

applies to major sources, as defined in 40 CFR 63.320(g). Dry cleaning facilities which are major sources remain subject to subpart M.

(ii) Puget Sound Clean Air is not delegated the authority of 40 CFR 63.325 to determine equivalency of emissions control technologies. Any source seeking permission to use an alternative means of emission limitation under Puget Sound Clean Air Regulation I, section 3.23 must also receive approval from the Administrator before using such alternative means of emission limitation for the purpose of complying with section 112.

(B) [reserved].

[FR Doc. 01-1343 Filed 3-9-01; 8:45 am]

BILLING CODE 6560-50-U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301104; FRL-6769-8]

RIN 2070-AB78

Butene, Homopolymer; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of butene, homopolymer; when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Miller Chemical and Fertilizer Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of butene, homopolymer.

DATES: This regulation is effective March 12, 2001. Objections and requests for hearings, identified by docket control number OPP-301104 must be received by EPA on or before May 11, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301104 in

the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-6379 and e-mail address: gairola.indira@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at <http://www.access.gpo.gov/nara/cfr/>

cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301104. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of December 20, 2000 (65 FR 79839) (FRL-6760-6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 1E6239) by Miller Chemical and Fertilizer Corporation, P.O. Box 333, Radio Road, Hanover, PA 17331. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001 (c) and (e) be amended by establishing an exemption from the requirement of a tolerance for residues of butene, homopolymer; (CAS Reg. No. 9003-29-6).

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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 an exemption from the requirement of 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..." and specifies factors EPA is to consider in establishing an exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity,

completeness and reliability and the relationship of this information 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. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers that should present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b). The following exclusion criteria for identifying these low risk polymers are described in 40 CFR 723.250(d).

1. The polymer, butene, homopolymer, is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does not contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

Additionally, the polymer, butene, homopolymer, also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

7. The polymer's number average molecular weight (MW) of 1,330 is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, butene, homopolymer meets all the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the above criteria, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to butene, homopolymer.

V. Aggregate Exposures

For the purposes of assessing potential exposure under this

exemption, EPA considered that butene, homopolymer could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of butene, homopolymer is 1330 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since butene, homopolymer conforms to the criteria that identify a low risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

VI. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of a particular chemical's residues and "other substances that have a common mechanism of toxicity." The Agency has not made any conclusions as to whether or not butene, homopolymer shares a common mechanism of toxicity with any other chemicals. However, butene, homopolymer conforms to the criteria that identify a low risk polymer. Due to the expected lack of toxicity based on the above conformance, the Agency has determined that a cumulative risk assessment is not necessary.

VII. Determination of Safety for U.S. Population

Based on the conformance to the criteria used to identify a low risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of butene, homopolymer.

VIII. Determination of Safety for Infants and Children

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 prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin safety will be safe for infants and children. Due to the expected low toxicity of butene, homopolymer, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

IX. Other Considerations

A. Endocrine Disruptors

There is no available evidence that butene, homopolymer is an endocrine disruptor.

B. Existing Exemptions from a Tolerance

Currently there is an existing tolerance exemption under (40 CFR 180.1037) for polybutylene, which is also known as butene, homopolymer.

C. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for butene, homopolymer nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusion

Accordingly, EPA finds that exempting residues of butene, homopolymer from the requirement of a tolerance will be safe.

XI. Objections and Hearing Requests

Under section 408(g) of the FFDCa, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCa by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCa sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control

number OPP-301104 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 on or before May 11, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must

mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301104 to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement 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) (Public Law 104-4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that

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.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small

Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 rule in the **Federal Register**. This 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: February 23, 2001.

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. 321(q), (346a) and 371.

2. In § 180.1001 the tables in paragraphs (c) and (e) are amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredients	Limits	Uses
* * * *	* * *	
Butene, homopolymer minimum number average molecular weight (in amu) 1,330 (CAS Reg. No. 9003-29-6)	* * *	Sticker, surfactant and related adjuvant.
* * * *	* * *	

(e) * * *

Inert ingredients	Limits	Uses
* * * *	* * *	
Butene, homopolymer minimum number average molecular weight (in amu) 1,330 (CAS Reg. No. 9003-29-6)	* * *	Sticker, surfactant and related adjuvant.
* * * *	* * *	

[FR Doc. 01-6086 Filed 3-9-01; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-301088; FRL-6759-4]

RIN 2070-AB78

Chlorothalonil; Pesticide Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS-3701) in or on almonds (nutmeats), almond hulls, asparagus, mangoes, non-bell peppers, and pistachios. In addition, tolerances for the metabolite SDS-3701 are established for milk and meat commodities. ISK Biosciences Corporation and the Interregional Research Project Number 4 (IR-4) 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 March 12, 2001. Objections and requests for hearings, identified by docket control number OPP-301088, must be received by EPA on or before May 11, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301088 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-305-7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

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2. *In person.* The Agency has established an official record for this action under docket control number OPP-301088. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of February 13, 1997 (PP 5F4558) (62 FR 6780) (FRL-5587-3), April 2, 1997 (PP 6F4676) (62 FR 15700) (FRL-5594-9), July 11, 1997 (PP 6F4611) (62 FR 37246) (FRL-5723-1), and September 17, 1997 (PP 2E4042, 2E4018 and 6E4672) (62 FR 48849) (FRL-5735-8), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of pesticide petitions (PP) for tolerances by ISK Biosciences Corporation, 15966 Heisley Road, P.O. Box 8000, Mentor, OH 44061-8000 and Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experimental Station, P.O. box 231, Rutgers University, New Brunswick, NJ 08903. These notices included a summary of the petition prepared by ISK Biosciences Corporation and IR-4, the registrants. The active ingredient has since been transferred to GB Biosciences Corporation, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850-5458. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.275 be amended by establishing tolerances for combined residues of the fungicide chlorothalonil, tetrachloroisophthalonitrile and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS-3701), in or on almonds (nutmeats) at 0.05 part per million (ppm), almond hulls at 1.0 ppm, asparagus at 0.1 ppm, mangoes at 1.0 ppm, non-bell peppers at 5 ppm, and pistachios at 0.2 ppm, and for residues of the metabolite SDS-3701 in or on the following milk and meat commodities: fat of cattle, hogs, goats, horses, and sheep at 0.1 ppm; kidney of cattle, hogs, goats, horses and sheep at 0.5 ppm; meat byproducts (mby) (except kidney) of cattle, goats, hogs, horses and sheep at 0.05 ppm and meat of cattle, goats, hogs, horses, and sheep at 0.03 ppm and milk at 0.1 ppm.

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