart D, as proposed in the NPRM, has not been changed.

Changes: None.

Comment: One commenter recommended that the regulations include guidance stating that research project descriptions include information about what safeguards will be put into place in order to respond to anticipated risks that actually occur.

Discussion: Information about safeguards for anticipated risks in research is important both for the review and approval of research activities and for the informed consent of potential research subjects. Subpart A of the existing regulations for the protection of human research subjects calls for information about available medical treatment in cases of injury as part of the informed consent process for research involving more than minimal risks. This information should be made available to any potential human research subject, not just children who are potential research subjects. Because existing regulations cover this subject, Subpart D, as proposed in the NPRM, has not been changed.

Changes: None.

Paperwork Reduction Act of 1995

These final regulations have been examined under the Paperwork Reduction Act of 1995 and have been found to contain no additional information collection requirements.

Assessment of Educational Impact

In the NPRM the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the NPRM and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

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Note: The official version of this document is the document published in the **Federal Register**.

List of Subjects in 34 CFR Part 97

Human subjects, Reporting and recordkeeping requirements, Research.

(Catalog of Federal Domestic Assistance Number does not apply)

Dated: November 18, 1997.

Richard W. Riley,

Secretary of Education.

The Secretary amends Part 97 of Title 34 of the Code of Federal Regulations as follows:

PART 97—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for Part 97 is revised to read as follows:

Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; 42 U.S.C. 300v–1(b).

2. Sections 97.101 through 97.124 are designated as Subpart A—Federal Policy for the Protection of Human Subjects (Basic ED Policy for Protection of Human Research Subjects) and Subparts B and C are reserved.

* * * * *

3. Sections 97.101, 97.102, 97.103, and 97.107 through 97.124 are amended by adding authority citations to read as follows:

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

4. A new Subpart D containing §§ 97.401 through 97.409 is added to read as follows:

Subpart D—Additional ED Protections for Children Who are Subjects in Research

Subpart D—Additional ED Protections for Children Who Are Subjects in Research

§ 97.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects conducted or supported by the Department of Education.

(1) This subpart applies to research conducted by Department employees.

(2) This subpart applies to research conducted or supported by the Department of Education outside the United States, but in appropriate circumstances the Secretary may, under § 97.101(i), waive the applicability of some or all of the requirements of the regulations in this subpart for that research.

(b) Exemptions in § 97.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption in § 97.101(b)(2) regarding educational tests is also applicable to this subpart. The exemption in § 97.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator or investigators do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 97.101(c) through (i) are applicable to this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b)).

§ 97.402 Definitions.

The definitions in § 97.102 apply to this subpart. In addition, the following definitions also apply to this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b)).

§ 97.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b)).

§ 97.404 Research not involving greater than minimal risk.

ED conducts or funds research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

ED conducts or funds research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that—

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

ED conducts or funds research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not

likely to contribute to the well-being of the subject, only if the IRB finds that—

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

ED conducts or funds research that the IRB does not believe meets the requirements of § 97.404, § 97.405, or § 97.406 only if—

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either that—

(1) The research in fact satisfies the conditions of § 97.404, § 97.405, or § 97.406, as applicable; or

(2)(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles; and

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, if in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even if the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 97.116.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 97.116, that adequate provisions are made for soliciting the permission of each child's parent(s) or guardian(s). If parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 97.404 or § 97.405. If research is covered by §§ 97.406 and 97.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or if only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 97.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians must be documented in accordance with and to the extent required by § 97.117.

(e) If the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity may be included in research approved under § 97.406 or § 97.407 only if that research is—

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or *in loco parentis.* One individual may serve as advocate for more than one child. The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator or investigators, or the guardian organization.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

[FR Doc. 97–31020 Filed 11–25–97; 8:45 am]
BILLING CODE 4000–01–P

Federal Register

Wednesday
November 26, 1997

Part III

Department of Defense

Corps of Engineers

Public Notice Concerning Changes to Nationwide Permit 26; Notice

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

Public Notice Concerning Changes to Nationwide Permit 26

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice for public comment.

SUMMARY: In response to a court order issued on October 27, 1997, the Corps is requesting comments on three changes to Nationwide Permit (NWP) 26, which were published in the **Federal Register** on Friday, December 13, 1996 (61 FR 65874–65922). The Corps is requesting comments on the following changes to NWP 26: (1) The expiration of NWP 26 on December 13, 1998; (2) the prohibition against filling or excavating more than 500 linear feet of stream bed under NWP 26; and (3) the prohibition against using other NWPs with NWP 26 to authorize the loss of more than 3 acres of waters of the United States. The Corps is not requesting comments on any other issues related to the recent modification of NWP 26 or any other NWP. Within 90 days of the close of the comment period, the Corps will publish its final determination on these issues in the **Federal Register**.

DATES: Comments must be received by February 24, 1998.

ADDRESSES: HQUSACE, CECW–OR, Washington, D.C. 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson or Mr. Sam Collinson, CECW–OR, at (202) 761–0199.

SUPPLEMENTARY INFORMATION:

Background

In the June 17, 1996, **Federal Register**, the Corps published a notice requesting comments on the issuance, reissuance, and modification of the NWPs and announced a public hearing to invite the public to provide comments on the NWPs. The Corps proposed changes to several NWPs, including several changes to NWP 26. In the June 17, 1996, **Federal Register** Notice, the Corps did not specifically request comments on limiting filling or excavation of stream beds to 500 linear feet under NWP 26, restricting the use of other NWPs with NWP 26 to limit impacts to waters of the United States to 3 acres for a single and complete project, or issuing NWP 26 for a period shorter than 5 years, which is the maximum legal limit for any NWP.

In response to the June 17, 1996, **Federal Register** Notice, the Corps received over 500 comments concerning NWP 26. Based on comments from the public and other agencies, as well as Corps internal review of the implementation of NWP 26 over the past five years, several changes were made to NWP 26 to ensure that NWP would comply with a number of legal requirements. These changes were published in the **Federal Register** on December 13, 1996 (61 FR 65874–65922) and became effective on February 11, 1997. On March 6, 1997, a lawsuit was filed by the National Association of Home Builders, objecting to three of these changes. These three changes are: (1) The expiration of NWP 26 on December 13, 1998; (2) the prohibition against filling or excavating more than 500 linear feet of stream bed under NWP 26; and (3) the prohibition against using other NWPs with NWP 26 to authorize the loss of more than 3 acres of waters of the United States.

The Corps believes that the changes we made to NWP 26 were promulgated in full compliance with all legal requirements, and were necessary to ensure compliance with the requirements of the Clean Water Act. However, in view of the public interest in the three changes explained below and in order to avoid the time and expense of litigation, the corps volunteered to seek comments on the three changes cited above. Accordingly, on October 27, 1997, a court order was issued remanding the action to the Corps to request public comments on the changes to NWP 26 cited in the previous paragraph.

The public is invited to provide comments on these three changes to NWP 26 within 90 days of the date of this notice. The Corps is not requesting comments on any other issues related to the recent modification of NWP 26. Within 90 days of the close of the comment period, the Corps will publish its decision on these issues in the **Federal Register**. In the interim, all the terms and conditions of NWP 26 as published in the December 13, 1996, **Federal Register**, including the three changes that are the subject of this notice, will remain in effect pending a Corps decision. The following is a brief discussion of the three changes to NWP 26. For more details, see the Preamble to the December 13, 1996, **Federal Register** Notice, (61 FR 65874–65922).

(1) Expiration of NWP 26 on December 13, 1998

As a result of an internal evaluation of NWP 26 and consideration of all comments received in response to the June 17, 1996, **Federal Register** Notice, the Corps determined that modification of NWP 26 was necessary and that it should be replaced with activity-specific NWPs to ensure that no more than minimal impacts to waters of the United States, both individually and cumulatively, are authorized. Knowing that it will take up to two years to issue replacement NWPs, the Corps reissued NWP 26 for a two year period, which will expire on December 13, 1998. Section 404(e) of the Clean Water Act states that no general permit can be issued for a period of more than five years, thereby, allowing the Corps to issue an NWP for a period of less than five years. This two year period will allow the Corps to collect detailed information on the types of activities being authorized by NWP 26, the nature and extent of wetlands and other waters being affected by the NWPs, and potential effects of the NWPs on the Nation's federally listed threatened and endangered species.

In the December 13, 1996, **Federal Register** Notice, the Corps requested comments from the public regarding specific categories of activities that should be considered for new NWPs. Prior to the expiration of NWP 26 on December 13, 1998, the Corps will develop, propose, and issue activity-specific replacement NWPs, with appropriate limitations, to provide consistency with the ''minimal adverse effects'' mandate of section 404(e). The public will have an opportunity to comment formally on the proposed replacement permits once they are officially proposed in the **Federal Register**. We anticipate that the activity-specific replacement NWPs will be published for public review and comment in approximately March 1998.

(2) Prohibition Against Filling More Than 500 Linear Feet of Stream Bed

In response to the June 17, 1996, **Federal Register** Notice, a few commenters recommended using linear footage to quantify stream bed impacts for the purpose of NWP 26, instead of acreage. They believed that using acreage to quantify impacts to stream beds is inappropriate, because it can allow losses of long segments of streams. For example, filling a 5-foot wide stream bed over a distance of ½ mile will result in a loss of 0.30 acre of stream bed. If acreage were used to quantify the stream bed impacts, notification to the Corps would not be required and the work could result in more than minimal impacts if the stream bed provides important functions, such as spawning habitat for fish. Limitations of 200 to 500 linear feet of stream bed impacts were recommended by commenters.

We concurred with these commenters and placed a prohibition in NWP 26 against activities directly affecting (i.e., filling or excavating) more than 500 linear feet of stream bed. Therefore, filling or excavating more than 500 linear feet of stream bed was not authorized under the revisions to NWP 26. The threshold of 500 linear feet was chosen to maintain consistency within the NWP Program, because NWPs 12 and 13 have pre-construction notification thresholds of 500 linear feet. We believe that this additional limitation enhances the Corps ability to ensure that projects with more than minimal adverse impacts will not be authorized under NWP 26.

(3) Use of NWP 26 With Other NWPs Cannot Exceed 3 Acres of Impact

Many commenters recommended that the use of multiple NWPs for a single and complete project (a practice also referred to as ''stacking'') should be eliminated or restricted because it would allow the possibility of more than minimal adverse effects to result under the NWP Program.

Under certain circumstances, NWPs can be used in combination and result in only minimal individual and cumulative adverse environmental effects. NWP regulations provide for multiple use of NWPs, as long as each NWP is used only once for a single and complete project and the combined adverse effects are minimal. However, the use of more than one NWP for a particular project could potentially result in more than minimal adverse effects. Many NWPs are usually ''stand alone'' project authorizations. Generally, only seven of the 37 NWPs are used more than occasionally with certain other NWPs for authorizing projects. These seven NWPs are 3, 12, 13, 18, 19, 26, and 33. We believe that of those seven NWPs, those with the potential to have more than minimal impacts when used with certain other NWPs, are NWPs 18 and 26 in combination with each other and with NWPs 14 and 29. To ensure that multiple use of NWPs does not result in more than minimal adverse effects, the Corps has added a General Condition to the NWPs and restricted certain combinations of nationwide permits. General Condition 15 requires permittees to submit a pre-construction notification to the District Engineer when any NWP 12 through 40 is combined with any other NWP 12 through 40, as part of a single and complete project. NWP 14 was modified so that it cannot be combined with NWP 18 or NWP 26 for the purpose of exceeding the limitations of any of these three NWPs. For example, NWPs 14 and 26 cannot be combined to authorize the loss of 3⅓ acres of waters of the United States. Furthermore, NWP 18 cannot be combined with NWP 26 to increase the thresholds or the limitations of NWP 26. NWP 29 is already conditioned so that it cannot be used with NWP 14, NWP 18, or NWP 26. We have also limited the amount of authorized impacts when combining any NWP with NWP 29 or NWP 26. If another NWP is used with NWP 29 to authorize a single and complete project, the total acreage of impacts to water of the United States cannot exceed 0.5 acres. Whenever any other NWP is used in conjunction with NWP 26, the total acreage of impacts to waters of the United States, for all NWPs combined, cannot exceed 3 acres. Likewise, the Corps is only requesting comments on the prohibition against combining other NWPs with NWP 26 to exceed the 3-acre limitation of NWP 26.

Dated: November 13, 1997.

Charles M. Hess,

Chief, Operations, Construction, and Readiness Division, Directorate of Civil Works.

[FR Doc. 97–30278 Filed 11–25–97; 8:45 am]

BILLING CODE 3710–92–M

Federal Register

Wednesday
November 26, 1997

Part IV

Environmental Protection Agency

40 CFR Part 180

Cypermethrin and Zeta-Cypermethrin; Pesticide Tolerance; Final Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300583; FRL–5755–3]

RIN 2070–AB78

Cypermethrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for residues of cypermethrin (±)alpha-cyano-(3-phenoxyphenyl)methyl(±)cis,trans-3(2,2-dichloroethyenyl)-2,2-dimethylcyclopropane carboxylate in or on the commodities brassica, head and stem at 2.0 parts per million (ppm); brassica, leafy at 14.0 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts (mbyp) at 0.05 ppm; cottonseed at 0.5 ppm; goats, fat at 0.05 ppm; goats, meat at 0.05 ppm; goats, mbyp at 0.05 ppm; hogs, fat at 0.05 ppm; hogs, meat at 0.05 ppm; hogs, mbyp at 0.05 ppm; horses, fat at 0.05 ppm; horses, meat at 0.05 ppm; horses, mbyp at 0.05 ppm; lettuce, head at 10.0 ppm; milk at 0.05 ppm; onions, bulb at 0.10 ppm; pecans 0.05 ppm; sheep, fat at 0.05; sheep, meat at 0.05 ppm; and sheep, mbyp at 0.05 ppm. It also removes the time limitations for tolerances for cypermethrin on the same commodities expires on November 15, 1997. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300583, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk, identified by the docket control number, OPP–300583, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions in Unit VI. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: George T. Larocca, Product Manager (PM–13), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 15, 1984 (49 FR 24864), EPA established time-limited tolerances under section 408 and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of cypermethrin. These tolerances expire on November 15, 1997. On September 15, 1997, FMC Corporation requested that the time limitation for tolerances established for residues of the insecticide cypermethrin in these commodities be removed based on environmental effects data that they had submitted as a condition of the registration. FMC Corporation also submitted a summary of its petitions as required under the FFDCA, as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170).

In the **Federal Register** of September 25, 1997, (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 2F2623, 4F2986, 4F2986, 3F2824, 7F3498, 4F3011, and 4F4291) for tolerances by the FMC Corporation, 1735 Market St., Philadelphia, PA 19103. This notice included a summary of the petitions prepared by the FMC Corporation. There were no comments received in response to the notice of filing. The petitions requested that 40 CFR 180.418 be amended by removing the time limitations for tolerances of the insecticide cypermethrin ((±)alpha-cyano-(3-phenoxyphenyl)methyl(±)cis,trans-3(2,2-dichloroethyenyl)-2,2-dimethylcyclopropane carboxylate) in or on the commodities brassica, head and stem at 2.0 ppm; brassica, leafy at 14.0 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, mbyp at 0.05 ppm; cottonseed at 0.5 ppm; goats, fat at 0.05 ppm; goats, meat at 0.05 ppm; goats, mbyp at 0.05 ppm; hogs, fat at 0.05 ppm; hogs, meat at 0.05 ppm; hogs, mbyp at 0.05 ppm; horses, fat at 0.05 ppm; horses, meat at 0.05 ppm; horses, mbyp at 0.05 ppm; lettuce, head at 10.0 ppm; milk at 0.05 ppm; onions, bulb at 0.10 ppm; pecans 0.05 ppm; sheep, fat at 0.05; sheep, meat at 0.05 ppm; and sheep, mbyp at 0.05 ppm. Tolerances for livestock commodities were inadvertently not listed in the notice of filing, although the tolerance petition, PP2F2623 previously establishing these tolerances was listed. The livestock commodity tolerances were considered by EPA for risk assessment purposes.

The basis for time-limited tolerances that expire November 15, 1997, was given in the October 20, 1993, **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), as amended. It is current EPA policy to no longer establish time limitations on tolerances with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition actions meet that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section

408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no-observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low-dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate-term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single-oral exposure to the pesticide residues. High-end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, section 408 of the FFDCA requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the

assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of cypermethrin and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of cypermethrin in or on the commodities brassica, head and stem at 2.0 ppm; brassica, leafy at 14.0 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, mbyp at 0.05 ppm; cottonseed at 0.5 ppm; goats, fat at 0.05 ppm; goats, meat at 0.05 ppm; goats, mbyp at 0.05 ppm; hogs, fat at 0.05 ppm; hogs, meat at 0.05 ppm; hogs, mbyp at 0.05 ppm; horses, fat at 0.05 ppm; horses, meat at 0.05 ppm; horses, mbyp at 0.05 ppm; lettuce, head at 10.0 ppm; milk at 0.05 ppm; onions, bulb at 0.10 ppm; pecans 0.05 ppm; sheep, fat at 0.05; sheep, meat at 0.05 ppm; and sheep, mbyp at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cypermethrin are discussed in this unit.

1. *Acute toxicity.* The required battery of acute toxicity studies has been submitted and found adequate. The findings were as follows: oral toxicity, LD_{50} > 263 milligram/kilogram (mg/kg); dermal toxicity, LD_{50} > 2,460 mg/kg; inhalation toxicity LC_{50}, 2.5 mg/liter (L); primary eye irritation—Toxicity Category III; primary dermal irritation—Toxicity Category IV. Cypermethrin is considered to be a dermal sensitizer.

2. *Mutagenicity.* The Agency has reviewed several mutagenicity studies. Types include an Ames mutagenicity assay; a dominant lethal study, a mouse lymphoma mutagenicity assay, a Chinese hamster ovary/hypoxanthine quanine phosphoribose transferase (CHO/HGPRT) assay, and a bone marrow cytogenic study. The data base for mutagenicity is considered to be adequate. Based on the available mutagenicity studies, there are no concerns for mutagenicity at this time.

3. *Reproductive and developmental toxicity*—i. *Developmental toxicity study in the rat.* Cypermethrin was administered by gavage to rats at dose levels of 0, 17.5, 35, or 70 mg/kg/day on days 6–15 of gestation. The maternal lowest-observed effect level (LOEL) is 35 mg/kg/day, based on bodyweight. The maternal NOEL is 17.5 mg/kg/day. The developmental LOEL was > 70 mg/kg/day. The developmental NOEL is > 70 mg/kg/day. The developmental toxicity study in the rat was classified acceptable.

ii. *Developmental toxicity study in the rabbit.* Cypermethrin was administered to rabbits by gelatin capsule at dose levels of 0, 3, 10, or 30 mg/kg/day on days 6 to 18 inclusive of gestation. There were no effects on the does of any kind reported. The maternal LOEL was > 30 mg/kg/day. The maternal NOEL is > 30 mg/kg/day. There were no treatment related effects on either the skeletal or visceral structures reported. The developmental LOEL is > 30 mg/kg/day. The developmental NOEL was > 30 mg/kg/day. The developmental toxicity study in the rabbit is classified supplementary and does not satisfy the guideline requirement for a developmental toxicity study in the rabbit. The study was not considered upgradeable because the dose levels selected are too low.

iii. *Developmental toxicity study in the rabbit.* Cypermethrin was administered to 20 New Zealand White rabbits per dose group by gavage at dose levels of 0, 100, 450, or 700 mg/kg/day from days 7 through 19 of gestation. The does were sacrificed on day 29 of gestation. The maternal LOEL was 450 mg/kg/day, based on bodyweight gain. The maternal NOEL was 100 mg/kg/day. There were no indications of developmental toxicity. The NOEL and LOEL for developmental toxicity was > 700 mg/kg/day. This study in the rabbit was classified acceptable.

iv. *Three-generation reproduction study in rats.* Cypermethrin was administered to rats at dose levels of 0, 50, 150, or 1,000/750 ppm (reduced to 750 ppm after 12 weeks because of severe neurological symptoms). These dose levels correspond to 2.5, 7.5, or 50/37.5 mg/kg/day. Three successive generations were produced, each consisting of two separate breedings to produce six sets of litters. The LOEL is 150 ppm (7.5 mg/kg/day) based on consistent decreased bodyweight gain in both sexes. The NOEL was 50 ppm (2.5 mg/kg/day). The study was classified acceptable.

4. *Subchronic toxicity.* The data base for subchronic toxicity is considered to be complete except for a series 82–4 subchronic inhalation toxicity study of 90–days duration. This study is required if inhalation exposure is for periods greater than 21–days.

i. *Subchronic oral study in the rat.* Cypermethrin was administered to rats at dose levels of 0, 75, 150, or 1,500 ppm (corresponding to 0, 3.75, 7.5, or 75 mg/kg/day) for 90 days. The LOEL is 1,500 ppm (75 mg/kg/day) based on bodyweight. The NOEL was 150 ppm (7.5 mg/kg/day). This study did not satisfy the guideline requirement for a subchronic oral study (82–1) in rats, but did not require upgrading because an acceptable chronic feeding study with rats was available.

ii. *Subchronic oral study in the dog.* Cypermethrin was administered to beagle dogs at dose levels of 0, 5, 50, 500, or 1,500 ppm (corresponding to 0.125, 1.25, 12.5, and 37.5 mg/kg/day) for 13 weeks. The NOEL is 500 ppm (12.5 mg/kg/day). This subchronic toxicity study was classified supplementary.

iii. *21–Day dermal study in the rabbit.* Cypermethrin was applied at dose levels of control, 2, 20, or 200 mg/kg/day applied in 20% weight/weight (w/w) basis PEG 300 with daily applications for 3 weeks for a total of 15 applications. The LOEL is 200 mg/kg/day based on liver effects. The NOEL is 20 mg/kg/day. This subchronic dermal toxicity study was classified acceptable and satisfies the guideline requirement for a subchronic dermal study (82–2) in rabbit.

iv. *21–Day inhalation study in the rat.* Cypermethrin was administered to rats by nose only exposure at concentrations of 0, 0.01, 0.05, or 0.25 mg/L for 6 hours per day, 5 days per week for a total of 15 exposures. The LOEL was 0.05 mg/L based mainly on bodyweight decrease. The NOEL was 0.01 mg/L. This study was classified acceptable.

5. *Chronic toxicity/carcinogenicity*—i. *Chronic oral study in the dog.* Cypermethrin was administered to beagle dogs at dose levels of 0, 1, 5, or 15 mg/kg/day for 52 weeks. The LOEL

was 5 mg/kg/day based on gastrointestinal effects. The NOEL is 1 mg/kg/day. This chronic toxicity study was classified acceptable.

ii. *Carcinogenicity study in the mouse.* Cypermethrin was administered to mice at dose levels of control-1, control-2, 100, 400, and 1,600 ppm (corresponding to 0, 0, 14, 57, or 229 mg/kg/day) for 97 weeks for males and 101 weeks for females. The LOEL was 400 ppm (57 mg/kg/day) based on liver weight. The NOEL was 100 ppm (14 mg/kg/day). This study was determined to be positive for induction of benign alveologenic neoplasms. This carcinogenicity study was classified acceptable and satisfies the guideline requirement for a carcinogenicity study (83–2) in mice.

iii. *Chronic feeding/oncogenicity study in the rat.* Cypermethrin was administered to rats at dose levels of control-1, control-2, 20, 150, or 1500 ppm (corresponding to 0, 0, 1, 7.5, or 75 mg/kg/day) for 2 years. The LOEL is 1,500 ppm (75 mg/kg/day) based on bodyweight. The NOEL was 150 ppm (7.5 mg/kg/day). Cypermethrin was not considered to be oncogenic in this study. A possible association with increased testicular interstitial tumors was not considered definite. This chronic toxicity/carcinogenicity study was classified as acceptable and satisfies the guideline requirement for a chronic oral feeding/carcinogenicity study (83–5) in rats.

6. *Metabolism*. Studies in rats, dogs, and mice are available to support the requirement of metabolism in mammals. Studies show that cypermethrin is readily absorbed from the gastrointestinal tract and extensively metabolized. It is mostly excreted in the urine. Studies submitted to the Agency were acceptable. No additional data are required.

7. *Neurotoxicity.* Additional data considered by the Agency included an acute delayed type neurotoxicity in hens, an acute neurotoxicity screening study in rats with a NOEL of 30 mg/kg and a LOEL of 100 mg/kg, and a subchronic neurotoxicity screening study in rats with a NOEL of 31 mg/kg/day and a LOEL of 77 mg/kg/day. Additional data will be required under a special Data Call-In (DCI) letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking EPA has a sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. To assess risk from acute dietary exposure, the Agency used a NOEL of 1.0 mg/kg/day based on increased incidence of passage of liquid stools at 5 mg/kg/day and above starting the first weeks of dosing in a the chronic-dog study.

2. *Short- and intermediate-term toxicity.*To assess risk from (non-food) short- and intermediate-term dermal exposure, the Agency used a NOEL of 5 mg/kg/day from the chronic-dog study, incorporating 25% dermal absorption. A dermal absorption rate of 25% was derived based on the weight-of-evidence available for structurally related pyrethroids. For exposure via inhalation, the Agency used a NOEL of 0.01 mg/L from the 21-day inhalation study in rats.

3. *Chronic toxicity*. EPA has established the RfD for cypermethrin at 0.01 mg/kg/day. This RfD is based on a NOEL of 1.0 mg/kg/day from the chronic-dog study with an uncertainty factor of 100.

4. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992) the Carcinogenicity Peer Review Committee (CPRC) has classified cypermethrin as a Group C chemical, possible human carcinogen, based on increased incidence of lung adenomas in female mice, but did not recommend assignment of a cancer potency factor (Q*1) for a linear quantitative cancer risk assessment. Instead, the CPRC recommended the RfD approach. Based on the CPRC's recommendation that the RfD approach be used to assess dietary cancer risk, a quantitative linear dietary cancer risk assessment was not performed. Human health risk concerns due to long-term consumption of cypermethrin residues are adequately addressed by the dietary risk evaluation chronic exposure analysis using the RfD.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.418) for the residues of cypermethrin. For the purposes of dietary risk assessment, residue data generated from residue field trials conducted at maximum application rates and minimum preharvest intervals were used. To assess secondary exposure from edible animal commodities, animal dietary burdens were calculated using mean field trial residue, adjusted for percent crop treated and applying appropriate processing factors for all feed items. Risk assessments were conducted by EPA to assess dietary exposures and risks from cypermethrin as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The acute dietary exposure assessment used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinement. The acute exposure via dietary intake for the U.S. Population is estimated at 0.004438 mg/kg/day. The acute dietary risk estimated by as MOE at the 99.9th percentile for the U.S. population is 225. The acute dietary exposure for children is 0.005465 mg/kg/day with a resulting MOE of 183. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater.

ii. *Chronic exposure and risk.* The chronic dietary exposure assessment incorporated anticipated residues, tolerance values, FDA and PDP monitoring data, and percent crop treated information. The RfD used was 0.01 mg/kg/day. For the U.S. population, the exposure was estimated at 0.000025 mg/kg/day. The risk assessment resulted in use of 0.3% of the RfD. For children 0.000042 mg/kg/day, which uses 0.4% of the RfD.

Section 408(b)(2)(E) of the FFDCA authorizes EPA to consider available data and information on the anticipated residue levels of pesticides residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

a. That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues.

b. That the exposure estimate does not underestimate the exposure for any significant subpopulation.

c. Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population.

In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for cypermethrin were derived from Federal and market basket survey data.

EPA considers these data reliable. A range of estimates supplied by this data and upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer based model for evaluating exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to section 408(f) of the FFDCA requiring submission of data on anticipated residues in conjunction with approval of the registration under FIFRA.

2. *From drinking water.* Studies show that cypermethrin is immobile in soil and does not leach into ground water. Drinking water residue levels were estimated using the PRZM1/EXAMS computer models in 1993 for comparative ecological risk assessment.

i. *Acute exposure and risk.* For the U.S. population, acute exposure is estimated at 0.000126 mg/kg/day (MOE = 7,965). For non-nursing infants < 1 year old, exposure is estimated at 0.000242 mg/kg/day (MOE = 4,138).

ii. *Chronic exposure and risk.* For the U.S. population, chronic exposure is estimated at 0.000005 mg/kg/day, or essentially 0% of the RfD. For non-nursing infants < 1 year old, exposure is estimated at 0.000021 mg/kg/day, or 0.2% of the RfD.

3. *From non-dietary exposure.* i. Cypermethrin is currently registered for use on lawns and carpets. Non-occupational exposure to cypermethrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. Using surrogate data and conservative exposure scenarios, the Agency has estimated combined inhalation, dermal, and oral non-dietary exposure.

ii. *Short- and intermediate-term exposure and risk.* For the U.S. population, exposure is estimated at 0.0000515 mg/kg/day. For infants less than 1 year old, the exposure is estimated at 0.00259 mg/kg/day.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Four members of the insecticide class pyrethroids produce a common metabolite known as DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid). These insecticides are cyfluthrin, cypermethrin, zeta-cypermethrin and permethrin. Although the residues of DCVA can be estimated, no toxicology data on the compound per se are available to directly conduct a hazard evaluation and thereby establish an appropriate endpoint for use in a joint risk assessment. To date, for the purpose of assessing the risk of the parent compound the toxicity of DCVA has been assumed to be equivalent to the parent compound. However, due to the different toxicological profiles of cyfluthrin, cypermethrin, permethrin, and zeta-cypermethrin, EPA does not believe that it would be appropriate to cumulate DCVA for these pesticides, or DCVA residues from one of these pesticides with the parent of another of these pesticides, in conducting the risk assessment for these pesticides.

Accordingly, EPA does not have, at this time, available data to determine whether cypermethrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that cypermethrin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

The Agency has determined that an aggregate systemic oral and dermal exposure risk assessment is not appropriate due to difference in the toxicity endpoints observed between the oral (neurotoxicity) and dermal (hepatotoxicity) routes. An aggregate oral and inhalation risk assessment is appropriate due to the similarity of toxicity (neurotoxicity) observed in rats via these routes.

1. *Acute risk.* Aggregate acute risk represents the sum of acute food and acute drinking water exposure. For cypermethrin, the aggregate acute exposure is estimated at 0.004564 mg/kg/day, with a resulting MOE of 219 for the adult U.S. population.

2. *Chronic risk.* Aggregate chronic exposure is the sum of chronic exposure from food and chronic water. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to cypermethrin from food and water will utilize 0.3% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cypermethrin residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short-term and intermediate-term residential exposure. For cypermethrin, exposure is estimated at 0.000082 mg/kg/day, with a resulting MOE of 61,000 for the U.S. population.

E. Aggregate Cancer Risk for U.S. Population

Cypermethrin is classified as a weak Group C carcinogen based on the increased incidence of lung adenomas in female mice. An RfD approach was recommended for human risk assessment purposes. Therefore, a quantitative dietary cancer risk

assessment was not performed. Dietary risk concerns due to long-term consumption of cypermethrin are adequately addressed in the chronic exposure analysis. For the U.S. population, less than 1% of the RfD is occupied by aggregate chronic food and water exposure.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of cypermethrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a three-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Section 408 of the FFDCA provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional 10-fold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the prenatal developmental toxicity studies in rats and rabbits, there was no evidence of developmental toxicity at the highest dose tested (70 mg/kg/day in rats and 700 mg/kg/day in rabbits).

iii. *Reproductive toxicity study.* An acceptable three-generation reproduction study in rats has been submitted. Offspring toxicity was observed only at the highest dietary level tested, (700/1,000 ppm; 50/37.5 mg/kg/day), while toxicity in parental animals was observed at the lower treatment levels. The parental systemic NOEL was 50 ppm (2.5 mg/kg/day) and the parental systemic LOEL was 150 ppm (7.5 mg/kg/day).

iv. *Pre- and post-natal sensitivity.* The developmental and reproductive toxicity data demonstrated no indications of increased pre- and post-natal sensitivity.

v. Based on the above, EPA concludes that reliable data support the use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* For children 1 to 6 years old, (most highly exposed subgroup), the aggregate acute exposure is estimated at 0.005572 mg/kg/day, with a resulting MOE of 179. EPA generally has no concern for MOEs over 100.

3. *Chronic risk.* Using conservative exposure assumptions, EPA has concluded that aggregate chronic exposure to cypermethrin from food and water is estimated at 0.000044 mg/kg/day for children 1 to 6 years old (most highly exposed subgroup) will utilize 0.4% of the RfD.

4. *Short- or intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short-term and intermediate-term residential exposure. The MOE for non-nursing infants < 1 year old (most highly exposed subgroup) is estimated at 1,900.

Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to cypermethrin residues.

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry, and research scientists in developing a screening and testing program and a priority setting scheme to implement the program. Congress has allowed 3 years from passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disruption effects.

III. Other Considerations

A. Metabolism in Plants and Animals

The metabolism of cypermethrin in plants and animals is adequately understood. Studies have been conducted to delineate the metabolism of radiolabelled cypermethrin in various crops all showing similar results. The residue of concern is cypermethrin parent.

B. Analytical Enforcement Methodology

Adequate enforcement methodology Gas Chromatography with Electron Capture Detection (GC/ECD) is available in PAM II for enforcement of the tolerances.

C. Magnitude of Residues

Crop field trial residue data and animal feeding data from studies conducted at the maximum label rates for brassica, head and stem; brassica, leafy; cotton; lettuce, head; onions, bulb; and pecans show that the established cypermethrin tolerances on brassica, head and stem at 2.0 ppm; brassica, leafy at 14.0 ppm; cattle, fat at 0.05 ppm, cattle, meat at 0.05 ppm, cattle, mbyp at 0.05 ppm; cottonseed of 0.5 ppm; hogs, fat at 0.05 ppm, hogs, meat at 0.05 ppm, hogs, mbyp at 0.05 ppm; horses, fat at 0.05 ppm, horses, meat at 0.05 ppm, horses, mbyp at 0.05 ppm; lettuce, head at 10.0 ppm; milk at 0.05 ppm; onions, bulb at 0.10 ppm; pecans 0.05 ppm; sheep, fat at 0.05 ppm, sheep, meat at 0.05 ppm; and sheep, mbyp at 0.05 ppm will not be exceeded when the cypermethrin products labeled for these uses are used as directed.

D. International Residue Limits

The Codex tolerances for cypermethrin are: Brassica vegetables, 1 ppm; lettuce, 2 ppm; milk, 0.05 ppm; onions, bulb, 0.1 ppm; meat, fat basis, 0.2 ppm; mammalian edible mby, 0.05 ppm. Mexico has established a tolerance for cottonseed at 0.5 ppm. There are no Canadian tolerances established for cypermethrin. As indicated in Unit II. of this preamble, there are differences between the FFDCA section 408 tolerances and the Codex Maximum Residue Limits (MRLs) value for specific

commdities. These differences could be caused by differences in methods to establish tolerances, calculation of animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, permanent tolerances are established for residues of cypermethrin in or on the commodities brassica, head and stem at 2.0 ppm; brassica, leafy at 14.0 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, mbyp at 0.05 ppm; cottonseed at 0.5 ppm; goats, fat at 0.05 ppm; goats, meat at 0.05 ppm; goats, mbyp at 0.05 ppm; hogs, fat at 0.05 ppm; hogs, meat at 0.05 ppm; hogs, mbyp at 0.05 ppm; horses, fat at 0.05 ppm; horses, meat at 0.05 ppm; horses, mbyp at 0.05 ppm; lettuce, head at 10.0 ppm; milk at 0.05 ppm; onions, bulb at 0.10 ppm; pecans 0.05 ppm; sheep, fat at 0.05; sheep, meat at 0.05 ppm; and sheep, mbyp at 0.05 ppm.

V. Objections and Hearing Requests

New section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) of the FFDCA as was provided in the old section 408 and in section 409 of FFDCA. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP Docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number OPP–300583 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number, OPP–300583. No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**.

This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.418 is revised to read as follows:

§ 180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cypermethrin (±)alpha cyano-(3-phenoxyphenyl)methyl(±)cis,trans-3(2,2-dichloroethenyl-2,2-dimethylcyclopropanecarboxylate in or on the following commodities:

Commodity	Parts per million
Brassica, head and stem	2.0
Brassica, leafy	14.0
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Cottonseed	0.5
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Horses, fat	0.05
Horses, mbyp	0.05
Horses, meat	0.05
Lettuce, head	10.0
Milk	0.05
Onions, bulb	0.10
Pecans	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05

(2) [Reserved]

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–30947 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300577; FRL–5754–8]

RIN 2070–AB78

Zeta-Cypermethrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zeta-cypermethrin in or on cabbage at 2.0 parts per million (ppm); cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; pecans at 0.05 ppm; and the fat, meat, and meat byproducts (mbyp) of cattle, goats, hogs, horses, and sheep at 0.05 ppm. It also removes time limitations for tolerances for residues of zeta-cypermethrin on the same commodities that expire on November 15, 1997. FMC Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300577, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk, identified by the docket control number, OPP–300577, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions in Unit VI. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Beth Edwards, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5400, e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On June 15, 1984, EPA established time-limited tolerances under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) and 348 for residues of cypermethrin on cottonseed; fat, meat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep; and milk (49 FR 24864). As additional crop tolerances were established, they were also made time-limited. These tolerances expire on November 15, 1997. FMC Corporation, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticide zeta-cypermethrin in these commodities be removed based on environmental effects data that they had submitted as a condition of the registration. FMC Corporation also submitted a summary of its petition as required under the FFDCA, as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L 104–170).

In the **Federal Register** of September 25, 1997, (62 FR 50337) (FRL–5748–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 2F2623, 4F2986, 3F2824, 7F3498, and 4F3011) for tolerances by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. This notice included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.418 be amended by removing the time limitation for tolerances for residues of the insecticide and pyrethroid, zeta-cypermethrin in or on cabbage at 2.0 ppm; cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; and pecans at 0.05 ppm. Animal commodities were not

included in the notice of filing but are being included in this final rule.

The basis for the time-limited tolerances, that expire November 15, 1997, was given in the October 20, 1993, **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no-observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low-dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate-term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single-oral exposure to the pesticide residues. High-end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure,

and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, section 408 of the FFDCA requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of zeta-cypermethrin and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for residues of zeta-cypermethrin in or on cabbage at 2.0 ppm; cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; pecans at 0.05 ppm; and the fat, meat, and mbyp of cattle, goats, hogs, horses, and sheep at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by zeta-cypermethrin are discussed in this unit.

1. Acute toxicity studies with technical zeta-cypermethrin: oral LD_{50} in the rat is 134.4 milligram (mg)/kilogram (kg) for males and 86.0 mg/kg for females—Toxicity Category II.

2. Acute toxicity studies with cypermethrin bridged to zeta-cypermethrin: dermal $LD_{50} > 2460$ mg/kg in rabbits and $LD_{50} > 4920$ in rats—Toxicity Category III; inhalation (LC_{50} 2.5 mg/liter (L) for females and > 2.5 mg/L in males—Toxicity Category III; primary eye irritation— not irritating—Toxicity Category IV; primary dermal irritation, primary irritation score (PIS) 0.71 —Toxicity Category IV; dermal sensitization—moderate sensitizer in two studies, negative in other studies; delayed type neurotoxicity in hens—no evidence of delayed type neurotoxicity in hens at dose levels of 0, 2,500, 5,000, or 10,000 mg/kg; neurotoxicity screen in rats—NOEL and lowest-observed effect level (LOEL) established as < 20 mg/kg—at 20 mg/kg decreased motor activity and gait abnormalities.

3. In a 90-day feeding study, rats were dosed at 0, 10, 50, 150, 250, 500, or 900 ppm (0, 0.6, 2.7, 8.4, 13.8, 28.2, or 55.7 mg/kg/day for males and 0, 0.6, 3.3, 9.6, 16.3, 32.2, or 65.2 mg/kg/day for females). The NOEL is 250 ppm (13.9 mg/kg/day) and the LOEL is 500 ppm (28.2 mg/kg/day) based on decreases in bodyweight and bodyweight gains and food consumption at 28.2 mg/kg/day and above and deaths; clinical signs of neurotoxicity; decreases in erythrocyte and leukocyte counts, hemoglobin, and hematocrit, and increases in blood urea nitrogen (BUN) at 55.7 mg/kg/day.

4. The 21-day dermal, subchronic oral study in the dog and the 21-day inhalation studies are bridged from cypermethrin.

In a subchronic toxicity study, dogs were dosed at 0, 5, 50, 500, or 1,500 ppm (corresponding to 0, 125, 1.25, 12.5, and 37.5 mg/kg/day) for 13 weeks. The LOEL is 1,500 ppm (37.5 mg/kg/day, based on clinical signs indicating neurotoxicity). The NOEL is 500 ppm (12.5 mg/kg/day).

In a 21-day dermal toxicity study, rabbits were dosed at 2, 20, or 200 mg/kg/day with daily applications for 3 weeks for a total of 15 applications. Five/sex/group were abraded prior to application of the test material. The LOEL is 200 mg/kg/day based on liver effects. The NOEL is 20 mg/kg/day.

In a 21-day subchronic inhalation toxicity study, rats were dosed by nose only exposure at concentrations of 0, 0.01, 0.05, or 0.25 mg/L for 6 hours per day, 5 days per week for a total of 15 exposures. Additional satellite groups of five/sex were included for recovery assessment and analysis of cypermethrin in the brain. The LOEL is 0.05 mg/L based mainly on bodyweight decrease. The NOEL is 0.01 mg/L.

5. The chronic/oncogenicity studies are bridged from cypermethrin.

In a chronic toxicity study, dogs were dosed at 0, 1, 5, or 15 mg/kg/day for 52 weeks. The LOEL is 5 mg/kg/day based on gastrointestinal effects. The NOEL is 1 mg/kg/day.

In a carcinogenicity study, mice were dosed at control-1, control-2, 100, 400, and 1,600 ppm (corresponding to 0, 0, 14, 57, or 229 mg/kg/day) for 97 weeks for males and 101 weeks for females. The LOEL is 400 ppm (57 mg/kg/day) based on liver weight. The NOEL is 100 ppm (14 mg/kg/day). This study was determined to be positive for induction of benign alveologenic neoplasms. Adequacy of dosing for carcinogenicity is based upon typically 9% decreases in males and 12% in females in the first months of the study.

In a chronic toxicity/carcinogenicity study, rats were dosed at control-1, control-2, 20, 150, or 1,500 ppm (corresponding to 0, 0, 1, 7.5, or 75 mg/kg/day) for 2 years. Satellite groups of 12/sex were sacrificed after 1 year of dosing. The LOEL is 1,500 ppm (75 mg/kg/day) based on bodyweight. The NOEL is 150 ppm (7.5 mg/kg/day). Cypermethrin was not considered to be

oncogenic in this study. A possible association with increased testicular interstitial tumors was not considered definite.

6. Zeta-cypermethrin was tested in a developmental toxicity study in rats at the following dose levels: 0, 5, 12, 25, or 35 mg/kg/day. Groups of 25 females were administered the test chemical by gavage on gestation days 6 through 15 in a volume of 5 milliliter (ml)/kg bodyweight. No developmental toxicity was observed at any dose level. The maternal NOEL is 12.5 mg/kg and the maternal LOEL is 25 mg/kg based on decreases in bodyweight and bodyweight gain and food consumption and clinical signs of toxicity, particularly neurotoxicity. The developmental NOEL is 35 mg/kg/day highest dose tested (HDT). The LOEL was not established.

7. The developmental toxicity study in the rabbit is bridged from cypermethrin.

In a developmental toxicity study, rabbits were dosed at 0 (empty capsule), 0 (capsule plus corn oil), 3, 10, or 30 mg/kg/day on days 6 to 18 inclusive of gestation. There were no effects of any kind reported on the does. The maternal LOEL is > 30 mg/kg/day. The maternal NOEL is > 30 mg/kg/day. There were no treatment related effects on either the skeletal or visceral structures reported. The developmental LOEL is > 30 mg/kg/day. The developmental NOEL is > 30 mg/kg/day.

In a developmental toxicity study, rabbits were dosed at 0, 100, 450, or 700 mg/kg/day from days 7 through 19 of gestation. The does were sacrificed on day 29 of gestation. The maternal LOEL is 450 mg/kg/day, based on bodyweight gain. The maternal NOEL is 100 mg/kg/day. There were no indications of developmental toxicity. The NOEL and LOEL for developmental toxicity is > 700 mg/kg/day.

8. Zeta-cypermethrin was tested in a two-generation reproduction study in groups of 30 male and 30 female rats at the following dose levels: 0, 7.5, 25, 100, 375, or 750 ppm (0, 0.5, 1.8, 7, 27, or 45 mg/kg/day). The parental and reproductive NOELs are 7 mg/kg/day and LOELs are 27 mg/kg/day based on decreased parental and pup weight, particularly during lactation, clinical signs of toxicity, and death at 45 mg/kg/day.

9. Zeta-cypermethrin was tested in a reverse mutation assay in salmonella typhimurium strains TA1535, TA1537, TA100, TA1538, and TA98 at 0, 100, 333, 1,000, 3,333, 5,000, or 10,000 microgram (μg)/plate. It gave a very weak positive response (two-fold increase in revertants/plate) in strain TA100 at 10,000 μg/plate without S–9 activation in two-separate experiments. Doses of 3,333 and 5,000 μg/plate gave 1.5 and 1.6-fold increases in revertants/plate, respectively. Strains TA98, TA1535, TA1537, and TA1538 treated in the presence and absence of mammalian S–9 activation were not affected. Zeta-cypermethrin is therefore considered a possible weak mutagen under the conditions of the assay.

10. Zeta-cypermethrin was tested in an *in vitro* mammalian cell gene mutation assay in Chinese hamster ovary (CHO) cells ($CHO–K_1–BH_4$, subclone D_1) at the following dose levels: 0, 1, 10, 25, 50, 100, 400, 700, or 1,000 μg/ml, both in the absence and presence of S–9 activation. No evidence of increased forward mutation rate at the hypoxanthine guanine phosphoribose transferase (HGPRT) locus was observed at any dose tested under the conditions of these assays. The solubility limit of the test compound in culture media was approximately 100 μg/ml.

11. Zeta-cypermethrin was tested in an *in vivo* rat bone marrow chromosomal aberration assay. Groups of 15 male and 15 female Sprague-Dawley rats were administered single doses by gavage with 0, 31.25, 62.5, or 125 mg/kg zeta-cypermethrin in corn oil. Five rats/sex were sacrificed at 6, 18, and 30 hours-post dosing. Cyclophosphamide was used as the positive control (60 mg/kg). No evidence of structural chromosomal aberrations was demonstrated at either 6, 18, or 30 hours-post dosing.

12. Zeta-cypermethrin was tested in an unscheduled deoxyribonucleic acid (DNA) synthesis assay in male Fischer 344 rat primary hepatocyte cells. The dose levels tested were 0, 14, 45, 140, 450, 1,400, or 4,500 μg/ml. No unscheduled DNA synthesis was observed at any dose level up to 4,500 μg/ml in the primary hepatocyte cultures under the conditions of the assay. Minimal cytotoxicity was observed at the highest doses. Incomplete solubility of the test compound in culture media was observed, particularly at the higher doses. The positive control gave clear positive responses. The study is acceptable for regulatory purposes.

13. The metabolism studies are bridged from cypermethrin.

Several studies with both rats, dogs, and mice are available to support the requirement for metabolism in mammals. Some of these studies assess individual cis- and trans-radiolabeled isomers and other studies assess the metabolism of cypermethrin with the label in either the cyclopropyl of the phenoxybenzyl ring. In general the following has been demonstrated from these studies:

Cypermethrin is readily absorbed from the gastrointestinal tract and extensively metabolized. It is mostly excreted in the urine and contains several characterized metabolites derived from conjugation of the hydrolysis products of the parent compound following cleavage of the esteratic linkage site. The following three executive summaries describe the metabolism of cypermethrin in rats.

First study—First group. Six/sex rats, Wistar strain rats, were dosed with a single dose 0.61 mg/animal of labeled cis-cypermethrin isomers in 0.5 ml of corn oil. The rats were individually housed in metabolism cages and their urine and fecal matter collected daily until sacrifice. Two rats of each sex were sacrificed after 24 and 72 hours and after 8 days. Samples of the blood and selected tissues were assessed for radioactivity content.

Second group. Three/sex rats were dosed with 0.615 mg/animal of labeled trans-cypermethrin in 0.8 ml of corn oil. In addition to the urine and fecal collections, expired air was also collected from one male and one female. Total recovery was from 97.2% to 100.5%. About 70% of cis- and 80% of trans-cypermethrin was excreted in 24 hours. Essentially all was excreted in 8 days. Most of the label was excreted in the urine (> 53%) with less in the feces and (< 20%) for the trans (males and females) and cis (males only) groups and < 1% in the air for all groups. A sex difference with respect to excretion in the urine from the cis-isomer was noted for females since about equal amounts (35%) were found in both the urine and feces. Several urinary and fecal metabolites were tentatively characterized.

Second study. One group of three/sex Wistar strain rats was dosed with a single-oral dose (approximately 1.3 mg/kg) of 14*C*-cyclopropyl labeled cypermethrin in corn oil (0.8 ml). The rats were then placed in glass metabolism cages and their urine and feces were collected. Special metabolism cages for trapping any radioactivity expired through their respiratory system were used for one male and one female rat. The rats were sacrificed after 3 days and their blood and selected tissues were assessed for radioactivity, 85.5% for males and 97.2% for females of 14*C* was excreted in 72 hours. The urine (55.8% for males and 69.4% for females) was the major route of excretion with the feces containing the balance. The air contained only 0.1% or less. Tissue

retention was highest in the skin (1.2%) and liver (0.74% for males but only 0.18% for females) and fat (0.57 to 0.66%).

Third study. In a series of nine different studies, labeled cypermethrin (1 mg/kg or less) in corn oil or separated cis- or trans-cypermethrin isomers were given by gavage to single or groups of two or three Wistar strain rats. Their urine and in some cases fecal matter was collected at various intervals such as 18 hours to 3 days. In another set of experiments, labeled cypermethrin was administered to rats that were fitted with bile duct cannalulas and their bile collected for 4-5 hours while the rat was under anesthesia. Cis- and trans-14*C*-cyclopropyl labeled cypermethrin was demonstrated to form glucuronide conjugations of cis- and trans-acids and hydroxyacids. Only 1.6% or less of the total dose is excreted in the bile. Most of the cypermethrin in the feces was unmetabolized. The glucuronide conjugates in the urine were found to be unstable and subject to hydrolysis.

14. *Acute delayed type neurotoxicity-hens*. Cypermethrin was tested in the hen following a protocol similar to the series 81–7 guideline. The dose levels tested were 0, 2,500, 5,000, and 10,000 mg/kg but there was no indication of the delayed type neurotoxicity noted.

15. *Acute neurotoxicity screen-rats*. There are two acute neurotoxicity studies with cypermethrin.

First study. Rats were dosed with cypermethrin at dose levels of 0, 20, 60, or 120/100 mg/kg. The rats displayed gait, muscle effects, and choreoathetosis. Motor activity was decreased for all dose groups for males (estimated 45%, 66%, and 85% for the 20, 60, and 100 mg/kg dose group respectively) and gait abnormalities were present in the low-dose group. Body temperature was increased about 1 °C in the low-dose male group but decreased for the higher groups. Some 10 other parameters were affected at 60 mg/kg and/or above. These included: Salivation, urination, arousal, abnormal motor movement, forelimb, or hindlimb grip strength, landing foot splay, touch response, and tail pinch response. The LOEL and NOELs for neurotoxicity are < 20 mg/kg. At 20 mg/kg decreased motor activity and gait abnormalities resulted.

Second study. Rats were dosed with cypermethrin in corn oil as control, 30, 100, or 200 mg/kg. The rats were assessed at pretest, 4 hours after treatment and on days 7 and 14 for Functional Observational Battery (FOB) and motor activity. After day 14, five/sex were prepared for neurohistopathology. At 100 mg/kg, ataxia (two males and two females) and related conditions (staggered or impaired gait, decreased activity, splayed hindlimbs, and limp condition) and decreased motor activity (49%, $p < 0.001$ for males and 33%, $p < 0.01$ for females) resulted. In addition, some females had salivation, lacrimation and/or soiled fur. At 200 mg/kg, deaths resulted (one male and two females) as well as several other parameters being affected. The LEL is 100 mg/kg based primarily on ataxia and related conditions. The NOEL is 30 mg/kg.

The first study in Unit II. A.15. of this preamble is considered to define the neurotoxicity to cypermethrin because responses were noted at lower-dose levels. The second study used a variable and large dose of corn oil and a different strain of rat.

16. *Subchronic neurotoxicity screen in rats*. Rats were dosed with cypermethrin as control, 500, 1,300 or 1,700 ppm (31, 77, or 102 for males and 37, 95, or 121 for females mg/kg/day) for 90 days in a subchronic neurotoxicity study. At 1,300 ppm, females displayed ataxia (1/10), splayed hindlimbs (5/16), impaired gait (4/10), and decreased feces (4/10) as well as decreased bodyweight gain (~41%). Males had only decreased bodyweight gain (~27%) and increased landing foot splay. At 1,700 ppm, males showed ataxia (8/10) and additional related symptoms and females had decreased motor activity (~27%). The LEL is 1,300 ppm (77 mg/kg/day) based on several effects. The NOEL is 500 ppm (31 mg/kg/day).

Because the studies in Units II. A.15. and 16. of this preamble are screens, neurotoxicity studies will be required under a special Data Call-In (DCI) letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data base to support these tolerances and these additional studies are not expected to significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of a NOEL of 0.5 mg/kg/day based on the NOEL of 1.0 mg/kg/day from the cypermethrin chronic toxicity study in dogs and a correction factor of two to account for the differences in the percentage of the biologically active isomer. The LOEL of this study of 5.0 mg/kg/day was based on gastrointestinal disturbances observed in the first week of the study.

2. *Short- and intermediate-term toxicity*. For short- and intermediate-term MOE's, EPA recommends use of a NOEL of 2.5 mg/kg/day based on neurotoxic signs in dogs starting at week 1. The inhalation NOEL is 5.0 with a correction factor of 2. Dermal absorption rate was 25%. A dermal absorption rate of 25% was recommended based on the weight-of-the-evidence available for structurally related pyrethroids.

3. *Chronic toxicity*. EPA has established the RfD for zeta-cypermethrin at 0.005 mg/kg/day. This RfD is based on gastrointestinal disturbances in dogs with an uncertainty factor of 200 to account for differences in percent biologically active isomers in enriched product.

Since insufficient data on zeta-cypermethrin are available to establish an RfD, the data from cypermethrin were used in establishing an RfD for zeta-cypermethrin. The NOELs from the cypermethrin studies were divided by 2 as a correction factor, assuming the worst case that the biologically active isomers are the ones which carry most of the toxicity. The following paragraph summarizes the decision logic for establishing the RfD for zeta-cypermethrin from the cypermethrin data base.

In general, the most sensitive species for the 10 synthetic pyrethroids appears to be the dog. For zeta-cypermethrin the Agency does not have any toxicity data on the dog that can be compared with the dog studies conducted with cypermethrin. In addition, the Agency also does not have any chronic studies on zeta-cypermethrin that can be compared with those conducted with cypermethrin. Therefore, although a comparison of the LEL's from the zeta-cypermethrin studies with the corresponding LEL's from the cypermethrin studies does not show a pronounced difference in toxicity, for risk assessment purposes, the Agency has decided to use the toxicity endpoints from cypermethrin with a two-fold correction factor to account for the differences in the percentages of the more biologically active isomers in the enriched technical product (zeta-cypermethrin). This would also apply to the inhalation endpoint because the Agency has no inhalation studies with zeta-cypermethrin. The Agency is making a conservative assumption that most of the toxicity for cypermethrin will be from the four more biologically active isomers of zeta-cypermethrin. Based on previous documentation, the Agency is assuming that the percentages of the isomers are approximately as follows:

Cypermethrin, eight isomers with percentage compositions ranging from 11–14% and zeta-cypermethrin, eight isomers with four insecticidally less active ones at a concentration of 1% each. The remaining four isomers, two

of which are regarded as being the most insecticidally active, will be present at a concentration of 24% each.

4. *Carcinogenicity.* No carcinogenicity studies are available for zeta-cypermethrin. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992) the Carcinogenicity Peer Review Committee (CPRC) has classified cypermethrin as a weak Group C (possible human carcinogen) based on the increased incidence in lung adenomas in female CD-1 mice, but did not recommend assignment of a cancer potency factor (Q*1) for a linear quantitative cancer risk assessment. An RfD approach was recommended for human risk assessment purposes. It is assumed that zeta-cypermethrin would also test positively for lung adenomas in female CD-1 mice.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.418) for the residues of zeta-cypermethrin in or on a variety of raw agricultural commodities. Tolerances range from 0.05 ppm in animal commodities to 10.0 ppm in head lettuce. Registered uses include cabbage, cotton, head lettuce, onions, and pecans. Risk assessments were conducted by EPA to assess dietary exposures and risks from zeta-cypermethrin as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The acute dietary exposure assessment used Monte Carlo modeling incorporating anticipated residues and percent crop treated refinements. The acute dietary MOE at the 99.9th percentile for the overall U.S. population is 126. The MOE at the 99.9th percentile for children 1–6 years of age is 105. EPA concludes that there is a reasonable certainty of no harm for MOEs of 100 or greater. Therefore, the acute dietary risk assessment for zeta-cypermethrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk.* The RfD used for the chronic dietary analysis is 0.005 mg/kg/day based on a NOEL of 1.0 mg/kg/day from the cypermethrin chronic dog study and an uncertainty factor of 200 (used to account for the differences in the percentage of the biologically active isomer). The endpoint effect of concern was based on gastrointestinal disturbances observed in the first week of the study at the LOEL of 5.0 mg/kg/day. The chronic dietary exposure assessment used anticipated residues, monitoring data, and percent of crop treated information . The chronic dietary exposure estimate for the overall U.S. population was calculated to be 0.000018 mg/kg/day (0.4% RfD utilized) and for children 1–6 years was calculated to be 0.00027 mg/kg/day (0.5% RfD utilized).

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent of crop treated refinements. The chronic dietary risk assessments used anticipated residues and percent crop treated information.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a timeframe it deems appropriate. Section 408(b)(2)(F) allows the Agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

a. That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues.

b. That the exposure estimate does not underestimate the exposure for any significant subpopulation.

c. Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population.

In addition, the Agency must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for zeta-cypermethrin were derived from Federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper-end estimate of percent crop treated, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a DCI notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under the FIFRA.

2. *From drinking water.* Laboratory and field data have demonstrated that cypermethrin is immobile in soil and will not leach into ground water. Estimates of zeta-cypermethrin drinking water concentrations were generated with the PRZM1 and EXAMS computer models. Based on these analyses, the contribution of water to the dietary risk estimate is negligible. Therefore, EPA concludes that together these data indicate that residues are not expected to occur in drinking water.

i. *Acute exposure and risk.* The acute drinking water exposure and risk estimates are 0.000126 mg/kg/day (MOE of 3,982) and 0.000242 mg/kg/day (MOE of 2,069) for the overall U.S. population and non-nursing infants < 1 year old, respectively.

ii. *Chronic exposure and risk.* The chronic drinking water exposure and risk estimates are 0.000005 mg/kg/day (0.1% of RfD utilized) and 0.000021 mg/kg/day (0.4% of RfD utilized) for the overall U.S. population and non-nursing infants < 1 year old, respectively.

3. *From non-occupational non-dietary exposure.* Zeta-cypermethrin is registered for agricultural crop applications only; therefore, no non-occupational, non-dietary exposure is expected.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common

mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Four members of the insecticide class pyrethroids produce a common metabolite known as DCVA (3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid). These insecticides are cyfluthrin, cypermethrin, zeta-cypermethrin, and permethrin. Although the residues of DCVA can be estimated, no toxicology data on the compound per se are available to directly conduct a hazard evaluation and thereby establish an appropriate endpoint for use in a joint risk assessment. To date, for the purpose of assessing the risk of the parent compound, the toxicity of the DCVA has been assumed to be equivalent to the parent compound. However, due to the markedly different toxicological profiles of cyfluthrin, cypermethrin, zeta-cypermethrin, and permethrin, EPA does not believe that it would be appropriate to cumulate DCVA residues from these pesticides, or DCVA residues from one of these pesticides with the parent of another of these pesticides, in conducting the risk assessment for these pesticides.

Accordingly, EPA does not have, at this time, available data to determine whether zeta-cypermethrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that zeta-cypermethrin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and water. The MOE calculated at the 99.9th percentile for the overall U.S. population is 122. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to zeta-cypermethrin through food and drinking water.

2. *Chronic risk.* Using the Anticipated Residue Contribution (ARC) exposure assumptions, EPA has concluded that aggregate exposure to zeta-cypermethrin from food and water will utilize 0.5% of the RfD for the U.S. population. The major identifiable subgroup with the highest-aggregate exposure is children, ages 1–6 years old, discussed in Unit II. F. of this preamble. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to zeta-cypermethrin residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Based on zeta-cypermethrin not being registered for residential non-food sites, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern (MOE less than 100), and that there is reasonable certainty that no harm will result from aggregate exposure to zeta-cypermethrin residues.

E. Aggregate Cancer Risk for U.S. Population

No carcinogenicity studies are available for zeta-cypermethrin. However, cypermethrin has been classified as a weak Group C carcinogen with no Q*1 based on the increased incidence in lung adenomas in female CD-1 mice. Based on the recommendation that the RfD approach be used, a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of cypermethrin are adequately addressed by the DRES chronic exposure analysis using the RfD. For the U.S. population, less than 1% of the RfD is occupied by aggregate chronic food and water exposure.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of zeta-cypermethrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Section 408 of the FFDCA provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional 10-fold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a prenatal developmental toxicity study in rats, there was no evidence of developmental toxicity at the HDT (35 mg/kg/day). Maternal toxicity (ataxia, urine and feces stained fur, decreased bodyweight gain and food consumption) was observed at the maternal LOEL (25 mg/kg/day), and the maternal NOEL was established at 12.5 mg/kg/day. In

addition, an acceptable prenatal developmental toxicity study in rabbits conducted with cypermethrin was submitted.

iii. *Reproductive toxicity study.* In the two-generation reproduction study in rats, offspring toxicity (decreased pup weight gain during lactation) was observed at the same treatment level which resulted in parental systemic toxicity (NOEL = 100 ppm or 27 mg/kg/day; LOEL = 375 ppm or 45 mg/kg/day).

iv. *Pre- and post-natal sensitivity.* There is no evidence of additional sensitivity to young rats following pre- or post-natal exposure to zeta-cypermethrin.

v. *Conclusion.* The data base related to pre- and post-natal sensitivity is complete. Based on the information in Unit II. F. of this preamble, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and water. The MOE calculated at the 99.9th percentile for children age 1–6 is 102. The Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields an MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to zeta-cypermethrin through food and drinking water.

3. *Chronic risk.* Using conservative exposure assumptions, EPA has concluded that aggregate exposure to zeta-cypermethrin from food and water will utilize 0.6% of the RfD for children, ages 1–6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to zeta-cypermethrin residues.

4. *Short- or intermediate-term risk.* Based on zeta-cypermethrin not being registered for residential non-food sites, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is reasonable certainty that no harm will result.

5. *Special docket.* The complete acute and chronic exposure analyses (including dietary, non-dietary, drinking water, and residential exposure, and analysis of exposure to infants and children) used for risk assessment purposes can be found in the Special Docket for the FQPA under the title ''Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids.'' Further explanation regarding EPA's decision regarding the additional safety factor can also be found in the Special Docket.

G. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry, and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolites found in plants and livestock also are formed in the rat. It was concluded that 3-phenoxybenzoic acid (PBA) and its conjugates are not of concern based on toxicology data for PBA. In the absence of toxicology data, the cis- and trans-isomers of DCVA are considered to be of comparable toxicity to the parent. In light of Codex Maximum Residue Limits (MRLs) including only the parent compound, the parent being recoverable by the Food and Drug Administration (FDA) multi-residue Methods I and II, and the DCVA is not likely to be measured by these methods, it was concluded that tolerances should be set in terms of cypermethrin only. Crop field trials should continue to include analyses for residues of cis- and trans-DCVA.

B. Analytical Enforcement Methodology

Adequate enforcement methodology Gas Chromatography/Electron Capture Detector (GC/ECD) is available in Pesticide Analytical Method II (PAM II) as Method I to enforce the tolerance expression.

C. Magnitude of Residues

Residue data from field trials and the FDA monitoring program (1992–1995) and the PDP monitoring program (1994) were used to estimate chronic dietary exposure. For the chronic analyses, mean residues from FDA monitoring were used for lettuce and onions (dry bulb). Residue field trial data were used for broccoli, cabbage, cotton, green onions, mustard greens, and pecans.

For acute dietary exposure analysis, field trial residue data, along with percent of crop treated data, were used in the Monte Carlo analysis.

D. International Residue Limits

Codex MRLs for cypermethrin have been established which are in harmony with the U.S. tolerances for meat and mbyp of cattle, goats, hogs, horses, and sheep (0.05 ppm); milk (0.05 ppm); and onions, bulb (0.10 ppm).

Codex MRLs have been established which exceed the U.S. tolerances for meat (fat basis) of cattle, goats, hogs, horses, and sheep (0.2 vs. 0.05 ppm).

Codex MRLs have been established which are below their U.S. counterparts for cabbage (brassica vegetables) (1.0 vs. 2.0 ppm) and lettuce, head (2.0 vs. 10.0 ppm).

No Canadian MRLs have been established for residues of cypermethrin.

Mexico has established a tolerance for residues of cypermethrin on cottonseed (0.5 ppm) which is in harmony with the U.S. tolerance.

As indicated in this unit, there are differences between the FFDCA section 408 tolerances and the Codex MRL values for specific commodities. These differences could be caused by differences in methods to establish tolerances, calculations of animal feed dietary exposure, and as a result of different agricultural practices. EPA will specifically address these differences when the pesticides are reregistered and the tolerances made permanent.

IV. Conclusion

Therefore, the tolerances are established for residues of zeta-cypermethrin (*s*-cyano(3-phenoxyphenyl) methyl (±) cis, trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on cabbage at 2.0 ppm; cottonseed at 0.5 ppm; lettuce, head at 10.0 ppm; onions, bulb at 0.10 ppm; pecans at 0.05 ppm; and fat, meat, and mbyp of cattle, goats, hogs, horses, and sheep at 0.05 ppm.

V. Objections and Hearing Requests

The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) of the FFDCA as was provided in the old section 408 and in section 409 of the FFDCA. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations

which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 26, 1998 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP Docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number OPP–300577 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number, OPP–300577. No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA)(Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR7 629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.418 is amended by adding a new paragraph (a)(2) to read as follows:

§ 180.418 Cypermethrin and an isomer zeta-cypermethrin; tolerances for residues.

(a) * * *

(2) Tolerances are established for residues of the insecticide zeta-cypermethrin (*s*-cyano(3-phenoxyphenyl) methyl (±) cis, trans 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the following commodities:

Commodity	Parts per million
Cabbage	2.0
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Cottonseed	0.5
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Horses, fat	0.05
Horses, mbyp	0.05
Horses, meat	0.05
Lettuce, head	10.0
Milk	0.05
Onions, bulb	0.10
Pecans	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05

* * * * *

[FR Doc. 97–30938 Filed 11–25–97; 8:45 am]

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Federal Register

Wednesday
November 26, 1997

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Parts 27 and 29

Normal and Transport Category Rotorcraft Regulations; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 27 and 29

[Docket No. 29008; Amendment No. 27–34, 29–41]

Normal and Transport Category Rotorcraft Regulations

AGENCY: Federal Aviation Administration, DOT.

ACTION: Technical amendments; confirmation of effective date.

SUMMARY: This document confirms the effective date for the technical amendments to the airworthiness standards for normal and transport category rotorcraft under CFR parts 27 and 29.

EFFECTIVE DATE: The rule is effective on November 28, 1997.

FOR FURTHER INFORMATION CONTACT: Mary June Bruner, FAA, Forth Worth, Texas 76193–0111, telephone (817) 222–5118.

SUPPLEMENTARY INFORMATION: The FAA published the technical amendments; request for comments in the **Federal Register** on August 29, 1997 (62 FR 46172). The FAA uses the direct final rulemaking procedure for a noncontroversial rule where the FAA believes that there will be no adverse public comment. The technical amendments document advised the public that no adverse comments were anticipated, and that unless a written adverse comment or a written notice of intent to submit such an adverse comment were received within the comment period, the technical amendments would become effective on November 28, 1997. No adverse comments were received, and thus this notice confirms that the technical amendments will become effective on that date.

Issued in Washington, DC on November 21, 1997.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 97–31105 Filed 11–25–97; 8:45 am]

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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Visa waiver pilot program—
Probationary entry status eliminated, designation of Ireland as permanent participating country, and extention of program to Slovenia; comments due by 12-1-97; published 9-30-97

TRANSPORTATION DEPARTMENT
Coast Guard
Vessel identification system; comments due by 12-4-97; published 10-20-97

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Air traffic operating and flight rules:
Aircraft operator security; comments due by 12-1-97; published 8-1-97
Airport security; comments due by 12-1-97; published 8-1-97
Class B airspace; comments due by 12-1-97; published 10-30-97
Class E airspace; comments due by 12-1-97; published 10-17-97

TRANSPORTATION DEPARTMENT
Federal Transit Administration
Prohibited drug use and alcohol misuse prevention in transit operations:
Post-accident drug and alcohol test results taken by State and local law enforcement personnel; use by employers; comments due by 12-1-97; published 9-30-97

TREASURY DEPARTMENT
Thrift Supervision Office
Federal regulatory review:
Electronic operations; banking services delivered electronically; comments due by 12-2-97; published 10-3-97

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at http://www.nara.gov/nara/fedreg/fedreg.html.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–2470). The text will also be made available on the Internet from GPO Access at http://www.access.gpo.gov/su_docs/. Some laws may not yet be available.

H.R. 1090/P.L. 105–111

To amend title 38, United States Code, to allow revision of veterans benefits decisions based on clear and unmistakable error. (Nov. 21, 1997; 111 Stat. 2271)

H.R. 1840/P.L. 105–112

Law Enforcement Technology Advertisement Clarification Act of 1997 (Nov. 21, 1997; 111 Stat. 2273)

H.R. 2366/P.L. 105–113

Census of Agriculture Act of 1997 (Nov. 21, 1997; 111 Stat. 2274)

S. 714/P.L. 105–114

Veterans' Benefits Act of 1997 (Nov. 21, 1997; 111 Stat. 2277)

S. 830/P.L. 105–115

Food and Drug Administration Modernization Act of 1997 (Nov. 21, 1997; 111 Stat. 2296)

S. 923/P.L. 105–116

To amend title 38, United States Code, to prohibit interment or memorialization in certain cemeteries of persons committing Federal or State capital crimes. (Nov. 21, 1997; 111 Stat. 2381)

S. 1258/P.L. 105–117

To amend the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 to prohibit an alien who is not lawfully present in the United States from receiving assistance under that Act. (Nov. 21, 1997; 111 Stat. 2384)

Last List November 25, 1997