VI. Statutory and Executive Order Reviews

This action establishes 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 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: July 2, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 40 CFR chapter I 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. In § 180.350, amend paragraph (a) by adding to the table, in alphabetical order, the commodities, ''Beet, sugar, molasses'', ''Beet, sugar, roots'', ''Beet, sugar, tops'', ''Rapeseed, seed'', and ''Vegetable, tuberous and corm, crop subgroup 1C'' to read as follows:

§ 180.350 Nitrapyrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Beet, sugar, molasses	0.5
Beet, sugar, roots	0.3
Beet, sugar, tops	0.7
* * * * *	
Rapeseed, seed	0.3
* * * * *	
Vegetable, tuberous and corm, crop subgroup 1C	0.6
* * * * *	

* * * * *

[FR Doc. 2020–16456 Filed 8–11–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0510; FRL–10008–94]

Pethoxamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pethoxamid in or on multiple commodities which are identified and discussed later in this document. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 12, 2020. Objections and requests for hearings must be received on or before October 13, 2020 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–2017–0510, 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 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 Printing 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–2017–0510 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 October 13, 2020. 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–2017–0510, 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

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL–9975–57), 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 7F8572) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pethoxamid in or on corn, field, forage at 0.015 parts per million (ppm); corn, field, stover at 0.02 ppm; corn, field, grain at 0.01 ppm; popcorn, stover at 0.01 ppm; popcorn, grain at 0.01 ppm; corn, sweet, forage at 0.50 ppm; corn, sweet, stover at 0.60 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; cotton, undelinted seed at 0.01 ppm; cotton, gin byproducts at 0.09 ppm; soybean, forage at 3.0 ppm; soybean, hay at 4.5 ppm; and soybean, seed at 0.01 ppm.

In the **Federal Register** of October 28, 2019 (84 FR 57685) (FRL–10001–11), 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 7F8572) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pethoxamid in or on cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, field, forage at 0.015 ppm; corn, field, stover at 0.02 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.60 ppm; cotton, gin byproducts at 0.09 ppm; cotton, undelinted seed at 0.01 ppm; egg at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; popcorn, grain at 0.01 ppm; popcorn, stover at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; soybean, forage at 3.0 ppm; soybean, hay at 4.5 ppm; and soybean, seed at 0.01 ppm. The October 28, 2019 Notice of Filing (NOF) supersedes the April 11, 2018 NOF. The documents referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.*

Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what was requested. The reason for these changes is 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 pethoxamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pethoxamid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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 hazard database for pethoxamid indicates that the primary effects occur in the liver and thyroid, including increased changes in thyroid weight, thyroid hypertrophy, thyroid hyperplasia, thyroid follicular cell adenomas, and benign hepatocellular adenomas in mice. Potential signs of neurotoxicity occurring at very high doses were considered agonal, rather than adverse. Reproductive toxicity was not observed, and developmental/offspring toxicity was limited to decreased fetal body weights and late abortions. Specific information on the studies received and the nature of the adverse effects caused by pethoxamid 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, ''*Pethoxamid: Human Health Risk Assessment for Proposed Section 3 Registration of the New Active Ingredient on Corn, Cotton, and Soybeans and in/on Turf and Ornamental Sites*'' (hereinafter ''Pethoxamid Human Health Risk Assessment'') on pages 43–52 in docket ID number EPA–HQ–OPP–2017–0510.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide.*

A summary of the toxicological endpoints for permethrin used for human risk assessment can be found in the Pethoxamid Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pethoxamid, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from pethoxamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for pethoxamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used 2003–2008 food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the chronic analysis assumed tolerance-level residues, default processing factors and 100 percent crop treated (PCT) estimates.

iii. *Cancer.* Based on the Agency's analysis of the available data, EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pethoxamid. Quantification of cancer risk using a non-linear RfD approach will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to pethoxamid; therefore, a separate cancer dietary assessment was not conducted.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for pethoxamid. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for pethoxamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pethoxamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Using the Pesticides in Water Calculator (PWC) and Pesticide Root Zone Model and the Varying Volume Water Model (PRZM/VVWM) models, EPA calculated the estimated drinking water concentrations (EDWCs) of pethoxamid for chronic exposures in surface and ground water. EPA used the modeled EDWCs directly in the dietary exposure model to account for the contribution of pethoxamid residues in drinking water as follows: 7.45 ppb was used in the chronic assessment.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pethoxamid is proposed to be registered for the following uses that could result in residential exposures: Residential lawns and golf courses. EPA assessed residential exposure using the following assumptions: Because labels will include language stating that these products are to be applied by professional applicators only, residential handler exposures are not expected.

There is the potential for short-term post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with pethoxamid. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios: Incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) following a broadcast turf application. Neither an adult nor child dermal assessment was conducted because a dermal endpoint was not

selected. While not the only life stage potentially exposed for these post-application scenarios, the life stage that is included in the quantitative assessment (child 1 to less than 2 years old) is health protective for the exposures and risk estimates for any other potentially exposed life stage.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pethoxamid and any other substances, and pethoxamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pethoxamid has 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. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Pethoxamid did not cause reproductive toxicity in rats. Developmental/offspring toxicity in rats was limited to decreased body weight and was observed at the same doses that caused maternal/parental toxicity. Developmental toxicity in rabbits was limited to decreased fetal body weights and late abortions observed at the same doses that caused maternal toxicity (late abortions, clinical signs, decreased body weight, and red substance on fur/in the cage).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pethoxamid is complete.

ii. There is evidence of potential neurotoxicity in the pethoxamid database in the acute neurotoxicity study and in the developmental toxicity study in rats. However, concern is low because: (1) The observed effects are well characterized, with clear NOAELs; (2) they occur only at the highest doses tested and are likely agonal in nature; and (3) PODs are based on the most sensitive effects and are protective of any potential neurotoxicity.

iii. There is no evidence that pethoxamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pethoxamid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pethoxamid.

E. 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 PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, pethoxamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pethoxamid from food and water will utilize less than 1% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pethoxamid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pethoxamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pethoxamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 720 for children 1 to less than 2 years old. Because EPA's level of concern for pethoxamid is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, pethoxamid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the

chronic dietary risk assessment for evaluating intermediate-term risk for pethoxamid.

5. *Aggregate cancer risk for U.S. population.* Based on the Agency's chronic risk assessment, EPA does not expect cancer risk to result from aggregate exposure to pethoxamid.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pethoxamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed a multi-residue method (quick, easy, cheap, effective, rugged and safe; QuEChERS; Method No. AGR/MOA/PTX–8) for the determination of pethoxamid in plant commodities. Method EAS Study Code S15–03519 is proposed as the enforcement method for determination of residues of pethoxamid in livestock commodities. The extraction and analysis procedures are based on the QuEChERS method and are very similar to those of the proposed enforcement method for crop commodities, EAS Method No. AGR/MOA/PTX–8.

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.

The Codex has not established any MRLs for pethoxamid.

C. Response to Comments

Two comments were received in response to the April 11, 2018 NOF, and 21 comments were received in response to the October 28, 2019 NOF. One comment was in support of the petition. One raised concern about bats and wind turbines that is unrelated to pesticides and this petition. The other comments were generally opposed to the Agency approving the use of pesticides on food, many stating that ''there are NO acceptable levels of pesticide residues in foods.'' Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these pethoxamid tolerances are safe. The commenters have provided no information to indicate that pethoxamid is not safe.

D. Revisions to Petitioned-For Tolerances

The following tolerances are being set at 0.01 ppm because crop field trials indicated that residues of pethoxamid were below the limit of quantitation (<0.01 ppm) in/on all soybean, cotton and corn commodities: Corn, field forage; corn, field stover; corn, sweet, forage; corn, sweet, stover; cotton gin byproducts; soybean, forage; and soybean, hay.

V. Conclusion

Therefore, tolerances are established for residues of pethoxamid, including its metabolites and degradates, in or on cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; corn, field, forage at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.01 ppm; corn, sweet, forage at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.01 ppm; cotton, gin byproducts at 0.01 ppm; cotton, undelinted seed at 0.01 ppm; egg at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; soybean, forage at 0.01 ppm; soybean, hay at 0.01 ppm; and soybean, seed at 0.01 ppm.

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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 26, 2020.

Michael Goodis,

Acting Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 40 CFR chapter I 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. Add § 180.710 to subpart C to read as follows:

§ 180.710 Pethoxamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide pethoxamid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only pethoxamid, 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenyl-1-propen-1-yl) acetamide in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husk removed	0.01
Corn, sweet, stover	0.01
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Egg	0.01
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01
Soybean, forage	0.01
Soybean, hay	0.01
Soybean, seed	0.01

(b) [Reserved]

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