



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0691; FRL-9273-01-OCSP]

MCPA; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation modifies existing tolerances for residues of MCPA in or on clover, forage and clover, hay. The Interregional Research Project Number 4 (IR-4) 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 docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0691, is available at <https://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.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide customer service via email, phone, and webform. For the latest status information on EPA/DC services,

docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, 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 Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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-2020-0691 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 number EPA-HQ-OPP-2020-0691, by one of the following methods:

- *Federal eRulemaking Portal*: <https://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 <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of June 28, 2021 (86 FR 33922) (FRL-10025-08) EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8864) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.339 be

amended by revising tolerances for residues of the herbicide MCPA ((4-chloro-2-methylphenoxy)acetic acid), both free and conjugated, resulting from the direct application of MCPA or its sodium, dimethylamine salts or its 2-ethylhexyl ester in or on the raw agricultural commodities clover, forage at 0.1 parts per million (ppm), and clover, hay at 0.1 ppm. The petitioned-for tolerances are lower than the existing tolerances for these commodities due to the results from clover residue data that were generated by IR-4 which indicated that lower tolerances were appropriate for clover, forage and clover, hay. Previously, no clover-specific data had been generated. That document referenced a summary of the petition, which is available in the docket, <https://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 the tolerances at different levels than petitioned for. Additionally, the tolerance expression is being modified to be consistent with Agency policy. A discussion of these modifications can be found in Unit IV.C.

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 therein, 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 MCPA including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with MCPA follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for MCPA in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to MCPA and established tolerances for residues of that chemical. EPA is incorporating previously published sections from that rulemaking as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of MCPA, see Unit III.A. of the MCPA tolerance rulemaking published in the *Federal Register* of April 13, 2021 (86 FR 19145) (FRL-10020-79).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for MCPA used for human risk assessment, please reference Unit III.B. of the April 13, 2021 rulemaking.

Exposure assessment. The new use on clover does not impact the dietary assessment, because the clover use does not result in a significant increase in dietary exposure. For a description of the approach to and assumptions for the exposure assessment, including with respect to estimated drinking water concentrations, non-occupational exposure, and cumulative exposure, please reference Unit III.C. of the April 13, 2021 rulemaking.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X, except for acute dietary (general population, including infants and children) and inhalation scenarios where a 10X safety factor is retained as a lowest-observed-adverse-effect-level (LOAEL) to no-observed-adverse-effect-level (NOAEL) extrapolation factor. See Unit III.D. of the April 13, 2021 rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 29% of the aPAD for all infants less than 1 year old, the group with the highest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 28% of the cPAD for all infants less than 1 year old, the group with the highest exposure. EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposure at or above the level of concern of 100 for all scenarios assessed and are not of concern. An intermediate-term adverse effect was identified; however, MCPA is not registered for any use patterns that would result in intermediate-term residential exposure. EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for MCPA, which is below the Agency's level of concern. MCPA is classified as "Not Likely to Be Carcinogenic to Humans"; therefore, EPA does not expect MCPA exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, 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 MCPA residues. More detailed information on this action can be found in the document titled “MCPA. Human Health Risk Assessment in Support of a Section 3 Registration for Use of MCPA on Clover” in docket ID EPA-HQ-OPP-2020-0691.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the April 13, 2021 rulemaking.

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).

Currently, there are no Codex MRLs for residues of MCPA in or on clover. Therefore, harmonization is not an issue.

C. Revisions to Petitioned-For Tolerances

All residues at or below the limit of quantitation (LOQ) equate to a recommended LOQ tolerance level of 0.05 ppm for both clover, forage and clover, hay, as opposed to the tolerances that were proposed (0.1 ppm for both clover, forage and clover, hay). The tolerances include residues of parent (MCPA) and metabolite 2-HMCPA [(4-chloro-2-hydroxymethylphenoxy)acetic acid]. However, MCPA is the only residue of concern for tolerance enforcement purposes. In addition, EPA is modifying the tolerance expression to use the Chemical Abstracts Service (CAS) name for consistency with other tolerance expressions.

Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in

FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of MCPA not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compound mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are modified for residues of MCPA in or on Clover, forage from 0.5 ppm to 0.05 ppm, and Clover, hay from 2.0 ppm to 0.05 ppm and the tolerance expression is updated.

VI. Statutory and Executive Order Reviews

This action modifies tolerances 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 to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). 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 (CRA)

Pursuant to the CRA (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: December 9, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.339, to read as follows:

§ 180.339 MCPA; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide MCPA, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a). Compliance with the tolerance levels specified in Table 1 to this paragraph (a) is to be determined by measuring only MCPA, 2-(4-chloro-2-methylphenoxy)acetic acid, in or on the commodity.

Table 1 to Paragraph (a)

Commodity	Parts per million
Alfalfa, forage	0.5
Alfalfa, hay	2.0
Barley, grain	1.0
Barley, hay	40
Barley, straw	25
Cattle, fat	0.1
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Clover, forage	0.05
Clover, hay	0.05
Flax, seed	0.1
Goat, fat	0.1
Goat, meat	0.1
Goat, meat byproducts	0.1
Grain, aspirated fractions	3.0
Grass, forage	300
Grass, hay	20
Hog, fat	0.1
Hog, meat	0.1
Hog, meat byproducts	0.1
Horse, fat	0.1
Horse, meat	0.1
Horse, meat byproducts	0.1
Lespedeza, forage	0.5

Lespedeza, hay	2.0
Milk	0.1
Oat, forage	20
Oat, grain	1.0
Oat, hay	115
Oat, straw	25
Pea, dry	0.1
Pea, field, hay	0.1
Pea, field, vines	0.1
Pea, succulent	0.1
Rye, forage	20
Rye, grain	1.0
Rye, straw	25
Sheep meat	0.1
Sheep meat byproducts	0.1
Sheep, fat	0.1
Tea, dried	0.3
Trefoil, forage	0.5
Trefoil, hay	2.0
Vetch, forage	0.5
Vetch, hay	2.0
Wheat, forage	20
Wheat, grain	1.0
Wheat, hay	115
Wheat, straw	25
Wheatgrass, intermediate, forage	50
Wheatgrass, intermediate, grain	0.2
Wheatgrass, intermediate, hay	50
Wheatgrass, intermediate, straw	50

(b) – (d) [Reserved]

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