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: October 25, 2019.

Daniel Rosenblatt,

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 § 180.474, amend the table in paragraph (a)(1) as follows:
■ a. Remove the entry for ''Brassica, leafy greens, subgroup 5B'';
■ b. Add alphabetically the entry for ''*Brassica,* leafy greens, subgroup 4–16B, except watercress'';
■ c. Remove the entry for ''Cotton, undelinted seed'';
■ d. Add alphabetically the entry for ''Cottonseed, subgroup 20C'';
■ e. Remove the entry for ''Fruit, pome, group 11'';
■ f. Add alphabetically the entries for ''Fruit, pome, group 11–10'' and ''Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F'';
■ g. Remove the entries for ''Fruit, stone, group 12, except cherry''; ''Grape''; ''Lychee''; and ''Nut, tree, group 14'';
■ h. Add alphabetically the entry for ''Nut, tree, group 14–12'';
■ i. Remove the entry for ''Peach'';
■ j. Add alphabetically the entry for ''Peach subgroup 12–12B'';
■ k. Remove the entries for ''Pistachio'' and ''Plum, pre- and post-harvest'';
■ l. Add alphabetically the entry for ''Plum subgroup 12–12C'';
■ m. Remove the entry for ''Sunflower, seed''; and
■ n. Add alphabetically the entries for ''Sunflower, subgroup 20B''; ''Tropical and subtropical, small fruit, inedible peel, subgroup 24A''; and ''Watercress''.

The additions read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) * * *
(1) * * *

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B, except watercress	2.5
* * * * *	
Cottonseed, subgroup 20C	2
Fruit, pome, group 11–10	1
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	6
* * * * *	
Nut, tree, group 14–12	0.05
* * * * *	
Peach subgroup 12–12B	2
* * * * *	
Plum subgroup 12–12C	1
* * * * *	
Sunflower, subgroup 20B	0.1
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	1.6
* * * * *	
Watercress	9
* * * * *	

* * * * *

[FR Doc. 2019–24267 Filed 11–8–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0283; FRL–10000–50]

Propyzamide; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of propyzamide in or on cranberry. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cranberry. This regulation establishes a maximum permissible level for residues of propyzamide in or on this commodity. The time-limited tolerance expires on December 31, 2022.

DATES: This regulation is effective November 12, 2019. Objections and requests for hearings must be received on or before January 13, 2020 and must be filed in accordance with the

instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0283, 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, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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–2019–0283 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 January 13, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0283, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of the herbicide propyzamide, including its metabolites and degradates in or on cranberry. Compliance with the tolerance level in or on cranberry at 1 part per million (ppm) is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide. This time-limited tolerance expires on December 31, 2022.

Section 408(l)(6) of 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 under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received any petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Propyzamide on Cranberry and FFDCA Tolerances

The Massachusetts Department of Food and Agriculture (MDAR) notified EPA that an emergency condition exists for cranberry growers due to the presence of dodder in newly planted and renovated cranberry fields in five

counties throughout the state. According to MDAR, dodder is a serious and devasting pest in commercial cranberry production. The state reported that an urgent and nonroutine situation exists because cranberry fields are heavily infested with dodder and that the available registered alternatives do not provide effective control. Significant economic losses were expected due to yield and quality decreases without a suitable pesticide tool to control dodder.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of propyzamide on cranberry for control of dodder in Massachusetts.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of propyzamide in or on cranberry. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2022, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cranberry after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether propyzamide meets FIFRA's registration requirements for use on cranberry or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of propyzamide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Massachusetts to use this pesticide on the applicable crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for propyzamide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with 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 expected as a result of this emergency exemption request and the time-limited tolerance for propyzamide on cranberry at 1 ppm. EPA's assessment of exposures and risks associated with establishing this time-limited tolerance follows.

A. 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 *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for propyzamide used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROPYZAMIDE 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 to 49 years of age).	An endpoint attributable to a single exposure was not available in the database including the developmental toxicity studies in rats and rabbits.		
Acute dietary (All Populations)	LOAEL = 40 mg/kg/day.	Acute RfD = 0.04 mg/kg/day.	Acute Neurotoxicity Rat Study.
	UF_A = 10x UF_H = 10x FQPA SF (UF_L) = 10x (LOAEL to NOAEL extrapolation).	aPAD = 0.04 mg/kg/day	NOAEL was not established; LOAEL = 40 mg/kg/day (the lowest dose tested) based on increased landing foot splay in females and decreased motor activity in both sexes on Day 1.
Chronic dietary (All populations)	LOAEL= 40 mg/kg/day.	Chronic RfD = 0.013 mg/kg/day.	The POD of 40 mg/kg/day based on a weight of evidence approach from the 4 rat studies listed below.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
	UF_A = 10x UF_H = 10x FQPA SF (UF_L/UF_{DB}) = 30x (for lack of CTA study and LOAEL to NOAEL extrapolation).	cPAD = 0.013 mg/kg/day	*Subchronic neurotoxicity (SCN) (Fischer rat):* NOAEL of 2.38 mg/kg/day based on the significant decreases in body weight, body weight gain, and food consumption seen at 11.28 mg/kg/day (LOAEL) in males. *Acute neurotoxicity (ACN) (Fischer rat):* NOAEL was not established. The LOAEL is 40 mg/kg/day based on the increase in landing foot splay in female rats and the decrease in motor activity seen in both genders on Day 1. (A 10X LOAEL to NOAEL uncertainty factor (UF_L) yields a derived POD of 4 mg/kg/day (40÷10)). *Combined chronic toxicity/carcinogenicity (CD rats):* NOAEL of 8.46/10.69 mg/kg/day based on increased relative liver weight and histopathological lesions in the liver, thyroid, and ovaries at 42.59/55.09 mg/kg/day (LOAEL). *Male pubertal study (CD rats):* NOAEL of 2.5 mg/kg/day based on decreased serum T4 at 10 mg/kg/day (LOAEL).
Incidental oral short-term (1 to 30 days).	LOAEL= 40 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF (UF_L /UF_{DB}) = 30x (for lack of CTA study and LOAEL to NOAEL extrapolation).	Residential LOC for MOE = 3000.	Same as Chronic RfD.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 100 mg/kg/day.	Residential LOC for MOE = 1000. UF_A = 10x UF_H = 10x FQPA SF (UF_{DB}) =10x (for lack of CTA study).	28-day dermal toxicity study in rat: LOAEL = 500 mg/kg/day based on decreases in body weight and food consumption in males.
Inhalation short-term (1 to 30 days) and Intermediate-term (1 to 6 months).	LOAEL= 40 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF (UF_L/UF_{DB}) = 30x (for lack of CTA study and LOAEL to NOAEL extrapolation).	Residential LOC for MOE = 3,000.	Same as Chronic RfD.
Cancer (Oral, dermal, inhalation).	Classification: ''Not Likely to be Carcinogenic to Humans'' at doses that do not result in induction of hepatic cell proliferation or metabolic enzymes leading to disruption of thyroid or gonadal endocrine axes.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. $UF_{S\ =}$ use of a short-term study for long-term risk assessment.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propyzamide, EPA considered exposure under the time-limited tolerance established by this action as well as all existing propyzamide tolerances in 40 CFR 180.317. EPA assessed dietary exposures from propyzamide in food as follows:

i. *Acute exposure.* Such effects were identified for propyzamide. In estimating acute dietary exposure, EPA used food consumption information from the Dietary Exposure Evaluation and Model-Food Commodity Intake

Database (DEEM–FCID). As to residue levels in food, EPA assumed that propyzamide residues were present at tolerance levels in all commodities for which tolerances have been established or proposed and that 100% of the crops were treated with propyzamide.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the Dietary Exposure Evaluation and Model-Food Commodity Intake Database (DEEM–FCID). As to residue levels in food, EPA assumed that propyzamide residues were present at tolerance levels in all commodities for which tolerances have been established or proposed and that 100% of the crops were treated with propyzamide.

iii. *Cancer.* Based on the data summarized in Unit IV.A., EPA has concluded that propyzamide 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 propyzamide. Tolerance level residues and 100% CT were assumed for all food commodities.

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

Based on the Tier II Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of propyzamide for acute exposures are estimated to be 102 parts per billion (ppb) for surface water and 21 ppb for ground water; for chronic exposures for non-cancer assessments are estimated to be 47 ppb for surface water and 18.6 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 102 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value of 47 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). Propyzamide is currently registered for use on golf courses that could result in post-application residential exposures to adults and children. EPA assessed residential post-application dermal exposures from golfing for adults, children 6 to <11 and children 11 to <16 and determined that there are no post-application risk estimates of concern since the dermal margin of exposures (MOEs) are >1,000. For the golf course post-application scenarios for adults and children identified above, MOEs ranged from 1,900 to 2,500.

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

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found propyzamide to share a common mechanism of toxicity with any other substances, and propyzamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propyzamide 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 *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

C. 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 SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of quantitative or qualitative increased susceptibility in developing fetuses or in offspring of rats or rabbits following prenatal and/or postnatal exposure to propyzamide. However, a comparative thyroid assay study is required to determine whether pregnant women or developing young are more or less susceptible, compared to adults, to thyroid toxicity.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were increased to 10X for both interspecies and intraspecies variation, and 30X for the lack of a NOAEL and lack of a comparative thyroid study. That decision is based on the following findings:

i. The toxicity database for propyzamide is incomplete. The required comparative thyroid assay and subchronic inhalation studies have not been received for propyzamide; therefore, uncertainty factors identified above have been applied to account for these deficiencies. In addition, the acute dietary endpoint for the general population (including infants and children) was chosen from an acute neurotoxicity study with a lowest observed adverse effect level of 40 mg/kg/day based on the increase in landing foot splay in female rats and the decrease in motor activity observed on Day 1. As such, the lack of an established NOAEL as well as uncertainties attributed to intraspecies variability and interspecies extrapolations contributed to an incomplete toxicity database for propyzamide.

ii. There is no indication that propyzamide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study; however, there is need for additional UFs to account for the lack of a comparative thyroid study and the use of a LOAEL to extrapolate a NOAEL.

iii. There is no evidence that propyzamide 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 propyzamide in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by propyzamide.

D. 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 propyzamide will occupy 46% of the aPAD for all infants <1 year 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 dietary exposure to propyzamide from food and water will utilize 33% of the cPAD for children 1 to 2 years old, 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). Propyzamide is currently registered for a use that could result in short-term residential exposure. The Agency has identified and assessed short-term residential dermal post-application exposures for the registered golf course use for propyzamide. There are no post-application risk estimates of concern (*i.e.,* dermal MOEs ≥1,000) for the golf course use. The short-term residential exposures from the golfing use pattern were not aggregated with dietary exposures since the risk assessment endpoints for dermal and oral toxicity were different. The acute and chronic aggregate risk estimates are equivalent to the dietary risk estimates and are not of concern.

4. *Intermediate-term risk.* Intermediate-term residential exposures are not anticipated from the registered propyzamide uses, therefore, an intermediate-term aggregate assessment was not conducted.

5. *Aggregate cancer risk for U.S. population.* In accordance with the Agency's 2005 Guidelines for Carcinogenic Risk Assessment, propyzamide is classified as ''Not likely to be Carcinogenic to Humans'' at doses that do not result in induction of hepatic cell proliferation or metabolic enzymes leading to disruption of thyroid or gonadal endocrine axes. Quantification of carcinogenic risk is not required.

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 propyzamide residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression of residues in/or plant commodities (PAM II Method I, using gas-liquid chromatography with electron-capture detection (GLC/ECD)) and livestock commodities (Method GRM 02.21, using gas chromatography with negative-ion chemical ionization mass spectrometry detection (GC/MS)). These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established any MRLs for propyzamide.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of the herbicide propyzamide, including its metabolites and degradates. Compliance with the tolerance level in or on cranberry at 1 ppm is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-N-(1,1-dimethyl-2propynyl)benzamide. This tolerance expires on December 31, 2022.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 in accordance with FFDCA sections 408(e) and 408(l)(6), 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).

VIII. 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: October 16, 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 § 180.317, revise paragraph (b) to read as follows:

§ 180.317 Propyzamide; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* The time-limited tolerance specified in the table in this paragraph (b) is established for residues of the herbicide propyzamide, including its metabolites and degradates, in or on the specified agricultural commodity in the table in this paragraph (b), resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance level specified in the table in this paragraph (b) is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide in or on the commodity. The time-limited tolerance expires on the date specified in the table in this paragraph (b).

Commodity	Parts per million	Expiration date
Cranberry.	1	December 31, 2022.

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