ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0645; FRL–9998–67]

Florpyrauxifen-benzyl; 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 florpyrauxifen-benzyl on all food and feed commodities when applied or used as an herbicide under good agricultural practices. This regulation eliminates the need to establish a maximum permissible level for residues of florpyrauxifen-benzyl.

DATES: This regulation is effective September 26, 2019. Objections and requests for hearings must be received on or before November 25, 2019, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2018–0645, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2018–0645 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before November 25, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2018–0645, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance Action

In the **Federal Register** of December 21, 2018 (83 FR 65660) (FRL–9985–67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F8675) by Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of florpyrauxifen-benzyl. That document referenced a summary of the petition prepared by the petitioner, Dow AgroSciences, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of 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 exemption is ''safe.'' Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which requires EPA to give special consideration to exposure of infants and children to the pesticide

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

A. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), 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. The nature of the toxic effects caused by florpyrauxifen-benzyl are discussed in this unit.

Florpyrauxifen-benzyl is not genotoxic and there were no treatment related findings up to the limit dose (1,000 milligrams/kilogram (mg/kg)/day) or highest doses tested in the acute, short-term, sub-chronic, or chronic oral toxicity studies, 2-generation reproduction or developmental toxicity studies or in the neurotoxicity study.

Chronic administration of florpyrauxifen-benzyl did not show any carcinogenicity potential and did not cause any adverse effects in mice, rats or dogs even up to the highest doses tested. Given the absence of adverse effects or toxicity in the database, the Agency did not establish any toxicity endpoints or points of departure for conducting a quantitative risk assessment. In a qualitative assessment of risk, the Agency does not use uncertainty factors, which means that the safety factor required section 408(b)(2)(C) of FFDCA in the case of threshold effects for the protection of infants and children is not applicable. The Agency has determined that there are no residual uncertainties in the toxicity or exposure databases, and there is no evidence of increased susceptibility of infants or children from exposure to florpyrauxifen-benzyl. Based on its review of the available data, the Agency concludes that a qualitative assessment without uncertainty or safety factors would be safe for infants and children.

Specific information on the studies received and the nature of the adverse effects caused by florpyrauxifen-benzyl 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 titled ''Florpyrauxifen-benzyl: New Active Ingredient, First Food Use. Human Health Risk Assessment for the Establishment of Permanent Tolerances on Rice, Fish, and Shellfish and Registration for Uses on Rice and Freshwater Aquatic Weed Control'' in docket ID number EPA–HQ–OPP–2018–0645.

B. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is potential for exposure to florpyrauxifen-benzyl via food and drinking water based on the proposed and approved uses. In addition, there is a potential for non-occupational, non-dietary exposure to swimmers in waters treated with florpyrauxifen-benzyl. But because no adverse effects were observed in the submitted toxicological studies for florpyrauxifen-benzyl regardless of the route of exposure, a qualitative assessment of risk is appropriate for this compound.

C. 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.''

EPA has not found florpyrauxifen-benzyl to share a common mechanism of toxicity with any other substances, and florpyrauxifen-benzyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that florpyrauxifen-benzyl does not have 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Determination of Safety for U.S. Population, Infants and Children

Based on the information in this preamble and the supporting documentation, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to florpyrauxifen-benzyl residues. Accordingly, EPA finds that exempting florpyrauxifen-benzyl residues from the requirement of a tolerance when applied or used as an herbicide in accordance with good agricultural practices will be safe.

IV. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation because of the lack of toxicity concern about the presence of residues.

V. Conclusion

Therefore, an exemption is established for residues of florpyrauxifen-benzyl, including its metabolites and degradates, in or on all food commodities, when it is applied as an herbicide according to good agricultural practices. In addition, although not requested in the petition, EPA is removing from the Title 40 of the Code of Federal Regulations section 180.695 and the established tolerances on fish—freshwater finfish; fish—shellfish, crustacean; fish—shellfish, mollusc; and rice, grain. The residues on those commodities are subsumed within the new exemption, so the existing numerical tolerances are redundant and no longer necessary.

VI. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action 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 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.

This action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: August 29, 2019.

Michael Goodis,

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.

§ 180.695 [Removed]

■ 2. Remove § 180.695.

■ 3. Add § 180.1371 to subpart D to read as follows:

§ 180.1371 Florpyrauxifen-benzyl; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of florpyrauxifen-benzyl, including its metabolites and degradates, in or on all food and feed commodities, when it is applied as an herbicide in accordance with good agricultural practices.

[FR Doc. 2019–20530 Filed 9–25–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R05–RCRA–2018–0375; FRL–10000–08–Region 5]

Ohio: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final authorization.

SUMMARY: The Environmental Protection Agency (EPA) is granting Ohio final authorization for changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Agency published a proposed rule on June 11, 2019 and provided for public comment. No comments were received on the proposed revisions. No further opportunity for comment will be provided.

DATES: This final authorization is effective September 26, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R05–RCRA–2018–0375. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* 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 electronically through *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Jean Gromnicki, Ohio Regulatory Specialist, US EPA Region 5, LL–17J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312)–886–6162, email *Gromnicki.jean@epa.gov*.

SUPPLEMENTARY INFORMATION:

A. What changes to Ohio's hazardous waste program is EPA authorizing with this action?

On February 19, 2019, Ohio submitted a complete program revision application seeking authorization of changes to its hazardous waste program in accordance with 40 CFR 271.21. EPA now makes a final decision that Ohio's hazardous waste program revisions that are being authorized are equivalent to, consistent with, and no less stringent than the Federal program, and therefore satisfy all of the requirements necessary to qualify for final authorization. For a list of State rules being authorized with this final authorization, please see the proposed rule published in the June 11, 2019 **Federal Register** at 84 FR 27057.

B. What is codification and is EPA codifying the Ohio's hazardous waste program as authorized in this action?

Codification is the process of placing citations and references to the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. EPA does this by adding those citations and references to the authorized State rules in 40 CFR part 272. EPA is not codifying the authorization of Ohio's revisions at this time. However, EPA reserves the ability to amend 40 CFR part 272, subpart KK, for the authorization of Ohio's program changes at a later date.