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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2007-1106; FRL-8402-7]

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

SUMMARY: This regulation establishes tolerances for combined residues of chlorothalonil and its 4-hydroxy metabolite in or on lychee and starfruit. The United States Department of Agriculture (USDA) requested that EPA establish these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 4, 2009. Objections and requests for hearings must be received on or before May 4, 2009, 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-2007-1106. All documents in the docket are listed in the docket index available at <http://www.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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 electronically available documents 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 e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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-2007-1106 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 May 4, 2009.

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-2007-1106, 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 Facility'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. Background

In the **Federal Register** of December 3, 2008 (73 FR 73632) (FRL-8390-1), EPA issued a proposed rule pursuant to sections 408(e) of FFDCA, 21 U.S.C. 346a(d)(3). The rule proposed that 40 CFR 180.275 be amended by establishing tolerances for combined residues of chlorothalonil and its 4-hydroxy metabolite in or on lychee at 15 parts per million (ppm) and starfruit at 3.0 ppm. The USDA requested that EPA establish these tolerances. Because USDA did not submit a petition in support of establishing these tolerances, EPA did not publish a Notice of Filing of a petition for these tolerances. Rather, EPA issued a proposed rule that included a summary of the exposure assessment prepared by the Agency and explained the basis for EPA's conclusion that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to chlorothalonil. The proposal established a 60-day public comment period. Comments were received in response to the proposed rule. EPA's response to these comments is discussed in Unit III.

III. Response to Comments

Comments were received in response to the proposed rule from two United States citizens. The comments and EPA's response are presented below:

An anonymous citizen objected to the presence of any pesticide residues on crops and stated that EPA should set no pesticide tolerance greater than zero. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of FFDCA contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

A second citizen indicated her support for the tolerances on lychee and starfruit based on EPA's determination that the proposed tolerance levels are safe, but, at the same time, expressed hope that all pesticide residues will eventually be removed from food. The commenter also expressed "great" concern about the carcinogenicity of chlorothalonil, notwithstanding EPA's determination that the cancer risk is below the level of concern; and voiced concerns that EPA's risk assessment for chlorothalonil did not adequately address the risks of cancer from "aggregate" residues of multiple pesticides on food.

The Agency understands the commenter's concerns about establishing food tolerances for pesticides that have the potential to cause cancer. Prior to establishing such tolerances, EPA conducts an aggregate exposure assessment to evaluate cancer risk to ensure that the tolerance meets the safety standard of a "reasonable certainty of no harm" established by FFDCA. The cancer effect observed in chlorothalonil animal studies is believed to be a threshold effect resulting from a non-linear mode of action. In the case of a threshold effect for a pesticide, EPA considers that a tolerance will provide a "reasonable certainty of no harm" if the aggregate exposure to the pesticide residue is lower by an ample margin of safety than the level at which the pesticide will not cause or contribute to any known or anticipated harm to human health. Aggregate exposures that are at least 100-fold lower than the no observable

adverse effect level (NOAEL) are considered to provide an ample margin of safety when data are extrapolated from animals. The aggregate exposure assessment conducted to evaluate cancer risk for chlorothalonil indicates that aggregate exposures are more than 100-fold lower than the NOAEL for chlorothalonil; therefore, EPA has concluded that the proposed tolerances are acceptable.

EPA disagrees with the comment that the chlorothalonil risk assessment did not adequately address cancer risk from residues of multiple pesticides on food. The Agency is required by section 408 of FFDCA to consider available information concerning the cumulative toxicological effects of the residues of a pesticide and of other substances having a common mechanism of toxicity with it. This requirement applies to all types of toxicological effects, including cancer. At this time, EPA has not identified any other substances having a common mechanism of carcinogenicity with chlorothalonil. Therefore, EPA did evaluate potential cancer risk from exposure to chlorothalonil and other pesticides.

IV. Conclusion

Based on the information, analysis, and conclusions in the December 3, 2008 proposal (73 FR 73632) (FRL-8390-1), tolerances are established for residues of chlorothalonil, tetrachloroisophthalonitrile, and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile, in or on lychee at 15 ppm and starfruit at 3.0 ppm.

V. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA on EPA's own initiative. 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 due to its lack of significance, 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). 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). Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food, and thus such an action will not have any negative economic impact on any entities, including small entities.

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 section 408(n)(4) of FFDCA. 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* (59 FR 22951, 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.

VI. 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: February 12, 2009.

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 180.275 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.275 Chlorothalonil; tolerances for residues.

- (a) * * *
- (1) * * *

Commodity	Parts per million
* * * *	*
Lychee	15
* * * *	*
Starfruit	3.0
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0066; FRL-8401-1]

Fluazifop-P-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazifop-P-butyl in or on beans, dry, seed; peanut; peanut, meal and soybean, seed. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 4, 2009. Objections and requests for hearings must be received on or before May 4, 2009, 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-2008-0066. All documents in the docket are listed in the docket index available at <http://www.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: Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(703) 305-6224; e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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