paragraph (a) of this section unless authorized by the COTP St. Petersburg or a designated representative.

(2) Designated representatives may control vessel traffic throughout the enforcement area as determined by the prevailing conditions.

(3) Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated areas by contacting the COTP St. Petersburg by telephone at (727) 824–7506, or a designated representative via VHF radio on channel 16. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP St. Petersburg or a designated representative.

(4) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners and/or Broadcast Notice to Mariners.

(d) *Enforcement period.* This section will be enforced daily from 9:30 a.m. until 5:30 p.m., on October 10, 2019, through October 12, 2019.

Dated: September 27, 2019.

Matthew A. Thompson

Captain, U.S. Coast Guard, Captain of the Port Saint Petersburg.

[FR Doc. 2019–21527 Filed 10–4–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0286; FRL–9999–57]

Cyromazine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyromazine in or on multiple commodities which are identified and discussed later in this document. 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 October 7, 2019. Objections and requests for hearings must be received on or before December 6, 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–2018–0286, 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 Publishing 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–2018–0286 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 December 6, 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–2018–0286, 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 July 24, 2018 (83 FR 34968) (FRL–9980–31), 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 8E8673) by The Interregional Research Project Number 4 (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 180.414 be amended by establishing tolerances for residues of the insecticide cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on Brassica, leafy greens, subgroup 4–16B

at 10.0 parts per million (ppm); Celtuce at 7.0 ppm; Chickpea, edible podded at 0.4 ppm; Chickpea, succulent shelled at 0.3 ppm; Dwarf pea, edible podded at 0.4 ppm; Edible podded pea, edible podded at 0.4 ppm; English pea, succulent shelled at 0.3 ppm; Florence fennel at 7.0 ppm; Garden pea, succulent shelled at 0.3 ppm; Grass-pea, edible podded at 0.4 ppm; Green pea, edible podded at 0.4 ppm; Green pea, succulent shelled at 0.3 ppm; Kohlrabi at 10.0 ppm; Leaf petiole subgroup 22B at 7.0 ppm; Leafy green subgroup 4–16A at 7.0 ppm; Lentil, edible podded at 0.4 ppm; Lentil, succulent shelled at 0.3 ppm; Onion, bulb, subgroup 3–07A at 0.2 ppm; Onion, green, subgroup 3–07B at 3.0 ppm; Pepper/eggplant 8–10B at 1.0 ppm; Pigeon pea, edible podded at 0.4 ppm; Pigeon pea, succulent shelled at 0.3 ppm; Snap pea, edible podded at 0.4 ppm; Snow pea, edible podded at 0.4 ppm; Sugar snap pea, edible podded at 0.4 ppm; Tomato subgroup 8–10A at 1.0 ppm; Vegetable, brassica, head and stem, group 5–16, except broccoli at 10.0 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.8 ppm.

Upon establishing those tolerances, the petition also proposed to remove existing tolerances for residues of cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) in or on cabbage, abyssinian at 10.0 ppm; cabbage, seakale at 10.0 ppm; garlic at 0.2 ppm; garlic, great-headed, bulb at 0.2 ppm; Hanover salad, leaves at 10.0 ppm; leek at 3.0 ppm; onion, bulb at 0.2 ppm; onion, green at 3.0 ppm; onion, potato at 3.0 ppm; onion, tree at 3.0 ppm; onion, welsh at 3.0 ppm; pepper at 1.0 ppm; potato at 0.8 ppm; rakkyo, bulb at 0.2 ppm; shallot, bulb at 0.2 ppm; shallot, fresh leaves at 3.0 ppm; tomato at 0.5 ppm; turnip, greens at 10.0 ppm; vegetable, brassica, leafy, group 5, except broccoli at 10.0; vegetable, leafy, except brassica, group 4 at 7.0 ppm. That document referenced a summary of the petition prepared by Makhteshim Agan of North American, Inc., (ADAMA) and Syngenta Crop Protection, LLC, the registrants, which is available in the docket, *http://www.regulations.gov.* Three 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 has corrected the terminology for several commodities and is establishing tolerances at levels other than petitioned for on some of the commodities. 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 cyromazine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyromazine 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.

No specific toxicity was associated with cyromazine, with lowest observed adverse effects levels (LOAELs) occurring at relatively high doses. Decreases in body weight and food consumption are the common features of cyromazine toxicity following subchronic or chronic oral exposures as seen in dogs, rats, mice, and rabbits. Other effects reported were organ weight (relative) changes and changes to some hematological parameters that were biologically insignificant and non-adverse. No dermal or systemic toxicity was seen at the highest dose tested (greater than 2,000 mg/kg/day) in two 21-day dermal toxicity studies in rabbits. In a 28-day inhalation study in rats, cyromazine produced clinical signs of toxicity (hunched posture, piloerection, and reduced spontaneous activity) consistent with dyspnea at all concentrations tested. An acute neurotoxicity study demonstrated reduced motor activity as the main effect with no treatment-related effects on mortality, brain weight, or gross and histologic pathology or neuropathology up to the limit dose tested.

There is no evidence of developmental toxicity following *in utero* exposures or that offspring are more susceptible following postnatal exposure. In the 2-generation reproduction study in rats no reproductive effects were observed. The available oral perinatal, prenatal and postnatal data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* exposure to cyromazine. No quantitative or qualitative susceptibility was observed in any study. In the prenatal developmental rat toxicity study, the NOAEL (300 mg/kg/day) for developmental effects (increased incidence of minor skeletal variations) was higher than the maternal NOAEL (100 mg/kg/day). In the developmental toxicity study in rabbits, no evidence of developmental toxicity was noted since the NOAEL was the highest dose tested (60 mg/kg/day). In the 2-generation reproduction rat study, no reproductive effects were observed up to the highest dose tested (150 mg/kg/day).

Cyromazine was not carcinogenic in mice or rats following long-term dietary administration and was classified ''Group E—Evidence of Noncarcinogenicity for Humans.'' The available mutagenicity data suggest that cyromazine does not have genotoxic activity. Cyromazine is categorized as Toxicity Category III for acute oral, dermal and inhalation toxicity. Cyromazine is neither an eye irritant nor a dermal sensitizer; however, it is mild skin irritant.

Specific information on the studies received and the nature of the adverse effects caused by cyromazine 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 ''Cyromazine: Human health Risk Assessment for Proposed New Foliar Uses on Edible Podded pea and Succulent Shelled Pea Commodities, Crop Group Conversion on Leafy green subgroup 4–16A, Leaf petiole subgroup 22B, Celtuce, and Florence fennel; Vegetable, brassica, head and stem,

group 5–16, except broccoli; Brassica, leafy greens, subgroup 4–16B; Kohlrabi; Hanover salad, leaves; Turnip, greens; Cabbage, Abyssinian; and Cabbage, seakale; Tomato subgroup 8–10A; Pepper/eggplant subgroup 8–10B; and Expansion of Vegetable, tuberous ad corm, subgroup 1C, Onion, bulb, subgroup 3–07A; and Onion, green, subgroup 3–07B'' at page number 11 and ''Cyromazine: Human Health Risk Assessment for Registration Review'' at pages 51–53 in docket ID number EPA–HQ–OPP–2018–0286.

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 cyromazine used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYROMAZINE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13+ years of age).	No developmental effects attributable to a single dose were seen following *in utero* exposures to rats and rabbits.		
Acute dietary (All populations)	LOAEL = 250 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 3x	Acute RfD = 2.5 mg/kg/day. aPAD = 0.83 mg/kg/day	Acute Neurotoxicity Study in rats. LOAEL = 250 mg/kg/day based on decreased motor activity (mean cumulative ambulatory LMA counts, 44%) in males at the time of peak effect on Day 0, and decreased food consumption (17%) on Day 1.
Chronic dietary (All populations)	NOAEL = 50 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.5 mg/kg/day. cPAD = 0.5 mg/kg/day	Two-Generation Reproductive Study in rats. LOAEL = 150 mg/kg/day for decreased body weights (27%) that were associated with decreased food efficiency. Co-critical with: Chronic Carcinogenicity Study in the rat. LOAEL = 150 mg/kg/day based on decreased body weight (20% males, 29% females) associated with lower food consumption (10–15%) compared to controls.
Cancer (All routes)	Group E—No evidence for carcinogenicity in humans.		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyromazine, EPA considered exposure under the petitioned-for tolerances as well as all existing cyromazine tolerances in 40 CFR 180.414. EPA assessed dietary exposures from cyromazine 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 cyromazine. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/ WWEIA). As to residue levels in food, EPA used tolerance-level residues and 100% crop treated assumptions.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues and 100% crop treated assumptions.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that cyromazine 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 cyromazine. Tolerance level residues and 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 cyromazine in drinking water. These simulation models take into account data on the physical, chemical, and fate/ transport characteristics of cyromazine. 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 First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of cyromazine for acute exposures are estimated to be 47.1 parts per billion (ppb) for surface water and 111 ppb for ground water. For chronic exposures for non-cancer assessments, EDWCs are estimated to be 15.8 ppb for surface water and 86 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 111 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 86 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). Cyromazine 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 determined that the available toxicological data suggests cyromazine does not share a similar toxicological profile, and thus no common mechanism of toxicity, with other pesticides. No further cumulative evaluation is necessary for cyromazine. This analysis can be found at *http://www.regulations.gov* in document ''Chitin Synthesis Inhibitors (Buprofezin and Cyromazine): Screening Analysis of Toxicological Profiles to Consider Whether a Candidate Common Mechanism Group Can Be Established'' in docket ID number EPA–HQ–OPP–2018–0286.

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.* Based on the available data, there is no quantitative and qualitative evidence of increased susceptibility observed following *in utero* cyromazine exposure to rats and rabbits or following prenatal/postnatal exposure in the 2-generation reproduction study. The database is considered adequate for selection of study endpoints and determination of a dose/response to characterize the potential prenatal or postnatal toxicity of cyromazine to infants and children. No increase in susceptibility was seen in developmental toxicity studies in rat and rabbit or reproductive toxicity studies in the rat. Toxicity to offspring was observed at dose levels the same or greater than those causing maternal or parental toxicity. Based on the results of developmental and reproductive toxicity studies, there is not a concern or increased qualitative and/or quantitative susceptibility following *in utero* exposure to cyromazine.

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 for the chronic dietary exposure assessment and retained at 3X for the acute dietary exposure assessment. That decision is based on the following findings:

i. The toxicity database for cyromazine is complete for assessing the risks to infants and children. However, the study providing the basis for the acute dietary exposure POD lacks a NOAEL, so the Agency is retaining a 3X FQPA SF for extrapolating a NOAEL.

ii. There is no evidence of neurotoxicity in the cyromazine repeated dose studies, which include subchronic or chronic dosing in multiple species. However, in the acute neurotoxicity study conducted in rats, reduced motor activity was seen at all doses tested and additional neurological effects (decreased foot splay in males and increased rearing behavior in females) were observed at the highest dose tested. Because a NOAEL was not established for the acute neurotoxicity effects, an FQPA SF will be retained for the acute risk assessment. In this case, the default FQPA SF of 10X can be reduced to 3X for the following reasons:

(1) the toxicity database is considered complete for cyromazine and no other studies via the oral route showed clinical signs or histopathology indicative of neurotoxicity;

(2) a 3X SF yields an acute PAD of 0.83 mg/kg/day, which is similar to the chronic PAD of 0.5 mg/kg/day. The chronic POD is considered very conservative and is based on 27% decreased body weight seen at the LOAEL of 150 mg/kg/day in absence of any other significant effects. The aPAD is conservative because it is unlikely that decreased motor activity would occur at doses similar to the chronic endpoint. The effects used to derive the chronic POD (decrease in body weight) were observed only after repeated exposure (15 weeks) and there was no indication of decreased activity or other neurological clinical signs in the chronic study; and

(3) motor activity seems to be a very sensitive indicator of acute toxicity of cyromazine. While there are indications of neurotoxicity in the ACN and inhalation studies, the selected endpoints are protective of those effects, therefore there is no concern for developmental neurotoxicity resulting from exposure to cyromazine. Based on the findings in the acute neurotoxicity study and the total weight of evidence, the requirement for the subchronic neurotoxicity study was waived.

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

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, the acute dietary exposure from food and water to cyromazine will occupy 18% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyromazine from food and water will utilize 8.3% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for cyromazine that would result in chronic exposure.

3. *Short-term and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, cyromazine is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or 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 short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for cyromazine.

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

5. *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 cyromazine residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Adequate methods are available in Pesticide Analytical Manual (PAM), Vol. II for enforcement of the established tolerances for cyromazine in/on plant commodities. The working method ''Determination of Cyromazine in Bean (snap)'' Revision O, was derived from Ciba-Geigy Analytical Method No. AG0621, ''Analytical Method for the Determination of Cyromazine and its Metabolite Melamine residues in Crops by Gas Chromatography with a Nitrogen/Phosphorous detector in the Nitrogen Specific Mode. (January 12, 1995).'' Minor modifications were made to improve the performance of the method. The limit of quantitation for cyromazine is 0.05 ppm in most plant commodities. Adequate methods are available in PAM, Vol. II for enforcement of the established tolerances for cyromazine in/on meat, milk, poultry, and eggs. Cyromazine, per se, was recovered when analyzed through Protocol III (present Protocol D). The Agency concluded that the data were acceptable and no additional cyromazine multiresidue method (MRM) recovery data were required.

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.

There are Codex MRLs established for residues of cyromazine in/on several commodities. The U.S. tolerances being established for Onion, green, subgroup 3–07B and Tomato subgroup 8–10A are harmonized with Codex. The U.S. is not able to harmonize with Codex for Onion, bulb, subgroup 3–07A; Leafy green subgroup 4–16A; Leaf petiole subgroup 22B; Brassica, leafy greens, subgroup 4–16B; and pepper/eggplant subgroup 8–10B because differences in use patterns and residues in submitted field trials support higher U.S. tolerances; harmonization would cause tolerance exceedances and violative residues, despite legal use of cyromazine pursuant to U.S. labels. There are no Codex MRLs for the other commodities in this action.

C. Response to Comments

EPA received three comments to the Notice of Filing. Two comments expressed concerns about wildfires, health and habitats. These comments did not raise any issues related to the Agency's safety determination of cyromazine tolerances. The receipt of these comments is acknowledged however, these comments are not relevant to this action. Another commenter stated the following, ''In rule making, please use the following standard: The amounts of residues found in food must be safe for consumers and must be as low as possible.'' When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency, as is required by section 408 of the FFDCA, estimates the risk of the potential exposure to these residues. The Agency has concluded after this assessment, that there is a reasonable certainty that no harm will result from aggregate human exposure to cyromazine and that, accordingly, the cyromazine tolerances on these commodities are safe. The commenter has provided no information suggesting that the levels approved are not safe.

D. Revisions to Petitioned-For Tolerances

EPA made two minor wording changes to the existing tolerance expression by deleting the phrases ''the insecticide'' and ''. . . , in or on the commodity'' at the end of the tolerance expression for consistency with Agency policy. For harmonization purposes, the Agency is establishing different tolerances for the following commodities than what was petitioned for: Leafy green subgroup 4–l6A, Brassica, leafy greens, subgroup 4–16B, Celtuce, Fennel, Florence, fresh leaves and stalk, Kohlrabi, Leaf petiole vegetable subgroup 22B, Onion, bulb, subgroup 3–07A, Pepper/eggplant subgroup 8–10B, and Vegetable, brassica, head and stem, group 5–16, except broccoli. Additionally, the Agency revised the commodity terminology to use the following correct commodity definitions: Leafy greens subgroup 4–16A, Leaf petiole vegetable subgroup 22B, Fennel, Florence, fresh

leaves and stalk, and Pepper/eggplant subgroup 8–10B. Finally, EPA is establishing several tolerances that differ from the petitioned-for tolerance levels to conform to the Agency's rounding classes.

E. International Trade Considerations

In this rule, EPA is establishing lower tolerances for cyromazine residues in or on onion, potato than the current tolerance. The current tolerance for onion, potato is 3.0 ppm, but onion, potato is a commodity in the onion, bulb, subgroup 3–07A, for which EPA is establishing a new tolerance in this rulemaking at 0.3 ppm. As a result, EPA intends for the allowable residues onion, potato to be reduced. As discussed in EPA's crop grouping rulemaking, EPA has determined that onion, potato is similar to other bulb onions and appropriately categorized in subgroup 3–07A. *See* 72 FR 69150 (Dec. 7, 2007). Based on residue data supporting the 0.3 ppm tolerance for subgroup 3–07A and the similarity of onion, potato to other bulb onions, EPA concludes that it is appropriate to reduce the tolerance on onion, potato as well.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. 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. Accordingly, EPA is establishing an expiration date for the existing tolerance to allow this tolerance to remain in effect for a period of six months after the effective date of this final rule. After the six-month period expires, this tolerance will be reduced or revoked, as indicated in the regulatory text, and allowable residues on onion, potato must conform to the tolerance for subgroup 3–07A.

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

V. Conclusion

Therefore, tolerances are established for residues of the insecticide cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine, in or on Brassica, leafy greens, subgroup 4–16B at 35 ppm; Celtuce at 10 ppm; Chickpea, edible podded at 0.4 ppm; Chickpea, succulent shelled at 0.3 ppm; Dwarf pea, edible podded at 0.4 ppm; Edible podded pea, edible podded at 0.4 ppm; English pea, succulent shelled at 0.3 ppm; Fennel, Florence, fresh leaves and stalk at 10 ppm; Garden pea, succulent shelled at 0.3 ppm; Grass-pea, edible podded at 0.4 ppm; Green pea, edible podded at 0.4 ppm; Green pea, succulent shelled at 0.3 ppm; Kohlrabi at 35 ppm; Leaf petiole vegetable subgroup 22B at 10 ppm; Leafy greens subgroup 4–16A at 10 ppm; Lentil, edible podded at 0.4 ppm; Lentil, succulent shelled at 0.3 ppm; Onion, bulb, subgroup 3–07A at 0.3 ppm; Onion, green, subgroup 3–07B at 3 ppm; Pepper/eggplant subgroup 8–10B at 3 ppm; Pigeon pea, edible podded at 0.4 ppm; Pigeon pea, succulent shelled at 0.3 ppm; Snap pea, edible podded at 0.4 ppm; Snow pea, edible podded at 0.4 ppm; Sugar snap pea, edible podded at 0.4 ppm; Tomato subgroup 8–10A at 1 ppm; Vegetable, brassica, head and stem, group 5–16, except broccoli at 35 ppm; Vegetable, tuberous and corm, subgroup 1C at 0.8 ppm.

In addition, EPA is removing the following tolerances because they are superseded by the new tolerances being established in this rulemaking: Cabbage, abyssinian at 10.0 ppm; cabbage, seakale at 10.0 ppm, garlic at 0.2 ppm; garlic, great-headed, bulb at 0.2 ppm; Hanover salad, leaves at 10.0 ppm; leek at 3.0 ppm; onion, bulb at 0.2 ppm; onion, green at 3.0 ppm; onion, tree at 3.0 ppm; onion, welsh at 3.0 ppm; pepper at 1.0 ppm; potato at 0.8 ppm; rakkyo, bulb at 0.2 ppm; shallot, bulb at 0.2 ppm; shallot, fresh leaves at 3.0 ppm; tomato at 0.5 ppm; turnip, greens at 10.0 ppm; vegetable, brassica, leafy, group 5, except broccoli at 10.0; vegetable, leafy, except brassica, group 4 at 7.0 ppm. Finally, EPA is setting a six-month expiration date for the current onion, potato tolerance at 3.0 ppm.

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: September 20, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.414, revise paragraph (a)(1) introductory text and amend the table in paragraph (a)(1) as follows:
■ a. Add alphabetically the entries ''Brassica, leafy greens, subgroup 4–16B'';
■ b. Remove the entries for ''Cabbage, abyssinian''; and ''Cabbage, seakale'';
■ c. Add alphabetically the entries ''Celtuce''; ''Chickpea, edible podded''; ''Chickpea, succulent shelled''; ''Dwarf pea, edible podded''; ''Edible podded pea, edible podded''; ''English pea, succulent shelled''; ''Fennel, Florence, fresh leaves and stalk''; ''Garden pea, succulent shelled'';
■ d. Remove the entries for ''Garlic''; and ''Garlic, great-headed, bulb'';
■ e. Add alphabetically the entries ''Grass-pea, edible podded''; ''Green pea, edible podded''; and ''Green pea, succulent shelled'';
■ f. Remove the entry for ''Hanover salad, leaves'';
■ g. Add alphabetically the entries ''Kohlrabi''; ''Leaf petiole vegetable subgroup 22B''; and ''Leafy greens subgroup 4–16A'';
■ h. Remove the entry for ''Leek'';
■ i. Add alphabetically the entries ''Lentil, edible podded''; and ''Lentil, succulent shelled'';
■ j. Remove the entries for ''Onion, bulb''; and ''Onion, green'';
■ k. Add alphabetically the entries ''Onion, bulb, subgroup 3–07A''; and ''Onion, green, subgroup 3–07B'';
■ l. Revise the entry for ''Onion, potato''; to add a footnote 2;
■ m. Remove the entries for ''Onion, tree''; ''Onion, welsh''; and ''Pepper'';
■ n. Add alphabetically the entries ''Pepper/eggplant subgroup 8–10B''; ''Pigeon pea, edible podded''; and ''Pigeon pea, succulent shelled'';
■ o. Remove the entries for ''Potato''; ''Rakkyo, bulb''; ''Shallot, bulb''; and ''Shallot, fresh leaves'';
■ p. Add alphabetically the entries ''Snap pea, edible podded''; ''Snow pea, edible podded''; and ''Sugar snap pea, edible podded'';
■ q. Remove the entry for ''Tomato'';
■ r. Add alphabetically the entry ''Tomato subgroup 8–10A'';
■ s. Remove the entry for ''Turnip, greens'';
■ t. Add alphabetically the entry ''Vegetable, brassica, head and stem, group 5–16, except broccoli'';
■ u. Remove the entries for ''Vegetable, brassica, leafy, group 5, except broccoli''; and ''Vegetable, leafy, except brassica, group 4''; and
■ v. Add alphabetically the entry ''Vegetable, tuberous and corm, subgroup 1C''.

The revisions and additions read as follows:

§ 180.414 Cyromazine; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of cyromazine, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only cyromazine, *N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine.

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B	35
* * * * *	
Celtuce	10
Chickpea, edible podded	0.4
Chickpea, succulent shelled	0.3
Dwarf pea, edible podded	0.4
Edible podded pea, edible podded	0.4
* * * * *	
English pea, succulent shelled	0.3
Fennel, Florence, fresh leaves and stalk	10
Garden pea, succulent shelled	0.3
* * * * *	
Grass-pea, edible podded	0.4
Green pea, edible podded	0.4
Green pea, succulent shelled	0.3
* * * * *	
Kohlrabi	35
Leaf petiole vegetable subgroup 22B	10
Leafy greens subgroup 4–16A	10
Lentil, edible podded	0.4
Lentil, succulent shelled	0.3
* * * * *	
Onion, bulb, subgroup 3–07A	0.3
Onion, green, subgroup 3–07B	3
Onion, potato [2]	3.0
Pepper/eggplant subgroup 8–10B	3
Pigeon pea, edible podded	0.4
Pigeon pea, succulent shelled	0.3
* * * * *	
Snap pea, edible podded	0.4
Snow pea, edible podded	0.4
Sugar snap pea, edible podded	0.4
Tomato subgroup 8–10A	1
Vegetable, brassica, head and stem, group 5–16, except broccoli	35
* * * * *	
Vegetable, tuberous and corm, subgroup 1C	0.8

* * *

[2] This tolerance expires on April 7, 2020.

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[FR Doc. 2019–21542 Filed 10–4–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0656; FRL–9999–54]

Chlorantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of chlorantraniliprole in or on palm, oil. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 7, 2019. Objections and requests for hearings must be received on or before December 6, 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–2018–0656, 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