

*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 9, 2000) do not apply to this final rule. In addition, this final 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: June 30, 2008.

**Lois Rossi,**

*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 180.412 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.412 Sethoxydim; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Crambe, meal .....	40.0
Crambe, seed .....	35.0
* * *	* *
Cuphea, seed .....	35.0
* * *	* *
Echium, seed .....	35.0
* * *	* *
Gold of pleasure, meal ...	40.0
Gold of pleasure, seed ...	35.0
* * *	* *
Hare's ear mustard, seed	35.0
* * *	* *
Lesquerella, seed .....	35.0
* * *	* *
Lunaria, seed .....	35.0
Meadowfoam, seed .....	35.0
* * *	* *
Milkweed, seed .....	35.0
Mustard, seed .....	35.0
* * *	* *
Oil radish, seed .....	35.0
* * *	* *
Poppy, seed .....	35.0
* * *	* *
Sesame, seed .....	35.0
* * *	* *
Sweet rocket, seed .....	35.0
* * *	* *

\* \* \* \* \*

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**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0096; FRL-8372-6]

**Gamma-cyhalothrin; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of Gamma-cyhalothrin in or on all food commodities (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, pistachio and okra. Pytech Chemicals GmbH and Interregional Research Project No. 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 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-2007-0096. 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:**

BeWanda Alexander, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7460; e-mail address: alexander.bewanda@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-2007-0096 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 September 8, 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-2007-0096, 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 Registers** of February 28, 2007 (72 FR 9000) (FRL-8115-5) and February 6, 2008 (73 FR 6964) (FRL-8350-9), 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 petition (PP 6H7114) by Pytech Chemicals GmbH, 9330 Zionsville Road, Indianapolis, IN

46268 and PP 7E7287 by IR-4, 500 College Road East, Suite 201 W. Princeton, NJ 08540-6635 respectively. The petitions requested that 40 CFR 180.438 be amended by establishing tolerances for residues of the insecticide gamma-cyhalothrin, (S)-alpha-cyano-3-phenoxybenzy-(Z)-(1R, 3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl-2,2-dimethylcyclopropanecarboxylate, in all food commodities (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, at 0.01 parts per million (ppm), pistachio at 0.05 ppm, and okra at 0.20 ppm. These notices referenced a summary of the petitions prepared by Dow Agro Sciences (on behalf of Pytech Chemicals), 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.

The tolerance expression under 40 CFR 180.438(a)(3) currently identifies the tolerance as a "food additive" and also lists specific instructions for use in food handling establishments under paragraphs, 180.438(a)(3)(ii) thru (v). The term "food additive tolerance" is obsolete since EPA no longer regulates pesticide residues under section 409 of the Federal Food Drug and Cosmetic Act. In addition it is no longer necessary to identify specific instructions for use in food handling establishments since these instructions are identified on the pesticide label. Therefore EPA is revising the tolerance expression under 40 CFR 180.438(a)(3) to read, "A tolerance of 0.01 part per million is established for residues of the insecticide lambda-cyhalothrin and an isomer gamma-cyhalothrin as follows:", and is deleting sections 180.438(a)(3)(ii) thru (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. . . .”

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 tolerances for residues of gamma-cyhalothrin on all food commodities (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, at 0.01 ppm, pistachio at 0.05 ppm, and okra at 0.20 ppm. EPA’s assessment of exposures and risks associated with establishing tolerances follows.

Gamma-cyhalothrin is a single, resolved isomer of the pyrethroid insecticide cyhalothrin. As such, it shares physical, chemical and biological properties with both cyhalothrin and lambda-cyhalothrin, which are mixtures of 4 and 2 isomers, respectively. Gamma-cyhalothrin is the most insecticidally active isomer of cyhalothrin/lambda-cyhalothrin, and thus the gamma-cyhalothrin technical product is considered a refined form of cyhalothrin/lambda-cyhalothrin that has been purified by removal of less-active and inactive isomers. Therefore, similar levels of insecticidal efficacy for gamma-cyhalothrin can be obtained with significantly reduced application rates as compared with either cyhalothrin or lambda-cyhalothrin. EPA has previously concluded that residue data supporting registered uses of lambda-cyhalothrin are sufficient to support registration of gamma-cyhalothrin for the same uses, as long as the use rates of gamma-cyhalothrin are no greater than half the corresponding use rates of lambda-cyhalothrin. The proposed application rates of gamma-cyhalothrin for the requested new uses (considered herein) are no greater than half of the corresponding, existing application rates for similar registered uses of lambda-cyhalothrin.

Tolerances are currently established under 40 CFR 180.438 for residues of lambda-cyhalothrin in food-handling establishments. Through the use of bridging data, the toxicology database for gamma-cyhalothrin is complete using developmental, reproduction, chronic (rodent), and oncogenicity

studies conducted with cyhalothrin and lambda-cyhalothrin. The nature of the toxic effects caused by lambda-cyhalothrin as well as gamma-cyhalothrin are discussed in detail in the **Federal Register** of September 27, 2002 (67 FR 60902)(FRL-7200-1). Therefore the toxicology database for gamma-cyhalothrin when bridged with cyhalothrin and lambda-cyhalothrin are complete for purposes of supporting the proposed use in food handling establishments.

In the August 15, 2007 final rule, establishing tolerances for lambda-cyhalothrin on a number of crops including pistachios. EPA included residues at the tolerance level 0.05 ppm in assessing the use of lambda-cyhalothrin in/on pistachios. Since EPA considered the pistachio use in this most recent risk assessment establishing the tolerance on pistachios for gamma-cyhalothrin will not change the estimated aggregate risks resulting from use of lambda-cyhalothrin as discussed in the August 15, 2007 (72 FR 45656) **Federal Register**. Refer to this **Federal Register** document available at <http://www.regulations.gov> for a detailed discussion of the aggregate risk assessments and determination of safety.

A tolerance for residues of lambda-cyhalothrin in okra has not been established; however, there are adequate residue data for lambda-cyhalothrin on fruiting vegetables (crop group 8) to support a tolerance for residues of gamma-cyhalothrin in okra; and EPA included residues on okra at the fruiting vegetable tolerance level (0.20 ppm) in the risk assessments supporting the August 15, 2007 final rule discussed in the previous paragraph. Since EPA considered the okra use in this most recent assessment establishing the tolerance on okra for gamma-cyhalothrin will not change the aggregate risks resulting from use of lambda-cyhalothrin as discussed in the August 15, 2007 (72 FR 45656) **Federal Register**. Refer to this **Federal Register** document available at <http://www.regulations.gov> for a detailed discussion of the aggregate risk assessments and determination of safety.

EPA concludes that the previous risk assessments on lambda-cyhalothrin sufficiently covers the proposed gamma-cyhalothrin uses and no new aggregate risk assessment is needed for gamma-cyhalothrin. Based on the risk assessments discussed in the final rule published in the **Federal Register** August 15, 2007 (72 FR 45656, FRL 8143-1) EPA concludes that there is a reasonable certainty that no harm will

result to the general population and to infants and children from aggregate exposure to gamma-cyhalothrin residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology, gas chromatography/electron capture detector (GC/ECD), (ICI Method 81 (PRAM 81)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no established Mexican, Canadian, or Codex MRLs (maximum residue limits) for gamma-cyhalothrin.

#### V. Conclusion

Therefore, tolerances are established for residues of gamma-cyhalothrin, (S)-alpha-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, in or on all food commodities (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, at 0.01 ppm, pistachio at 0.05 ppm, and okra at 0.20 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final 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(m)(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 9, 2000) do not apply to this final rule. In addition, this final 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: June 30, 2008.

**Lois Rossi,**

*Direction, 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 180.438 is amended by:

■ i. Alphabetically adding okra and pistachios to the table in paragraph (a)(2).

■ ii. Revising paragraph (a)(3).

The amendments read as follows:

**§ 180.438 Lambda-cyhalothrin and an isomer gamma-cyhalothrin; tolerances for residues.**

(a) \* \* \* \* \*

(2) \* \* \*

Commodity	Parts per million
Okra .....	0.20
Pistachio .....	0.05

(3) A tolerance of 0.01 part per million is established for residues of the insecticide lambda-cyhalothrin and an isomer gamma-cyhalothrin in or on all food commodities (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.

\* \* \* \* \*

[FR Doc. E8-15518 Filed 7-8-08; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0571; FRL-8372-2]

**Ammonium Soap Salts of Higher Fatty Acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub>) unsaturated; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the ammonium soap salts of higher fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) in or on all food commodities when applied for the suppression and control of a wide variety of grasses and weeds. Falcon Lab, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by

the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ammonium soap salts of higher fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated).

**DATES:** This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 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-2007-0571. 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