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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0652 and EPA-HQ-OPP-2020-0047; FRL-10011-10]

S-metolachlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of S-metolachlor in or on multiple commodities which are identified and discussed later in this document. The Interregional Project Number 4 (IR-4) and Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], 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 dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2019-0652 and EPA-HQ-OPP-2020-0047, are 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 note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://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 EPA's tolerance regulations at 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 numbers EPA-HQ-OPP-2019-0652 and EPA-HQ-OPP-2020-0047 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 numbers EPA-HQ-OPP-2019-0652 and EPA-HQ-OPP-2020-0047, 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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets*. 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

In the *Federal Register* of May 8, 2020 (85 FR 27346) (FRL-10008-38), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8800) by IR-4, Rutgers, the State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.368(a)(2) be amended by establishing tolerances for residues of the herbicide S-metolachlor, S-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer, and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, calculated as the stoichiometric equivalent of S-metolachlor, in or on Dillweed at 5 parts per million (ppm); Dillweed, dried leaves at 9 ppm; Dill, seed at 15 ppm; Rosemary, dried leaves at 2 ppm and Rosemary, fresh leaves 1.5 ppm. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

In the *Federal Register* of March 3, 2020 (85 FR 12454) (FRL-10005-58), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8764) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.368(a)(2) be amended by revising the tolerances for residues of the herbicide S-metolachlor, S-2-chloro-N-(2-ethyl-6-

methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer, and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, calculated as the stoichiometric equivalent of S-metolachlor, in or on soybean seed to be 1.0 ppm and grain, aspirated fractions to be 2.0 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing several tolerances at different levels than petitioned-for tolerances and revised the commodity definitions for grain, aspirated fractions and soybean, seed. The reasons for these changes are explained in Unit IV.D.

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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA

section 408(b)(2)(D), 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 S-metolachlor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with S-metolachlor follows.

On March 11, 2019, EPA published in the *Federal Register* a final rule establishing tolerances for residues of S-metolachlor in or on several commodities based on the Agency's conclusion that aggregate exposure to S-metolachlor is safe for the general population, including infants and children. *See* (84 FR 8611) (FRL-9983-79). EPA is incorporating the following portions of that document by reference here, as they have not changed in the Agency's current assessment of S-metolachlor tolerances: the toxicological profile and points of departure, the cancer assessment and conclusion that a nonlinear reference dose (RfD) approach is appropriate for assessing cancer risk, the conclusions about cumulative risk, and the Agency's determination regarding the children's safety factor. Additionally, EPA is incorporating the assumptions for exposure assessment from the March 11, 2019 final rule, which have not changed except as explained in the following paragraph.

EPA's dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from the new uses of S-metolachlor on dill and rosemary and the revised use on soybean. EPA conducted an unrefined chronic dietary (food and drinking water) exposure and risk assessment that incorporates tolerance-level residue values, 100% crop treated, and EPA's 2018 default processing factors.

The estimated drinking water concentrations (EDWCs) of S-metolachlor and its metabolites for chronic exposures have also been updated; the new value used for the chronic

assessment to assess the contribution to drinking water is 830 parts per billion (ppb), which is lower than the previous value of 978 ppb.

An acute dietary endpoint (i.e., single dose endpoint) for risk assessment was not identified in the toxicity database for the general U.S. population or any other subpopulation for S-metolachlor; therefore, an acute dietary exposure assessment was not conducted. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD); they are estimated to be 19% of the cPAD for all infants less than 1 year old, the group with the highest exposure.

There are no proposed new residential uses for S-metolachlor, although commercial use in residential areas may result in the following short-term residential exposures that were used in the Agency's aggregate risk assessment: post-application dermal exposures to youth (11 to less than 16 years old) from treated turf, to children (6 to less than 11 years old) from treated gardens, and to children (1 to less than 2 years old) from treated turf and post-application incidental oral exposure to children (1 to less than 2 years old) from treated turf.

For aggregate risk assessment, exposures to S-metolachlor in food and drinking water are combined with residential exposures for the relevant exposure duration period. Because acute, intermediate-term, or long-term residential exposures are not expected, aggregate acute and chronic risk is equivalent to the dietary risks, which are below EPA's level of concern. Moreover, based on the chronic exposure assessment, which accounts for potential carcinogenicity, EPA does not expect S-metolachlor to pose a cancer risk. Short-term aggregate risk, which combines chronic (background) exposures with the expected short-term post-application exposures mentioned above, yields margins of exposure (MOEs) ranging from 110 to 1370, which are not of concern because they exceed EPA's level of concern (MOEs less than or

equal to 100).

Therefore, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to S-metolachlor residues. More detailed information can be found in the document entitled, "S-Metolachlor: Human Health Risk Assessment for Petition for the Establishment of Tolerances and Registration for Use in/on Rosemary and Dill (PP#9E8800) and Amended Use in/on Soybean (PP# 9F8764)," in docket IDs EPA-HQ-OPP-2019-0652 and EPA-HQ-2020-0047.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available in the Pesticide Analytical Manual (PAM) Vol. II for enforcement of S-metolachlor crop and livestock tolerances. Pesticide regulation section 180.368, lists a gas chromatography with nitrogen-phosphorus detector (GC/NPD) method (Method I) for determining residues in/on crop commodities and a gas chromatography with mass selective detector (GC/MSD) method (Method II) for determining residues in livestock commodities. These methods determine residues of metolachlor and its metabolites as either CGA-37913 or CGA-49751 following acid hydrolysis.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

No maximum residue limits (MRLs) for S-metolachlor have been established or proposed by Codex.

C. Response to Comments

There was one comment received on the notice of filing. The comment stated that IR-4 is trying to get this chemical through during a pandemic and without public notice. The commenter also stated that this chemical should not be used on any food products that American's eat. In response, EPA notes the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This comment appears to be directed at the underlying statute and not EPA's implementation of it; the comment provides no information relevant the Agency's safety determination.

D. Revisions to Petitioned-For Tolerances

The Agency is establishing the tolerances for grain, aspirated fractions and soybean, seed at different levels than the petitioner requested. For grain, aspirated fractions, EPA calculated the tolerance level using the highest average field trial (HAFT) residues in combination with the median processing factor from the submitted soybean data. This results in a tolerance of 4 ppm

rather than the proposed tolerance of 2.0 ppm. EPA calculated the tolerance level for soybean, seed using the HAFT residue values from the submitted soybean data in the Organization for Economic Cooperation and Development (OECD) MRL calculator. This results in a tolerance of 0.9 ppm rather than the proposed tolerance of 1.0 ppm. In addition, the commodity definitions were revised for grain, aspirated fractions and soybean, seed. Finally, a tolerance for residues in/on soybean, meal at 1.5 ppm has been added by the Agency based on the submitted soybean data, because the HAFT residues in combination with the median processing factor from the submitted data result in a value higher than the tolerance level for soybean, seed.

V. Conclusion

Therefore, tolerances are established for residues of S-metolachlor, S-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer, and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, calculated as the stoichiometric equivalent of S-metolachlor in or on dill, seed at 15 ppm; dillweed at 5 ppm; dillweed, dried leaves at 9 ppm; rosemary, dried leaves at 2 ppm; rosemary, fresh leaves at 1.5 ppm; and soybean, meal at 1.5 ppm. In addition, the Agency is increasing the tolerances for residues of S-metolachlor in or on grain, aspirated fractions to be 4 ppm and soybean, seed to be 0.9 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to petitions 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 tolerances 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: June 19, 2020.

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.

2. In § 180.368, paragraph (a)(2):

i. Add a heading to the table.

ii. Add alphabetically the entries “Dill, seed”; “Dillweed” and “Dillweed, dried leaves”.

iii. Revise the entry for “Grain, aspirated fractions”.

iv. Add alphabetically the entries “Rosemary, dried leaves”; “Rosemary, fresh leaves” and “Soybean, meal”.

v. Revise the entry for “Soybean, seed”.

The additions and revisions read as follows:

§ 180.368 Metolachlor, tolerances for residues.

(a) * * *

(2) * * *

Table 2 to Paragraph (a)(2)

Commodity	Parts per million
* * * * * * *	
Dill, seed	15
Dillweed	5
Dillweed, dried leaves	9
* * * * * * *	
Grain, aspirated fractions	4
* * * * * * *	
Rosemary, dried leaves	2
Rosemary, fresh leaves	1.5
* * * * * * *	
Soybean, meal	1.5
Soybean, seed	0.9
* * * * * * *	

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[FR Doc. 2020-14393 Filed: 7/2/2020 8:45 am; Publication Date: 7/6/2020]