Order 13175. This rule finds that California has failed to submit SIP revisions that satisfy certain nonattainment area planning requirements under sections 172, 188 and 189 of the CAA for the 1997, 2006, and 2012 $PM_{2.5}$ NAAQS for the San Joaquin Valley nonattainment area. No tribe is subject to the requirement to submit an implementation plan under section 172 or under subpart 4 of part D of Title I of the CAA. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern 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 is a finding that California has failed to submit certain SIP revisions that satisfy the nonattainment area planning requirements under sections 172, 188 and 189 of the CAA for the 1997, 2006, and 2012 $PM_{2.5}$ NAAQS for the San Joaquin Valley nonattainment area and does not directly or disproportionately affect children.

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. In finding that California has failed to submit SIP revisions that satisfy certain nonattainment area planning requirements under sections 172, 188 and 189 of the CAA for the1997, 2006, and 2012 $PM_{2.5}$ NAAQS for the San Joaquin Valley nonattainment area, this action does not directly affect the level of protection provided to human health or the environment.

L. Congressional Review Act (CRA)

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

M. Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (*see* section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedures, Air pollution control, Approval and promulgation of implementation plans, Administrative practice and procedures, Incorporation by reference, Intergovernmental relations, Particulate matter, and Reporting and recordkeeping requirements.

Dated: November 19, 2018.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2018–26359 Filed 12–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0372; FRL–9985–83]

Clomazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clomazone in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project No. 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 6, 2018. Objections and requests for hearings must be received on or before February 4, 2019, 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–2017–0372, 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 review the visitor instructions and additional information about the docket available at *http://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.*

To access the OCSPP test guidelines referenced in this document electronically, please go to *https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp* and select ''Test Methods and Guidelines.''

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–2017–0372 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 February 4, 2019. 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–2017–0372, 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 October 23, 2017 (82 FR 49020) (FRL–9967–37), 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 7E8581) 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 180.425 be amended by establishing tolerances for residues of the herbicide clomazone, 2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone, in or on Bean, dry at 0.05 parts per million (ppm); Bean, succulent at 0.05 ppm; Broccoli, Chinese at 0.10 ppm; Cilantro, dried leaves at 0.3 ppm; Cilantro, fresh leaves at 0.05 ppm; Coriander, seed at 0.05 ppm; Cottonseed subgroup 20C at 0.05 ppm; Dill, dried leaves at 0.4 ppm; Dill, fresh leaves at 0.08 ppm; Dill, oil at 0.06 ppm; Dill, seed at 0.05 ppm; Kohlrabi at 0.10 ppm; Rapeseed subgroup 20A at 0.05 ppm; Stalk and stem vegetable subgroup 22A, except kohlrabi at 0.05 ppm; Vegetable, brassica, head and stem, group 5–16 at 0.10 ppm; and Vegetable, cucurbit, group 9 at 0.1 ppm.

The petitioner also proposed to remove the following established tolerances Asparagus at 0.05 ppm; Bean, snap, succulent at 0.05 ppm; Brassica, head and stem, subgroup 5A at 0.10 ppm; Cotton, undelinted seed at 0.05 ppm; Cucumber at 0.1 ppm; Pea, southern, dry seed at 0.05 ppm; Pea, southern, succulent seed at 0.05 ppm; Pumpkin at 0.1 ppm; Squash, summer at 0.1 ppm; Squash, winter at 0.1 ppm; Sweet potato, roots at 0.05 ppm; Vegetable, cucurbit, group 9 at 0.05 ppm. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* EPA received one comment the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from the levels requested. 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 clomazone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clomazone 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 primary target of clomazone is the liver, with hepatocellular cytomegaly and increased liver weight noted in the sub-chronic rat study. There were no effects up to the limit dose in the chronic dog study. The 28-day dermal toxicity study in rats showed no effects up to the limit dose.

There was no quantitative or qualitative evidence of susceptibility in the developmental toxicity study in rabbits or in the 2-generation reproduction toxicity study in rats. In the developmental toxicity study in rabbits, no developmental effects were seen at the highest dose tested where maternal effects, including mortality, abortions, decreased body weight gain and decreased defecation or no feces, occurred. In the 2-generation reproduction study, decreased body weight was seen at the same dose in both parents and offspring. Qualitative susceptibility was observed in the developmental toxicity study in rats. Developmental effects, including delayed ossification in the form of either partial ossification or the absence of the manubrium sternebrae 3–4, xiphoid, caudal vertebrae and metacarpals, occurred at the same dose as maternal effects, which included chromorhinorrhea and abdominogenital staining. The concern is low since there are clear NOAELs and LOAELs in this study and the study was used for risk assessment, and, therefore, is protective of the developmental effects. Using a weight of evidence approach, the Agency concluded that the acute and sub-chronic neurotoxicity studies, mouse carcinogenicity study, inhalation study, and immunotoxicity study are not required at this time. There are no dermal absorption studies available for clomazone. An acceptable dermal toxicity study is available to assess hazard through the dermal route therefore, a dermal absorption study is not required at this time.

In the rat and mouse carcinogenicity studies, there was no evidence of carcinogenicity. The mouse carcinogenicity study was classified as unacceptable/guideline since no systemic toxicity was observed at the highest dose tested, however, the study was considered adequate to assess the carcinogenicity in mice. The Agency has determined that an additional mouse carcinogenicity study is not needed. This finding is based upon the following conclusions: (1) The rat is more sensitive than the mouse for the chronic assessment; (2) the consistent effect in rats (decreased body weight and increased liver weight) has been used as the point of departure for the chronic assessment; (3) a new mouse study would only use doses well above the current POD for the chronic assessment; and (4) even if a new mouse study identified positive carcinogenicity effects, that finding would not result in the adoption of a quantitative linear assessment of cancer risk due to the negative carcinogenicity finding in the rat study and the lack of a positive finding for genotoxicity. Clomazone is classified as ''Not Likely to be Carcinogenic to Humans''. Quantification of cancer risk is not required.

Clomazone has low acute toxicity (Category III and IV) via the oral, dermal and inhalation routes. It is non-irritating to the eyes and mildly irritating to the skin. It is not a dermal sensitizer. Clomazone is absorbed, metabolized (16 metabolites identified) and rapidly excreted in urine and feces in rats following oral administration. Most of the administered dose (48–85%) is eliminated within 24 hours, mostly in urine. The quantities of metabolites varied with dose regimen, sex and route of administration, but were the same qualitatively in urine and feces. The total recovery after 48 hours was 91–100%.

Specific information on the studies received and the nature of the adverse effects caused by clomazone 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 document *Clomazone: Human Health Risk Assessment for Proposed (1) New Uses on Cilantro, Dill, and Rapeseed Subgroup 20A; (2) Tolerance Revisions of Cucurbit Vegetable Group 9; (3) Tolerance Expansions of Representative Commodities to (i) Cottonseed Subgroup 20C, (ii) Stalk and Stem Vegetable Subgroup 22A, except Kohlrabi, (iii) Dry Bean, and (iv) Succulent Bean; and (4) Tolerance Conversions from Crop Subgroup 5A (Head and Stem Brassica) to Crop Group 5–16 (Brassica, Head and Stem Vegetable), Chinese Broccoli and Kohlrabi* at page 35 in docket ID number EPA–HQ–OPP–2017–0372.

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 no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

A summary of the toxicological endpoints for clomazone used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 10, 2016 (Vol. 81 FR 78914) (FRL–9953–88).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to clomazone, EPA considered exposure under the petitioned-for tolerances as well as all existing clomazone tolerances in 40 CFR 180.425. EPA assessed dietary exposures from clomazone 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.

Such effects were identified for clomazone. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16, which incorporates 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA incorporated tolerance level residues, assumed 100% crop treated, and used DEEM default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM–FCID Version 3.16, which incorporates 2003–2008 food consumption data from USDA's NHANES/WWEIA. As to residue levels in food, EPA incorporated tolerance level residues, assumed 100% crop treated, and used DEEM default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has

concluded that clomazone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for clomazone. Tolerance level residues and/or 100% CT 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 clomazone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of clomazone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Food Quality Protection Act (FQPA) Index Reservoir Screening Tool (FIRST), Tier 1 Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of clomazone and its degradate, FMC 65317 (N-[(2-chlorophenyl)methyl]-3-hydroxy-2,2-dimenthylpropanamide), for acute exposures are estimated to be 550 parts per billion (ppb) for surface water and 85.7 ppb for ground water.

The EDWCs of clomazone plus FMC 65317 for chronic exposures for non-cancer assessments are estimated to be 550 ppb for surface water and 77.4 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 550 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 550 ppb was used to assess the contribution to drinking water.

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). Clomazone is not registered for any specific use patterns that would result in residential exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.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.'' EPA has not found clomazone to share a common mechanism of toxicity with any other substances, and clomazone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that clomazone does not have 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 *https://www.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.* There was no evidence of increased quantitative or qualitative susceptibility in the prenatal developmental toxicity study in rabbits or in the reproductive toxicity study in rats with clomazone. In the developmental toxicity study in rats, delayed ossification occurred at doses that produced maternal effects (chromorhinorrhea and abdominogenital staining). Although qualitative susceptibility was observed in the developmental toxicity study in rats, the concern is low since there are clear NOAELs and LOAELs and the PODs selected for risk assessment are protective of the qualitative susceptibility.

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 clomazone is complete.

ii. There is no indication that clomazone is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that clomazone results in increased quantitative 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% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to clomazone in drinking water. These assessments will not underestimate the exposure and risks posed by clomazone.

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.* Using the exposure assumptions discussed in this unit for acute exposure analysis, the risk estimate for acute dietary exposure from food and water to clomazone is at 3.0% of the aPAD for females 13–49 years old, the only population group for which an acute dietary endpoint was selected. The acute dietary risk for females 13–49 years old is not of concern (<100% of aPAD).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure analysis, EPA has concluded that the risk estimates for chronic exposure to clomazone from food and water are not of concern (<100% of cPAD) with a risk estimate at 3.6% of the cPAD for all infants less

than 1 year of age, the population group receiving the greatest exposure.

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). Currently, there are no registered or proposed residential uses for clomazone, therefore, a short-term aggregate risk is the same as the chronic risk, which does not exceed the Agency's level 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). Currently, there are no registered or proposed residential uses for clomazone, therefore, an intermediate-term aggregate risk is the same as the chronic risk, which does not exceed the Agency's level of concern..

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, clomazone is not expected to pose a cancer risk to humans.

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 clomazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, gas chromatography (GC) using a nitrogen phosphorus detector (NPD) or mass spectrometer (MS), is available. A confirmatory procedure (GC/MS–SIM: Gas Chromatography/Mass Spectroscopy-Selected Ion Monitoring) is also available (Method I, PAM [Pesticide Analytical Manual] II) to enforce the tolerance expression. The method 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 clomazone.

C. Response to Comments

One comment was received on the Notice of Filing expressing concern about the effects of wind turbines on bats. The comment did not raise any issue related to the Agency's safety determination for clomazone tolerances. The receipt of this comment is acknowledged; however, this comment is not relevant to this action.

D. Revisions to Petitioned-For Tolerances

For dill oil, the Agency is establishing a tolerance at 0.07 ppm rather than 0.06 ppm due to rounding based on the available data. Although the petitioner requested a tolerance for vegetable, cucurbit, group 9 at 0.1 ppm, the Agency is maintaining the established tolerance of 0.05 ppm for cucurbit vegetable group 9 and setting an expiration date for the existing tolerances on the individual commodities of cucumber, summer squash, winter squash and pumpkin at 0.1 ppm. Available residue data demonstrates that the 0.05 ppm tolerance value is sufficient to cover residues on the commodities in this group so there is no need to maintain the separate higher tolerances. Moreover, setting these tolerances at 0.05 ppm would harmonize tolerance values with Canada. In addition, the Agency is adding significant figures to the tolerances requested for cilantro, dried leaves and dill, dried leaves to conform to Agency practice.

The petitioner requested tolerances on ''bean, dry'' and ''bean, succulent''. Although those terms are defined in 40 CFR 180.1(g), the Agency is establishing individual tolerances for each of the dry and succulent forms of the beans contained in that definition to more accurately reflect the commodities as distributed in interstate commerce: asparagus bean, chickpea, kidney bean, mung bean, navy bean, pinto bean, grain lupin, sweet lupin, white lupin, and white sweet lupin come in the dry bean form only; snap bean and wax bean come in succulent form only; and broad bean, lima bean, and southern pea come in both the dry and succulent forms. Tolerances for snap bean (succulent) and southern pea (dry and succulent) are already established and are being maintained.

E. International Trade Considerations

In this Final Rule, EPA is reducing the existing tolerances for the commodities of cucumber, pumpkin, and summer and winter squash from 0.1 ppm to 0.05 ppm as part of vegetable, cucurbit, group 9. The Agency is reducing these tolerances to harmonize with Canadian tolerances on cucurbit vegetables and available residue data demonstrates that tolerances at 0.05 ppm are sufficient to cover residues on these commodities.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of this revision in order to satisfy its obligation. In addition, the SPS Agreement requires that Members provide a ''reasonable interval'' between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. At this time, EPA is establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule, in order to address this requirement. After the six-month period expires, residues of clomazone on cucumber, pumpkin, and summer and winter squash cannot exceed the vegetable, cucurbit, group 9 tolerance of 0.05 ppm.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of clomazone, 2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone, in or on Bean, asparagus, dry seed at 0.05 parts per million (ppm); Bean, broad, dry seed at 0.05 ppm; Bean, broad, succulent seed at 0.05 ppm; Bean, kidney, dry seed at 0.05 ppm; Bean, lima, dry seed at 0.05 ppm; Bean, lima, succulent seed at 0.05 ppm; Bean, mung, dry seed at 0.05 ppm; Bean, navy, dry seed at 0.05 ppm; Bean, pinto, dry seed at 0.05 ppm; Bean, wax, succulent seed at 0.05 ppm; Broccoli,

Chinese at 0.10 ppm; Chickpea, dry seed at 0.05 ppm; Cilantro, dried leaves at 0.30 ppm; Cilantro, fresh leaves at 0.05 ppm; Coriander, seed at 0.05 ppm; Cottonseed subgroup 20C at 0.05 ppm; Dill, dried leaves at 0.40 ppm; Dill, fresh leaves at 0.08 ppm; Dill, oil at 0.07 ppm; Dill, seed at 0.05 ppm; Grain, lupin, dry seed at 0.05 ppm; Kohlrabi at 0.10 ppm; Rapeseed subgroup 20A at 0.05 ppm; Stalk and stem vegetable subgroup 22A, except kohlrabi at 0.05 ppm; Sweet, lupin, dry seed at 0.05 ppm; Vegetable, *Brassica,* head and stem, group 5–16 at 0.10 ppm; White lupin, dry seed at 0.05 ppm; and White sweet lupin, dry seed at 0.05 ppm. Upon the establishment of the tolerances referenced above, the following tolerances for residues of the herbicide clomazone, 2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone in or on the raw agricultural commodities should be removed: Asparagus at 0.05 parts per million (ppm); *Brassica,* head and stem, subgroup 5A at 0.10 ppm; Cotton, undelinted seed at 0.05 ppm; and Sweet potato, roots at 0.05 ppm. In addition, EPA is imposing an expiration date on the tolerances for Cucumber at 0.1 ppm; Pumpkin at 0.1 ppm; Squash, summer at 0.1 ppm; and Squash, winter at 0.1 ppm, so that they will expire six months after the publication of this rule.

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 tolerance 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: November 14, 2018.

Donna S. Davis,

Acting 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 § 180.425, amend the table in paragraph (a) by:

■ a. Removing the commodities: ''Asparagus''; ''*Brassica,* head and stem, subgroup 5A''; ''Cotton, undelinted seed''; and ''Sweet potato, roots''.

■ b. Adding alphabetically the commodities: ''Bean, asparagus, dry seed'' at 0.05 ppm; ''Bean, broad, dry seed'' at 0.05 ppm; ''Bean, broad, succulent seed'' at 0.05 ppm; ''Bean, kidney, dry seed'' at 0.05 ppm; ''Bean, lima, dry seed'' at 0.05 ppm; ''Bean, lima, succulent seed'' at 0.05 ppm; ''Bean, mung, dry seed'' at 0.05 ppm; ''Bean, navy, dry seed'' at 0.05 ppm; ''Bean, pinto, dry seed'' at 0.05 ppm; ''Bean, wax, succulent seed'' at 0.05 ppm; ''Broccoli, Chinese'' at 0.10 ppm; ''Chickpea, dry seed'' at 0.05 ppm; ''Cilantro, dried leaves'' at 0.30 ppm; ''Cilantro, fresh leaves'' at 0.05 ppm; ''Coriander, seed'' at 0.05 ppm; ''Cottonseed subgroup 20C'' at 0.05 ppm; ''Dill, dried leaves'' at 0.40 ppm; ''Dill, fresh leaves'' at 0.08 ppm; ''Dill, oil'' at 0.07 ppm; ''Dill, seed'' at 0.05 ppm; ''Grain, lupin, dry seed'' at 0.05 ppm; ''Kohlrabi'' at 0.10 ppm; ''Rapeseed subgroup 20A'' at 0.05 ppm; ''Stalk and stem vegetable subgroup 22A, except kohlrabi'' at 0.05 ppm; ''Sweet, lupin, dry seed'' at 0.05 ppm; ''Vegetable, *Brassica,* head and stem, group 5–16'' at 0.10 ppm; ''White lupin, dry seed'' at 0.05 ppm; and ''White sweet lupin, dry seed'' at 0.05 ppm.

■ c. Revise the entries for ''Cucumber''; ''Pumpkin''; ''Squash, summer''; and ''Squash, winter'' by adding a footnote.

The additions and revisions read as follows:

§ 180.425 Clomazone; tolerances for residues.

(a) * * *

Commodity	Parts per million
Bean, asparagus, dry seed	0.05
Bean, broad, dry seed	0.05
Bean, broad, succulent seed	0.05
Bean, kidney, dry seed	0.05
Bean, lima, dry seed	0.05
Bean, lima, succulent seed	0.05
Bean, mung, dry seed	0.05
Bean, navy, dry seed	0.05
Bean, pinto, dry seed	0.05
* * * * * * *	
Bean, wax, succulent seed	0.05
Broccoli, Chinese	0.10
Chickpea, dry seed	0.05
Cilantro, dried leaves	0.30
Cilantro, fresh leaves	0.05
Coriander, seed	0.05
Cottonseed subgroup 20C	0.05
* * * * * * *	
Cucumber *	0.1
Dill, dried leaves	0.40
Dill, fresh leaves	0.08
Dill, oil	0.07
Dill, seed	0.05
Grain lupin, dry seed	0.05
Kohlrabi	0.10
* * * * * * *	
Pumpkin *	0.1
Rapeseed subgroup 20A	0.05
* * * * * * *	
Squash, summer *	0.1
Squash, winter *	0.1
Stalk and stem vegetable subgroup 22A, except kohlrabi	0.05
* * * * * * *	
Sweet lupin, dry seed	0.05
Vegetable, *Brassica,* head and stem, group 5–16	0.10
* * * * * * *	
White lupin, dry seed	0.05
White sweet lupin, dry seed	0.05

* This tolerance expires on June 5, 2019.

* * * * *

[FR Doc. 2018–26345 Filed 12–4–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0717; FRL–9985–77]

Extension of Tolerances for Emergency Exemptions (Multiple Chemicals)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in this document. These actions are in response to EPA's granting of emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. In addition, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

DATES: This regulation is effective December 6, 2018. Objections and requests for hearings must be received on or before February 4, 2019, 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–2018–0717, 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. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200