government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

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

Dated: November 19, 2007,

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

■ 2. Section 174.528 is revised to read as follows:

§ 174.528 Bacillus thuringiensis Vip3Aa20 protein in corn; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa20 protein in corn are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities; corn, field; corn, sweet; and corn, pop. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when treated in accordance with the provisions of the experimental use permit 67979–EUP–6, which is being amended and extended in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked October 31, 2009; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the temporary tolerance exemption is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[FR Doc. E7–23308 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0195; FRL–8342–2]

Ethalfluralin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethalfluralin in or on dill, dried leaves; dill, fresh leaves; mustard, seed; potato; and rapeseed, seed. It also removes the current tolerance for residues of ethalfluralin on canola seed since residues on canola are covered by the rapeseed tolerance, thus making the canola tolerance unnecessary. Interregional Research Project Number 4 (IR–4) requested the new tolerances and removal of the canola tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2007. Objections and requests for hearings must be received on or before February 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0195. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers;

greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0195 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 4, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2005–0195, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of August 31, 2005 (70 FR 51797) (FRL–7730–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 1E6326, PP 2E6360 and PP2E6466) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petitions requested that 40 CFR 180.416 be amended by establishing tolerances for residues of the herbicide ethalfluralin, [N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine], in or on dill (PP 1E6326); rapeseed, canola, crambe and mustard seed (PP2E6466); and potato (PP 2E6360) at 0.05 parts per million (ppm). That notice included a summary of the petitions prepared by Dow AgroSciences LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA has modified the tolerances proposed in PP 1E6326 (rapeseed, canola, crambe and mustard). The reason for these changes is explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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 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 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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of 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 and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of ethalfluralin on dill, dried leaves; dill, fresh leaves; mustard, seed; potato; and rapeseed, seed at 0.05 ppm. EPA's assessment of 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. Specific information on the studies received and the nature of the adverse effects caused by ethalfluralin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Ethalfluralin: Human Health Risk Assessment for (IR–4) Proposed Uses on Dill and Potato*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as document number EPA–HQ–OPP–2005–0195–0001 in that docket.

The toxicity database for ethalfluralin is complete and indicates it has low acute toxicity by oral, dermal, and inhalation routes of exposure. It is moderately irritating to the eye and produces moderate to severe skin irritation. In one study ethalfluralin was negative for dermal sensitization, but in another, it was considered positive.

In general, subchronic and chronic feeding studies in rats, mice, and dogs

indicate the liver as the target organ, with consistent effects of enzymatic changes, liver weight increases, and histopathology (chronic mouse). A combined chronic/carcinogenicity study in rats showed no non-neoplastic effects at the highest dose tested (32 milligrams/kilogram/day ((mg/kg/day). However, mammary gland fibroadenomas were increased in a dose-related manner. The mouse carcinogenicity study showed no increase in tumor incidence. Ethalfluralin was classified as a possible human carcinogen in 1994 and, pursuant to that classification, cancer risk is assessed using quantitative linear low-dose extrapolation.

Ethalfluralin does not produce developmental toxicity in rats at doses up to 1,000 mg/kg/day. There are several rabbit developmental toxicity studies available; together, these studies indicate the potential for ethalfluralin to induce skeletal malformations at doses of >150 mg/kg/day. Maternal toxicity was observed at similar doses. Ethalfluralin did not produce reproductive or offspring effects in the 3-generation reproduction studies; the parental effects consisted of decreased body weight gains.

There is no evidence of neurotoxicity in the submitted toxicity studies for ethalfluralin.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for ethalfluralin used for human risk assessment can be found at *http://www.regulations.gov* in document *Ethalfluralin: Human Health Risk Assessment for (IR–4) Proposed Uses on Dill and Potato* at pages 13–17 in docket ID number EPA–HQ–OPP–2005–0195.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to ethalfluralin, EPA considered exposure under the petitioned-for tolerances as well as all existing ethalfluralin tolerances in (40 CFR 180.416). EPA assessed dietary exposures from ethalfluralin in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and 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. No such effect was identified for the general population, including infants and children, in the toxicological studies for ethalfluralin. However, EPA identified potential acute effects (increased number of resorptions and increased sternal and cranial variations seen in the rabbit developmental toxicity study) for the population subgroup females, 13 to 49 years old. In estimating acute dietary exposure of females, 13 to 49 years old, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied on anticipated residues derived from field trial data for certain commodities (dry bean, peanuts, dry peas, soybeans and sunflower seed) and assumed tolerance level residues for the remaining commodities, including dill and potato. EPA assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 1994–1996 and 1998 CSFII. As to residues in food, EPA relied on the same anticipated residues and tolerances as in the acute exposure assessment and assumed 100 PCT for all commodities.

iii. *Cancer*. EPA has classified ethalfluralin as a possible human carcinogen, based on a dose-related increase in mammary gland fibroadenomas observed in the rat carcinogenicity study. EPA evaluated cancer risk using a quantitative approach based on a cancer potency factor, or Q1*, of 8.9×10^{-2} $(mg/kg/day)^{-1}$. As to residues in food, EPA relied on the same estimates used in the acute and chronic exposure assessments for all commodities except soybean, watermelon and potato. For soybean and watermelon, EPA relied on anticipated residues derived from the USDA Pesticide Data Program monitoring data. The anticipated residue for potatoes was derived from field trial data. EPA assumed 100 PCT for all commodities.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant tosection 408(f)(1) of FFDCA 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. For the present action, EPA will issue such data call-ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

EPA did not use any information on the actual percent of crops treated with ethalfluralin, but rather assumed 100% of each crop would be treated and contain residues of ethalfluralin.

2. *Dietary exposure from drinking water*. Drinking water monitoring data collected by USDA's Pesticide Data Program (PDP) are available for ethalfluralin for the years 2003, 2004 and 2005. During this time period, a total of 1,253 water samples were collected and found to contain no detectable residues of ethalfluralin. The limit of detection (LOD) of the method used to collect the data was 45.4 parts per trillion (ppt). EPA used a value equal to ½ the LOD or 22.7 ppt (0.023 parts per billion (ppb)) to assess cancer risk from residues of ethalfluralin in drinking water.

The PDP drinking water monitoring data were considered to be appropriate to assess cancer risk from the established and new uses of ethalfluralin for the following reasons:

i. Application rates for both existing and new uses are similar; while peak drinking water estimates differ slightly from one crop to another, the Agency's modeled drinking water numbers for the average of yearly means did not differ significantly by crop, supporting the notion that the existing monitoring data can support new uses;

ii. The drinking water monitoring data were collected over multiple years from a variety of states which include potential ethalfluralin use areas;

iii. The lack of findings of detectable residues is supported by modeled drinking water estimates and by the environmental fate properties of ethalfluralin (e.g., 6–hour half-life for aqueous photolysis).

EPA did not use the PDP data to evaluate acute or chronic risk from residues of ethalfluralin in drinking water. PDP drinking water monitoring data are not appropriate for use in acute dietary exposure assessments, because the frequency of sample collection may not accurately capture peak drinking water values. However, for the purpose of chronic and cancer assessments, multiple years of data over multiple seasons and reflecting a variety of sampling regions are considered to provide an additional level of refinement over the use of modeled drinking water estimates. In the case of ethalfluralin, since estimated chronic risks based on more conservative modeled estimates are below the Agency's LOC, the additional refinement provided by the PDP data is not necessary. Therefore, for both the acute and chronic dietary exposure assessments EPA relied on estimates of ethalfluralin residues in drinking water developed through simulation or modeling taking into account data on the environmental fate characteristics of ethalfluralin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of ethalfluralin for acute exposures are estimated to be 11 ppb for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.4 ppb for surface water and 0.02 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 11 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.4 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Ethalfluralin is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ethalfluralin and any other substances and ethalfluralin 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 ethalfluralin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for ethalfluralin includes a rat developmental toxicity study, several rabbit developmental toxicity studies and a 3–generation reproduction toxicity study in rats. There was no quantitative or qualitative evidence of increased prenatal or postnatal sensitivity in the rat developmental toxicity study or 3–generation reproduction toxicity study in rats. The rabbit developmental toxicity studies indicate the potential for ethalfluralin to induce skeletal malformations at doses of ≥ 150 mg/kg/day. These effects were seen in the presence of maternal toxicity.

Although there is evidence of increased qualitative susceptibility in young in the developmental toxicity studies in rabbits, there are no residual uncertainties and the degree of concern is low. The developmental effects seen at the LOAEL of 150 mg/kg/day are slight (mainly sternal variations in one or two fetuses, incomplete cranial development in 2 fetuses and a slight increase in resorptions). There is a clear NOAEL for these effects and the effects occurred in the presence of maternal toxicity. Additionally, the dose used for risk assessment purposes is 75 mg/kg/day, the NOAEL from the developmental studies in rabbits. Use of this NOAEL for risk assessment is protective of any potential developmental effects.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for ethalfluralin is complete.

ii. There is no indication that ethalfluralin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rabbits, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of ethalfluralin. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases.

The dietary food exposure assessments were performed based on 100 PCT and tolerance-level or anticipated residues derived using reliable field trial data. Conservative ground and surface water modeling estimates were used to assess threshold acute and chronic risks. These assessments will not underestimate the exposure and risks posed by ethalfluralin.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to ethalfluralin will occupy less than 1% of the aPAD for females 13 to 49 years old, the population group of concern for acute exposure to ethalfluralin.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to ethalfluralin from food and water will utilize less than 1% of the cPAD for children, 1 to 2 years old, the population group with the greatest estimated exposure. There are no residential uses for ethalfluralin that result in chronic residential exposure to ethalfluralin.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Ethalfluralin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Ethalfluralin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for the cancer risk assessment, EPA has concluded that exposure to ethalfluralin from food and water will result in a lifetime cancer risk of 2×10^{-6} for the U.S. population. This risk estimate is based, in part, on the conservative assumption that 100% of all crops for which ethalfluralin is registered or proposed for registration are treated. Additional refinement using PCT estimates would result in a lower estimate of dietary cancer risk.

EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3.16×10^{-7} and 3.16×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark LOC of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. Since the calculated cancer risk for ethalfluralin falls below this level, estimated cancer risk is considered to be negligible.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to ethalfluralin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Two gas chromatograph (GC) methods, Methods I and II, both with electron capture detection (ECD) are listed in the Pesticide Analytical Manual (PAM, Vol. II, section 180.416). Methods I and II are applicable for the analysis of ethalfluralin residues in/on plant and animal commodities, respectively. The limits of detection (LODs) are 0.01 and <0.01 ppm for methods I and II, respectively.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) established on the commodities associated with these petitions.

V. Conclusion

EPA has determined that the proposed tolerance on crambe is unnecessary, since, pursuant to 40 CFR 180.1(g), the tolerance being established for rapeseed also applies to residues of ethalfluralin on crambe. The rapeseed tolerance also covers residues of ethalfluralin in or on canola seed. Since there is no longer a need for the canola tolerance, EPA is removing this tolerance as requested in IR–4's petition.

Therefore, tolerances are established for residues of ethalfluralin, N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine, in or on dill, dried leaves; dill, fresh leaves; mustard, seed; potato; and rapeseed, seed at 0.05 ppm. The current tolerance of 0.05 ppm on canola is removed.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments,

on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this final rule in the **Federal Register**. This final rule 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 26, 2007.

Donald R. Stubbs,

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. 321(q), 346a and 371.

■ 2. Section 180.416 is amended by removing the current tolerance on ''Canola, seed'' and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§180.416 Ethalfluralin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Dill, dried leaves	0.05
Dill, fresh leaves	0.05
Mustard, seed	0.05
* * *	* *
Potato	0.05
Rapeseed, seed	0.05
* * *	* *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0310; FRL–8339–8]

Spinosad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on spice, subgroup 19B, except black pepper; pineapple; and pineapple, process residue. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2007. Objections and requests for hearings must be received on or before February 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0310. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.