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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA-HQ-OPP-2018-0668; FRL-9984-52]

RIN 2070-AK41

Pesticides; Technical Amendment to Data Requirements for Antimicrobial Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing 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 was incorrectly implied by the previous 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. This action does not otherwise establish any new data requirements or any other revisions (substantive or otherwise) to existing requirements.

DATES: This final rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0668 is available online at *http://www.regulations.gov* or in person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the EPA 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: 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*.

SUPPLEMENTARY INFORMATION:

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:

• 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 Action is the Agency Taking?

EPA is finalizing a single correction to the data requirements for antimicrobial pesticide products that are codified in 40 CFR part 158, subpart W. EPA is not making any other changes (substantive or otherwise) or establishing any new data requirements. The correction to the "200 ppb level" that is 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.

This change will also harmonize the EPA standard with the U.S. Food and Drug Administration levels established for indirect food use biocides set forth in "Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations," Revised April 2002. For reference, a copy of the FDA guidance has been placed in the docket for this action.

C. 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).

D. Why is the Agency Taking this Action?

EPA has determined that the correction to the "200 ppb level" that is described in 40 CFR 158.2230(d) is necessary 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.

E. What are the Incremental Costs and Benefits of this Action?

This correction does not result in any new burden or costs being imposed. This change represents a technical correction. No new studies are being requested, registrants will not submit

more studies than they are currently submitting in their application packages, and there is no increase in the frequency at which existing data are required. 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) in which 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.

II. Summary of the Proposed Rule

On August 18, 2017 (82 FR 39399) (FRL-9965-54), EPA published and requested public comment on a proposal to correct the language at 40 CFR 158.2230(d) in a proposed rule entitled "Pesticides: Technical Amendment to Data Requirements for Antimicrobial Pesticides." As described in more detail in the proposed rule, the correction is in response to a petition filed by the American Chemistry Council (ACC) in the United States Court of Appeals for the District of Columbia Circuit on July 3, 2013 (American Chemistry Council, Inc. v. Environmental Protection Agency, No.13-1207 (D.C. Cir.)). That petition sought judicial review of the 2013 final rule, entitled "Data Requirements for Antimicrobial Pesticides" (78 FR 26936, May 8, 2013) (FRL-8886-5). EPA and ACC subsequently entered into a settlement agreement that

addressed the ACC petition. The settlement agreement, which became effective on March 2, 2015, is available at *http://www.regulations.gov* (Document ID No. EPA-HQ-OPP-2008-0110-0139). Under the settlement agreement with ACC, EPA agreed to propose a correction to the 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 the FDA document entitled "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 rulemaking.

In the 2017 proposed rule, EPA proposed to clarify that the 200 ppb level established in the 2013 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 issued interim guidance on April 30, 2015, which is available on EPA's website at *https://www.epa.gov/pesticide-registration/epa-data-requirements-registration-antimicrobial-pesticides-part-158w*.

III. Comments and Responses

The Agency appreciates the comments provided by the public, and the Agency's detailed response to the comments received is provided in a document that is posted in the docket for this action. EPA received two public comments. One commenter was supportive of the adoption of the technical correction without requesting any revisions to the text. The other commenter submitted an inquiry as to why 200 ppb instead of 100 ppb was the limit for concentrations of biocides on food.

The 200 ppb level was previously established by FDA for indirect food use biocides (see

Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations, Revised April 2002). The 200 ppb level is derived by dividing FDA's cumulative exposure upper limit of 1,000 ppb level by 5 to be conservative and to account for the fact that antimicrobial pesticides (e.g., biocides) are a class of pesticide that are generally toxic by design. It is important to note that EPA is not using this 200 ppb value as a risk level. It is used in this situation to determine if additional toxicity data are required. No substantive changes were suggested and EPA is finalizing the correction as proposed.

IV. FIFRA Review Requirements

In accordance with FIFRA sections 21 and 25(a), EPA submitted a draft of this final rule to the Secretary of the Department of Health and Human Services (HHS), and the Secretary of the U.S. Department of Agriculture (USDA). Under FIFRA section 25(d), EPA submitted a draft of this final rule to the FIFRA Scientific Advisory Panel (SAP). The SAP waived its review of the final rule on November 14, 2018, because the final rule does not contain scientific issues that warrant review by the Panel. A copy of FIFRA SAP response is available in the docket.

As required by FIFRA section 25(a)(3), copies of the draft final rule were also provided 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).

V. 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; and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735; October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

The burden reduction and controlling provisions in Executive Order 13771 (82 FR 9339, February 3, 2017), do not apply to this action because this action is not a significant regulatory action as defined by Executive Order 12866.

C. Paperwork Reduction Act (PRA).

This action does not impose any new information collection requirements that 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 is 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 approved under OMB Control No. 2070-0060 (EPA ICR No. 0277).

• The information collection activities associated with the generation of data for registration review is 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 approved under OMB Control No. 2070-0040 (EPA ICR No. 0276).

This final 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 final rule.

D. 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 final rule are registrants and manufacturers of antimicrobial pesticide products that qualify as a small business as defined by the Small Business Administration. Small nonprofit organizations and small government jurisdictions as defined by the RFA are not expected to become a registrant or manufacturer of an antimicrobial pesticide product and are not therefore expected to be impacted by this rule.

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 the small entities subject to the rule.

There will not be significant adverse economic impacts on a substantial number of small entities by this simple correction. On the contrary, all registrants and manufacturers of antimicrobial pesticide products, regardless of size, will benefit equally from the correction

related by likely reduction in the number of requests for further clarification of this data requirement, and may also enjoy a more streamlined registration process.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded federal mandate 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*.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 4, 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.

G. 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.

H. 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.

I. 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.

J. 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.

K. 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.

L. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to the U.S. Senate, and the U.S. House of Representatives, and the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 158

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

Dated: April 25, 2019

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR part 158 is amended 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 Toxicology.

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(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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