highest residues; the OECD tolerance-calculation procedure does not permit this.

C. Revisions to Petitioned-for Tolerances

For pepper and eggplant, the available data indicate that residues may be greater than the proposed 0.6 ppm tolerance. Using the OECD tolerance-calculation procedure, EPA determined that a tolerance of 1.5 ppm is appropriate for both pepper and eggplant. Based on the highest-average field-trial residue and an average tomato paste processing factor of 2.94x, the Agency concluded that a tomato, paste tolerance of 1.2 ppm should be established.

V. Conclusion

Therefore, tolerances are established for residues of metaflumizone, (E and Z isomers; 2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl)phenyl]ethylidene]-*N*-[4-(trifluoromethoxy)phenyl] hydrazinecarboxamide) and its metabolite 4-{2-oxo-2-[3-(trifluoromethyl)phenyl]ethyl}-benzonitrile, in or on eggplant at 1.5 ppm; pepper at 1.5 ppm; tomato at 0.60 ppm; and tomato, paste at 1.2 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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). This final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: March 28, 2014.

Lois Rossi,

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 § 180.657:

■ a. Add alphabetically the commodities to the table in paragraph (a).

■ b. Add footnote 1 to the table in paragraph (a).

The additions read as follows:

§ 180.657 Metaflumizone; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Eggplant [1]	1.5
* * * * *	
Pepper [1]	1.5
Tomato [1]	0.60
Tomato, paste [1]	1.2

[1] There are no U.S. registrations as of April 4, 2014.

* * * * *

[FR Doc. 2014–07559 Filed 4–3–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0164; FRL–9903–11]

Proquinazid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of proquinazid in or on grape and raisin. DuPont Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 4, 2014. Objections and requests for hearings must be received on or before June 3, 2014, 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–2012–0164, 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), EPA West

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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0164 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 June 3, 2014. 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–2012–0164, 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.htm.*

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 May 2, 2012 (77 FR 25954) (FRL–9346–1), 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 1E7972) by DuPont Crop Protection, Stine Haskell Research Center, P.O. Box 30, Newark, DE 19714–0030. The petition requested that 40 CFR 180.674 be amended by establishing tolerances for residues of the fungicide proquinazid, 6-Iodo-2-propoxy-3-propyl-3H-quinazolin-4-one, in or on imported commodities to include grape at 0.5 parts per million (ppm) and raisin at 1.0 ppm. That document referenced a summary of the petition prepared by DuPont Crop Protection., the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has changed one of the requested commodity names from raisin; to grape, raisin; and added a significant figure to the numerical grape tolerance. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified 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 proquinazid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with proquinazid 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.

Proquinazid has no significant acute toxicity via the oral, dermal, or inhalation routes of exposure. It is not an eye or skin irritant and does not cause skin sensitization. Based on the results of a 28-day dermal study in rats (as well as the dermal lethal dose (LD) study), proquinazid is poorly absorbed through the skin.

The liver and thyroid are the primary target organs for proquinazid. In rodents, body weight/body weight gain reductions, increased liver and thyroid organ weights, hypertrophy/hyperplasia, liver enzyme induction, and thyroid hormone changes were seen across varying durations and routes of exposure in rodents but not in dogs. In the 90-day oral rat study, the low dose effects of proquinazid are characterized primarily by altered thyroid hormones and associated follicular cell hypertrophy in the thyroid. Decrements in body weight and nutritional parameters, as well as histopathological changes in the liver (including hypertrophy) were observed at higher doses. In a 28-day oral rat study, hypertrophy of the thyroid and liver was completely reversible after a 6 week recovery period. In chronic rodent studies, non-neoplastic effects in both mice and rats included thyroid follicular hyperplasia and hypertrophy, with associated thyroid hormone changes (only investigated in rats), and some marked hepatic lesions, i.e., necrosis and hyperplasia (including oval cell hyperplasia in rats). In addition, chronic exposure in rats led to increases in the incidence of liver and thyroid tumors. The mode of action for the thyroid tumors in rats involves early changes in liver enzyme regulation that lead to dis-regulation of thyroid hormone homeostasis thyroid follicular hypertrophy/hyperplasia, and thyroid follicular adenoma formation. Mode of action data were submitted on the thyroid follicular cell tumors observed in male rats and the cholangiocarcinomas observed in female rats. The hypothesized mode of action (i.e., non-genotoxic) for each tumor type (i.e, the thyroid and cholangiocarcinoma) was supported by adequate studies that clearly identified the sequence of key events, dose-response concordance, and temporal relationship to the tumor types. No treatment-related tumors were observed in male or female mice. The overall weight-of-evidence was considered sufficient to demonstrate that proquinazid thyroid follicular tumors are the result of an anti-thyroidal mode of action and that a carcinogenic response would not be expected at doses below the threshold for changes in liver enzyme regulation leading to dis-regulation of thyroid hormone homeostasis. The data also shows that rats are substantially more sensitive than humans to the development of thyroid follicular cell tumors in response to thyroid hormone imbalance. Proquinazid induced cholangiocarcinomas in female rats only at doses that produced marked liver toxicity and oval cell hyperplasia microscopically. In contrast, in both male and female rats, doses that produced less severe or no hepatotoxicity or oval cell proliferation did not produce chlolangiocarcinomas. Therefore, at high enough doses, proquinazid can cause these biochemical and histopathological effects in livers of rodents but is unlikely to be carcinogenic at doses below those causing these changes. In contrast, in both male and female rats, doses that produced less severe or no hepatoxicity or oval cell proliferation did not produce cholangiocarcinomas. Therefore, at high enough doses, proquinazid can cause these biochemical and histopathological effects in livers of rodents but is unlikely to be carcinogenic at doses below those causing these changes. Therefore, the Agency determined that quantification of risk using a non-linear approach (i.e., reference dose (RfD) will adequately protect for all chronic toxicity, including carcinogenicity, that could result from exposure to proquinazid.

There is no mutagenicity concerns from *in vivo* or *in vitro* genetic toxicity assays. Proquinazid was not found to be immunotoxic. No evidence of increased quantitative or qualitative susceptibility was seen following *in utero* exposure to proquinazid with rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. The 2-generation rat reproduction study resulted in no effects on reproduction or fertility. The offspring effects (decreases in F_1 pup weight during lactation) occurred at the same dose which caused parental effects (thyroid hypertrophy, reduced body weight gain, and food consumption). Evidence of developmental delays were observed in developmental toxicity studies in rabbits and rats and were characterized by reduced fetal weight and an increased incidence of retarded ossification and patent ductus arteriosus, respectively. These developmental effects occurred in the presence of maternal toxicity and were considered of equal toxicity.

There is limited evidence for neurotoxicity following oral exposures to proquinazid. Following a single exposure, evidence for neurotoxicity at the lowest observed adverse effect level (LOAEL) was limited to decreased motor activity in both sexes with no behavioral or neuropathology changes. At doses above the study LOAEL other effects including decreased grip strength and food splay were observed. Following repeated (dietary) exposures, there were no treatment-related clinical signs of neurotoxicity, behavioral changes or neuropathology. Specific information on the studies received and the nature of the adverse effects caused by proquinazid as well as the no observed adverse effect level (NOAEL) and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document ''Proquinazid: Human Health Risk Assessment for the Tolerance on Imported Grapes'' dated September 2013 at pages 23 through 35 in docket ID number EPA–HQ–OPP–2012–0164.

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 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 proquinazid used for human risk assessment is shown in Table 1. of this unit. Because only oral exposure are anticipated for imported grapes, no other endpoints are relevant such as dermal and inhalation exposures.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROQUINAZID 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 (General population including infants and children).	NOAEL = 50 mg/kg/bw UF_A = 10x. UF_H = 10x FQPA SF = 10x UF_{DB}	Acute RfD = aPAD = 0.050 mg/kg/bw.	Acute Neurotoxicity Study-Rat. LOAEL = 100 mg/kg/bw based on decreased motor activity seen in females on day 1.
Chronic dietary (All populations)	NOAEL= 1.2 mg/kg/day. UF_A = 13x UF_H = 10x FQPA SF = 10x UF_{DB}	Chronic RfD = cPAD = 0.004 mg/kg/day.	Chronic Toxicity/Carcinogenicity Study-Rat. LOAEL = 12 mg/kg/day based on increases in non-neoplastic liver lesions and changes in thyroid hormones and thyroid pathology.
Cancer (Oral, dermal, inhalation).	A non linear approach (i.e., RfD will adequately protect for all chronic toxicity, including carcinogenicity, that could result from exposure to proquinazid. The cPAD for proquinazid will protect for carcinogenic effects because it is below the level that caused changes in liver enzyme regulation and liver toxicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest observed adverse effect level. mg/kg/bw = milligram/kilogram/body weight. 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_{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).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to proquinazid, EPA considered exposure under the petitioned-for tolerances as well as all existing proquinazid tolerances in 40 CFR 180.674. EPA assessed dietary exposures from proquinazid 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 proquinazid. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWIA). As to residue levels in food, EPA used tolerance level residues and 100% percent crop treated (PCT). Default processing factors were used for grape juice. The Agency considers these to be highly conservative assessments.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA used tolerance level residues and 100% PCT.

iii. *Cancer.* Quantification of risk using a non-linear approach (i.e., RfD will adequately protect for all chronic toxicity, including carcinogenicity, which could result from exposure to proquinazid. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

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

2. *Dietary exposure from drinking water.* There is no drinking water exposure in the U.S. associated with the establishment of an import tolerance.

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). Proquinazid is not registered for any specific use patterns that would result in residential exposure.

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 proquinazid to share a common mechanism of toxicity with any other substances, and proquinazid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that proquinazid 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

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.* No evidence of increased quantitative or qualitative susceptibility was seen following *in utero* exposure to proquinazid with rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. The 2-generation rat reproduction study resulted in no effects on reproduction or fertility. The

offspring effects (decreases in F_1 pup weight during lactation) occurred at the same dose which caused parental effects (thyroid hypertrophy, reduced body weight gain, and food consumption). Evidence of developmental delays were observed in developmental toxicity studies in rabbits and rats were characterized by reduced fetal weight and an increased incidence retarded ossification and paten ductus arteriosus, respectively. These developmental effects occurred in the presence of maternal toxicity. For the rats, the developmental effects were seen in the presence of clear maternal toxicity, including a marked reduction in body weight gain after adjustment for uterine contents and were considered to be of equal severity.

3. *Conclusion.* In determining whether there are reliable data to amend or remove the presumptive 10X FQPA safety factor, EPA considered the following factors:

i. The toxicity database for proquinazid required by 40 CFR Part 158 is complete. However, there remains some uncertainty regarding the potential for proquinazid effects on the thyroid in the young. Effects on the thyroid (manifested as changes in hormones, weight, and histopathology) following proquinazid exposure were consistently observed in adult animals (rats) following subchronic and chronic exposures. Thyroid effects, however, were not assessed in studies involving neo- or postnatal animals, and EPA is lacking data showing the comparative effect of proquinazid on the thyroid in adult and neo- and postnatal animals.

ii. There is only limited evidence that proquinazid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. There is limited evidence for neurotoxicity following oral exposures to proquinazid. Following a single exposure, evidence for neurotoxicity at the LOAEL was limited to decreased motor activity in both sexes with no behavioral or neuropathology changes. At doses above the study LOAEL other effects including decreased grip strength and foot splay were observed. Following repeated (dietary) exposures, there were no treatment-related clinical signs of neurotoxicity, behavioral changes, or neuropathology.

iii. As discussed in Unit III.D.2., there is no evidence that proquinazid results in increased susceptibility with *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. Drinking water is not a factor because this is an import tolerance assessment. These assessments will not underestimate the exposure and risks posed by proquinazid.

Despite the lack of any indication of sensitivity in the young and the very conservative exposure assessment, EPA has determined that it lacks reliable data to choose a FQPA safety factor other than the default value of 10X given (1) the absence of data on thyroid effects on the young, including comparative thyroid data on adults and the young, and (2) the fact that thyroid effects were the most sensitive effect seen in adult animals. At the same time, after considering all of the data on proquinazid toxicity and exposure, EPA has also determined that application of a FQPA safety factor of 10X, in conjunction with inter- and intraspecies safety factors, will result in a risk assessment that protects the safety of infants and children. Although there is some uncertainty as to whether the young might have greater sensitivity to proquinazid's thyroid effects due to the absence of comparative thyroid data, two developmental studies and a reproduction study have otherwise shown no indication of sensitivity in the young to proquinazid. Additionally, the exposure assessment provides an extra margin of safety given that it is based on the conservative assumption that all grapes, and all food products derived from grapes (e.g., raisins, grape juice, wine), consumed in the United States bear residues of proquinazid at the appropriate tolerance level. This assumption is particularly conservative here because proquinazid is not registered for use in the United States. Taking into account all of these considerations, EPA concludes that no safety factor in addition to the inter- and intraspecies factors, and the default FQPA safety factor is needed to protect the safety of infants and children.

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 dietary exposure from food to proquinazid will occupy 18% of the aPAD for children 1–2 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 proquinazid from food will utilize 47% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. There are no residential uses for proquinazid. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of proquinazid is not expected.

3. *Aggregate cancer risk for U.S. population.* The cPAD of 0.004 mg/kg/day will be protective of both non-cancer and cancer effects, including rat tumors (liver, thyroid, and cholangiocarcinomas). As discussed in Unit III.E., aggregate exposure to proquinazid is below the cPAD.

4. *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 proquinazid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron capture detection) is available to enforce the proposed tolerances for residues of proquinazid on grape commodities.

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 a MRL for proquinazid. However, the tolerances established in this rule are harmonized with Canadian MRLs.

C. Revisions to Petitioned-For Tolerances

The Agency is changing the proposed commodity definition for raisins from raisin to grape, raisin. The change in the commodity definition is to make the tolerance consistent with Agency naming-conventions for commodities and crop groups. No changes are recommended for the proposed tolerance levels, but the grape tolerance is being revised from 0.5 to 0.50 to correct the number of significant figures.

V. Conclusion

Therefore, tolerances are established for residues of proquinazid in or on grape at 0.50 ppm and grape, raisin 1.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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). This final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: March 25, 2014.

Marty Marnell,

Acting Director, 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. Add § 180.674 to read as follows:

§ 180.674 Proquinazid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide, proquinazid, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only proquinazid, [6-Iodo-2-propoxy-3-propyl-3H-quinazolin-4-one), in or on the following commodities:

Commodity	Parts per million
Grape [1]	0.50
Grape, raisin [1]	1.0

[1] No U.S. registrations for Proquinazid.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2014–07563 Filed 4–3–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0110; FRL–9400–3]

Imazapic; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of imazapic in or on soybean, seed. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 4, 2014. Objections and requests for hearings must be received on or before June 3, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).