BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA-HQ-OPP-2015-0683; FRL-9965-54]

[RIN 2070-AK41]

Pesticides; Technical Amendment to Data Requirements for Antimicrobial Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a correction pertaining to the "200 ppb (parts per billion) level" described in the antimicrobial pesticides data requirements regulation to clarify that the 200 ppb level is based on total estimated daily dietary intake for an individual and not on the amount of residue present on a single food, as is incorrectly implied by the current regulatory text. This change is intended to enhance understanding of the data required to support an antimicrobial pesticide registration and does not alter the burden or costs associated with these previously-promulgated requirements. Through this action, EPA is not proposing any new data requirements or any other revisions (substantive or otherwise) to existing requirements.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0683, 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 Confidential Business Information (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*.

FOR FURTHER INFORMATION CONTACT: Cameo Smoot, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; (703) 305-5454; email address: *smoot.cameo@epa.gov*.

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you are a producer or registrant of an antimicrobial pesticide product or device. 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, but are not limited to:

• NAICS code 325320, Pesticide and Other Agricultural Chemical Manufacturing, e.g., pesticide manufacturers or formulators of pesticide products, importers, exporters, or any person or company who seeks to register a pesticide product or to obtain a tolerance for a pesticide product.

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. What is the Agency's authority for taking this action?

This action is issued under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d).

C. What action is the Agency taking?

EPA is proposing a single correction to the data requirements for antimicrobial pesticide products that are codified in 40 CFR part 158, Subpart W. EPA is not proposing any other changes (substantive or otherwise) or any new data requirements. The correction to the "200 ppb level" described in 40 CFR §158.2230(d) will clarify that the 200 ppb level is based on total estimated daily dietary intake for an individual and not on the amount of residue present on a single food, as is incorrectly implied by the current regulatory text.

D. What are the incremental costs and benefits of this action?

No new data requirements are proposed and this correction does not result in any new burden or costs being imposed. The proposed change represents a technical correction; therefore, registrants will not submit more studies than they are currently submitting in their application packages. As a result, this change will not cause any increase in the cost to register an antimicrobial pesticide product.

EPA believes the correction should provide registrants with more specific information such that it could reduce the number of consultations (emails, phone calls, and meetings) registrants seek to ensure that they are correctly interpreting the regulations before they begin their testing programs. Applicants may save time and money by better understanding when studies are needed and by not submitting unneeded studies. Submission of all required studies at

the time of application may reduce potential delays in the registration process, thereby allowing products to enter the market earlier. The clarity derived from having more understandable data requirements may be especially important to small firms and new firms entering the industry who may have less experience with the pesticide registration program than those firms that routinely work with the Agency.

Although we believe that the correction reduces uncertainty and will result in a decrease in the number of inquiries registrants may make to EPA seeking clarification on this particular point, EPA did not attempt to determine whether or not, or the extent to which, the correction might result in any cost savings for the registrants or for EPA. Because EPA is not proposing any new data requirements and also made sure not to increase the frequency at which the existing data are required, EPA determined there is no need to perform an economic analysis for this proposed rulemaking.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

Under FIFRA, every pesticide product must be registered (or specifically exempted from registration under FIFRA section 25(b)) by EPA before the pesticide may be sold or distributed in the United States. To obtain a registration, an applicant or registrant must demonstrate to the Agency's satisfaction that, among other things, the pesticide product, when used in accordance with widespread and commonly recognized practice, will not cause ''unreasonable adverse effects'' to humans or the environment.

Under FIFRA, anyone seeking to register a pesticide product is required to provide information to EPA that demonstrates, among other things, that the product can be used without posing unreasonable adverse effects on the environment. The FFDCA section 408 dietary safety factor is incorporated into FIFRA's definition of "unreasonable adverse effects on the environment." Moreover, EPA has authority under FFDCA to establish a tolerance or an exemption from the need for a tolerance for a pesticide chemical residue in or on food, provided there is a reasonable certainty that no harm will result from aggregate exposures to the residues of the pesticide product, including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA's data requirement regulations in 40 CFR part 158 outline the kinds of data and related information typically needed to register a pesticide product. The data requirements are organized by major pesticide type (e.g., conventional, biochemical, microbial, or antimicrobial), scientific discipline (e.g., toxicology or residue chemistry) and major use sites (e.g., outdoor vs. indoor, terrestrial, aquatic, or greenhouse).

The data requirements in 40 CFR part 158 were first promulgated in 1984 (49 FR 42856, October 24, 1984), and principally focused on the data needed to register agricultural pesticide chemicals. In the **Federal Register** of October 26, 2007, EPA promulgated a final rule to revise

and update the data requirements for conventional pesticides (72 FR 60934) (FRL-8106-5). Also on October 26, 2007, EPA promulgated a rule to specifically describe the data requirements for biochemical and microbial pesticides (72 FR 60988) (FRL-8109-8). In the **Federal Register** of May 8, 2013, the data requirements specific to antimicrobial pesticides were promulgated (78 FR 26936) (FRL-8886-5) and became effective on July 8, 2013.

III. Legal Challenge to the 2013 Rule, Resulting Settlement Agreement, and This Proposal

On July 3, 2013, the American Chemistry Council (ACC) filed a petition for judicial review of the 2013 final rule, entitled "Data Requirements for Antimicrobial Pesticides" (78 FR 26936, May 8, 2013), in the United States Court of Appeals for the District of Columbia Circuit. (American Chemistry Council, Inc. v. Environmental Protection Agency, No.13-1207 (D. C. Cir.)). On July 8, 2013, the final rule became effective.

EPA and ACC subsequently entered into a settlement agreement that addressed ACC's petition for judicial review of the 40 CFR part 158, subpart W data requirements rule. The settlement agreement, which became effective on March 2, 2015, is available at *http://www.regulations.gov* using the docket identifier EPA-HQ-OPP-2008-0110-0139. Under the settlement agreement with ACC, EPA agreed to propose by September 2, 2017, a correction to the current language at 40 CFR 158.2230(d) referring to the 200 ppb level as "the concentration of the antimicrobial residues in or on the food item" in order to make the language consistent with the U.S. Food and Drug Administration's (FDA) policy set forth in "Guidance for Industry, Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations. Final Guidance. April 2002." A copy of the FDA guidance has been placed in the docket for this proposed rulemaking. Accordingly, the proposal clarifies that the 200 ppb level established in the rule is based on total estimated daily dietary intake, and not

on the amount of residue present on a single food item or commodity. As part of its obligations under the settlement agreement, EPA previously addressed this issue in interim guidance issued on April 30, 2015. This guidance is available on EPA's website *at https://www.epa.gov/pesticide-registration/epa-data-requirements-registration-antimicrobial-pesticides-part-158w*.

IV. Request for Comments

The Agency invites the public to provide its views and suggestions for the proposed change in this document, and will formally respond to any comments on this proposed change at the time of issuing a final rule. EPA is particularly interested in comments and any suggestions for better characterizing the benefits of burden reduction or savings resulting from this correction.

V. FIFRA Review Requirements

In accordance with FIFRA sections 21 and 25(a), EPA submitted a draft of this proposed rule to the Secretary of the U. S. Department of Agriculture (USDA), and the Secretary of the Department of Health and Human Services (HHS), with copies to the appropriate Congressional Committees (i.e., the Committee on Agriculture in the U. S. House of Representatives, and the Committee on Agriculture, Nutrition, and Forestry in the United States Senate). On June 1, 2017, USDA completed their review of the draft proposed rule and informed EPA that they did not have any comments. On July 17, 2017, HHS completed their review of the draft proposed rule and provided two comments. First, with regard to the section II. Background summary paragraph about FIFRA and FFDCA authority, HHS submitted suggested text to avoid the suggestion that the FFDCA contains provisions related to the registration of a pesticide product, and also inserted language concerning "aggregate" exposures. EPA has addressed the

comments submitted by HHS in the proposed rule and has provided additional clarifying language. The proposed rule now states that "Under FIFRA, anyone seeking to register a pesticide product is required to provide information to EPA that demonstrates, among other things, that the product can be used without posing unreasonable adverse effects on the environment. The FFDCA section 408 dietary safety factor is incorporated into FIFRA's definition of "unreasonable adverse effects on the environment." Moreover, EPA has authority under FFDCA to establish a tolerance or an exemption from the need for a tolerance for a pesticide chemical residue in or on food, provided there is a reasonable certainty that no harm will result from aggregate exposures to the residues of the pesticide product, including all anticipated dietary exposures and all other exposures for which there is reliable information." In the second HHS comment, HHS suggested that we specifically identify the FDA policy cited in the draft proposed rule. In response, EPA has specifically identified the FDA policy and placed a copy of the FDA's "Guidance for Industry, Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations. Final Guidance. April 2002," in the docket for this action.

Under FIFRA section 25(d), EPA also submitted a draft of this proposed rule to the FIFRA Scientific Advisory Panel (SAP). The SAP waived its review of the proposed rule on June 2, 2017, because the proposed rule does not contain scientific issues that warrant review by the Panel.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: *Regulatory Planning and Review; Executive Order 13563*:

Improving Regulation and Regulatory Review; and Executive Order 13777: Reducing Regulation and Controlling Regulatory Costs

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). In addition, since this action does not contain a new requirement or impose any new burden or costs, the burden reduction and controlling provisions in Executive Order 13771 (82 FR 9339, February 3, 2017), do not apply. Although we believe that the correction reduces uncertainty and will result in a decrease in the number of inquiries registrants may make to EPA seeking clarification on this particular point, EPA did not attempt to determine whether or not, or the extent to which, the correction might result in any cost savings for the registrants or for EPA.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection requirements that would require additional review or approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection requirements associated with the submission of data under 40 CFR part 158 have already been approved by OMB pursuant to the PRA and are covered by the following existing Information Collection Requests (ICRs):

• The information collection activities associated with the establishment of a tolerance are currently approved under OMB Control No. 2070-0024 (EPA ICR No. 0597).

• The information collection activities associated with the application for a new or amended registration of a pesticide are currently approved under OMB Control No. 2070-0060 (EPA ICR No. 0277).

• The information collection activities associated with the generation of data for

registration review are currently approved under OMB Control No. 2070-0174 (EPA ICR No. 2288).

• The information collection activities associated with the generation of data for experimental use permits are currently approved under OMB Control No. 2070-0040 (EPA ICR No. 0276).

This proposed rule does not involve a change in information collection activities associated with the generation of data for antimicrobial pesticide products or devices. EPA believes no additional burden for data submission would be imposed by the simple correction in this proposed rule. The most that may be needed is for an applicant to become familiar with the change. Although we believe that the correction reduces uncertainty and will result in a decrease in the number of inquiries registrants may make to EPA seeking clarification on this particular point, EPA did not attempt to determine whether or not, or the extent to which, the correction might result in any cost savings for the registrants or for EPA. EPA is seeking comment on this point in particular.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq*. The small entities directly regulated by this proposed rule are small manufacturers of antimicrobial pesticide products.

After considering the economic impacts of this proposed rule on small entities, EPA certifies that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and

address regulatory alternatives "which minimize any significant economic impact of the rule on small entities." 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

There will not be significant adverse economic impacts on a substantial number of small entities by the simple correction proposed. On the contrary, all registrants of pesticide products, regardless of size, will benefit equally by receiving the clearer editorial and/or technical direction, likely reduce the number of requests for further clarification of data requirements, and likely enjoy a more streamlined registration process.

We continue to be interested in the potential impacts of the correction in this proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded federal mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. Accordingly, this action is not subject to the requirements of UMRA, 2 U.S.C. 1501 *et seq.*

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not 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. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175: *Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have any effect on tribal governments, 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. Thus, Executive Order 13175 does not apply to this action.

EPA specifically solicits additional comment on this proposed action from tribal officials.

G. Executive Order 13045: *Protection of Children from Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866, nor does it affect energy supply, distribution or use.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards that would require the consideration of voluntary consensus standards pursuant to NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not involve special consideration of environmental justice related issues as specified in Executive Order 12898 (59 FR 7629, February 16, 1994), because this action does not address human health or environmental risks or otherwise have any disproportionate high and adverse human health or environmental effects on minority, low-income or indigenous populations.

List of Subjects in 40 CFR Part 158

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

Dated: August 4, 2017.

Louise P. Wise,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, the EPA proposes to amend 40 CFR part 158 as follows:

PART 158--[AMENDED]

1. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136-136y; subpart U is also issued under 31 U.S.C. 9701.

2. In §158.2230, revise paragraph (d) to read as follows:

§158.2230 Antimicrobial toxicology.

*** * * * ***

(d) *200 parts per billion (ppb).* The 200 ppb level was originally used by the Food and Drug Administration with respect to the concentration of residues in or on food for tiering of data requirements for indirect food use biocides. The Agency has also adopted this same residue level for determining toxicology data requirements for indirect food uses of antimicrobial pesticides. The 200 ppb level is the concentration of antimicrobial residues in the total estimated daily dietary intake.

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