ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0258; FRL–9907–67]

Metaflumizone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metaflumizone in or on eggplant, pepper, tomato, and tomato, paste. BASF Corporation 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–2013–0258, 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–2013–0258 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–2013–0258, 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 June 5, 2013 (78 FR 33785) (FRL–9386–2), 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 3E8146) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27790. The petition requested that 40 CFR 180.657 be amended by establishing tolerances for residues of the insecticide 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 0.6 parts per million (ppm); pepper at 0.6 ppm; and tomato at 0.6 ppm. That document referenced a summary of the petition prepared by BASF Corporation, 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 determined that the tolerances for eggplant and pepper should each be established at 1.5 ppm, the tolerance for tomato should be established at 0.60 ppm, and that an additional tolerance for tomato, paste should be established at 1.2 ppm. 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 metaflumizone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with metaflumizone 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.

Hematotoxicity (toxicity of the blood) was the primary toxic effect of concern following subchronic or chronic oral exposures to metaflumizone. Splenic extramedullary hematopoiesis, increased hemosiderin, and anemia were the most common hematotoxic effects reported after repeated oral dosing with metaflumizone. Chronic oral (gavage) exposures to dogs resulted in slight decreases in mean corpuscular hemoglobin concentration and total hemoglobin, leading to increased plasma bilirubin, increased urinary urobilinogen, and increased hemosiderin in the liver. In a chronic toxicity/carcinogenicity study in mice, anemia was observed in the form of increased hemosiderin in the spleen, increased mean absolute reticulocyte count, decreased mean corpuscular volume, and mean corpuscular hemoglobin.

The postulated pesticidal mode of action of metaflumizone involves inhibition of sodium channels in target insect species; however, in mammals (rats), there were only clinical signs of neurotoxicity (i.e., piloerection and body temperature variations) with no neuropathology in the presence of systemic toxicity (e.g., recumbency and poor general state) following acute or repeated exposures. Similarly, several immune system organs seem to be affected following metaflumizone administration via the oral, dermal, and inhalation routes (e.g., the presence of macrophages in the thymus, lymphocyte necrosis in the mesenteric lymph nodes, and diffuse atrophy of the mandibular); however, there was no evidence of any functional deficits at the highest dose tested in a recently submitted and reviewed guideline immunotoxicity study. Therefore, the clinical neurotoxicity signs and the effects on the immune system organs following metaflumizone administration are likely to be secondary to the hematotoxic effects.

Metaflumizone induced an increased incidence of a missing subclavian artery at a relatively high dose that also caused severe maternal toxicity (e.g., late term abortions) in the developmental toxicity study in rabbits. There was no evidence (quantitative or qualitative) of increased susceptibility following *in utero* exposures to rats or rabbit and following pre- and post natal exposures. There was no evidence that metaflumizone is genotoxic and carcinogenicity studies with mice and rabbits were negative.

Specific information on the studies received and the nature of the adverse effects caused by metaflumizone 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 ''Metaflumizone: Human-Health Risk Assessment for Tolerances in/on Imported Tomato, Pepper, and Eggplant'' in docket ID number EPA–HQ–OPP–2013–0258.

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 (LOCs) 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 metaflumizone used for human risk assessment is provided below:

i. *Acute dietary endpoint (general population including infants and children).* An acute dietary endpoint was not established for this population group since an endpoint of concern (effect) attributable to a single dose was not identified in the database. Studies considered for this endpoint included the acute neurotoxicity study for which no toxicity was observed at any dose including the highest dose tested: The limit dose (1,000 mg/kg/day).

ii. *Acute dietary endpoint (females 13–49 years old).* This endpoint was established based on a developmental effect observed in the rabbit developmental toxicity study that can be potentially due to a single dose of metaflumizone. This effect consisted of an increased incidence of an absent subclavian artery in the offspring at the LOAEL of 300 mg/kg bw/day metaflumizone (NOAEL = 100 mg/kg bw/day). The rat developmental toxicity study was also considered for this endpoint; however, no developmental effects were observed in this study at the highest dose tested of 120 mg/kg bw/day metaflumizone. A combined uncertainty factor (UF) of 300 was applied to account for interspecies (10x) and intraspecies (10x) extrapolation. A Food Quality Protection Act (FQPA) safety factor (SF) of 3x was retained because the rabbit developmental toxicity study was performed via oral gavage dosing. In an absorption study submitted by the petitioner, dietary exposures (which are more relevant for human exposures) exhibited an approximately 2-fold greater absorption into the systemic circulation than oral gavage dosing and, thus, can potentially lead to toxicity at 2-fold lower levels of exposure. Thus, the acute population adjusted dose (aPAD) for females 13–49 years old is estimated to be 0.33 mg/kg bw/day.

iii. *Chronic dietary endpoint.* This endpoint was established based on the systemic toxicity observed in the chronic toxicity study with dogs. At the LOAEL of 30 mg/kg bw/day (NOAEL =

12 mg/kg bw/day), the effects consisted of reduced general health condition, slight to severe ataxia, recumbency, and severe salivation, slight decreases in mean corpuscular hemoglobin concentration and total hemoglobin, increased plasma bilirubin, increased urinary urobilinogen, and increased hemosiderin in the liver. A combined UF of 300 was applied to account for interspecies (10x) and intraspecies (10x) extrapolation and an FQPA safety factor of 3x. The FQPA safety factor of 3x was retained because the chronic toxicity study was performed via capsule dosing, which is a bolus dose very similar to gavage dosing (this accounts for the 2-fold greater absorption observed in dietary versus oral gavage exposures, as described in Unit III.B.ii.). Thus, the chronic population adjusted dose (cPAD) is estimated to be 0.040 mg/kg bw/day.

iv. *Incidental oral (short- and intermediate-term).* This endpoint was selected on the basis of the maternal effects observed in the rat 2-generation reproductive toxicity study at the LOAEL of 50 mg/kg bw/day metaflumizone (NOAEL = 20 mg/kg bw/day). Maternal toxicity consisted of poor general health and body weight deficits which were also associated with improper nursing behavior. Similar effects were also noted in a developmental neurotoxicity study (gavage, range finding) also considered for this endpoint. In this study, poor maternal health was also observed at the LOAEL of 120 mg/kg bw/day metaflumizone (NOAEL = 80 mg/kg bw/day). Both studies considered for this endpoint achieved a clear maternal NOAEL for the offspring effects, but the NOAEL of 20 mg/kg bw/day for the 2-generation reproductive toxicity study is considered more protective. The Agency's LOC for this scenario is 300 based on a 10x intraspecies factor, a 10x interspecies factor, and an FQPA safety factor of 3x (to account for the 2-fold greater absorption observed in dietary versus oral gavage exposures, as described in Unit III.B.ii.).

v. *Dermal (short- and intermediate-term).* This endpoint was based on a rat 90-day dermal toxicity study in which deficits in body weight, body-weight gain and food consumption (in males and females); anogenital smearing; increased macrophages in the thymus; lymphocyte necrosis in the mesenteric lymph nodes; diffuse atrophy of the mandibular lymph node; and increased hemosiderin in the liver (females only) were observed at the LOAEL of 300 mg/kg bw/day (NOAEL = 100 mg/kg bw/day). The Agency's LOC for this scenario is 100 based on a 10x interspecies factor and a 10x intraspecies factor.

vi. *Inhalation (short- and intermediate-term).* There is a 28-day inhalation study that is adequate for both exposure durations. There was no NOAEL identified for female rats. At the LOAEL of 0.10 mg/L metaflumizone (NOAEL = 0.03 mg/L), histopathology of the nasal tissues, lungs, thymus, prostate, and adrenal cortex was observed in males. The LOAEL identified in females resulted in lymphocyte necrosis in the mesenteric lymph node.

The methods and dosimetry equations described in EPA's reference concentration (RfC) guidance (1994) are suited for calculating human-equivalent concentrations (HECs) based on the inhalation toxicity point of departure (NOAEL, LOAEL) for use in MOE calculations. The regional-deposited-dose ratio (RDDR), which accounts for the particulate diameter (mass median aerodynamic diameter (MMAD) and geometric standard deviation [σ_g] of aerosols), can be used to estimate the different dose fractions deposited along the respiratory tract. The RDDR accounts for interspecies differences in ventilation and respiratory-tract surface areas. Thus, the RDDR can be used to adjust an observed inhalation particulate exposure of an animal to the predicted inhalation exposure for a human. For the subchronic inhalation toxicity study with metaflumizone, an RDDR was estimated at 2.81 based on systemic effects (lymphocyte necrosis in the mesenteric lymph node) in females at the LOAEL of 0.03 mg/L (no NOAEL established) and a MMAD of 1.7μm and σ_g of 2.7.

For this action with metaflumizone, only residential handler scenarios are being assessed for which 2-hr/day inhalation exposures are assumed. Adjustment to shorter exposure scenarios relative to the animal toxicity study duration (e.g., 2 hr residential exposures) should only be made if there is time-course information that would support a shorter time-frame. Since there is no such information available for metaflumizone, the unadjusted animal POD was used for HEC estimation. The HEC equals the product of the LOAEL from the study and the RDDR or 0.084 mg/L. The FQPA SF of 10x is being retained for lack of a NOAEL for females in the study. The standard interspecies extrapolation UF can be reduced from 10x to 3x due to the HEC calculation accounting for interspecies differences in pharmacokinetics (not pharmacodynamic). The intraspecies UF remains at 10x. Therefore, the LOC for this scenario is 300, which includes the FQPA SF of 10x, interspecies (3x), and intraspecies (10x) extrapolation.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metaflumizone, EPA considered exposure under the petitioned-for tolerances as well as all existing metaflumizone tolerances in 40 CFR 180.657. EPA assessed dietary exposures from metaflumizone 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 metaflumizone. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance-level residues. It was further assumed that 100% of crops with the requested uses of metaflumizone were treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues. It was further assumed that 100% of crops with the requested uses of metaflumizone were treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that metaflumizone 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 or PCT information in the dietary assessment for metaflumizone. Tolerance level residues and/or 100% crop treated (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 metaflumizone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of metaflumizone. Further information regarding EPA drinking water models used in pesticide exposure assessment

can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of metaflumizone for acute exposures are estimated to be 1.14 parts per billion (ppb) for surface water and 0.00214 ppb for ground water. The EDWCs of metaflumizone for chronic exposures for non-cancer chronic assessments are estimated to be 0.597 ppb for surface water and 0.00214 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 1.14 ppb was used to assess the contribution of drinking water. For chronic dietary risk assessment, the water concentration value of 0.597 ppb was used to assess the contribution of 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). Metaflumizone is currently registered for the following uses that could result in residential exposures: As a fire ant bait for application to lawns, landscapes, golf courses, and other non-cropland area; and as a fly bait for use around industrial buildings, commercial facilities, agricultural structures/premises, and recreational facilities/areas.

EPA assessed residential exposure using the following assumptions: Fire ant bait applications to home lawns are expected to result in short-term, residential handler exposure to adults. Fire ant bait applications to lawns and golf-courses are expected to result in short-term, post-application dermal exposure to adults, children 11 to <16 years old, and children 1 to <2 years old, and incident oral exposure for children 1 to <2 years old. For the fly bait product, residential handler exposure is not expected, because the product is applied by commercial handlers. The fly bait product is expected to result in short-term, post-application dermal exposure to adults, children 11 to <16 years old, and children 1 to <2 years old, and incident oral exposure for children 1 to <2 years old.

For residential handlers, dermal and inhalation exposures are combined since the endpoints are similar for these routes. For children (1- to <2-year-olds), post-application hand-to-mouth and dermal exposures are combined. Since the LOCs for the dermal, inhalation and incidental oral routes are not the same (dermal LOC = 100, inhalation LOC = 300, and incidental oral LOC = 300), these routes were combined using the aggregate risk index approach. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 metaflumizone to share a common mechanism of toxicity with any other substances, and metaflumizone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that metaflumizone 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.* There is no evidence for increased qualitative or quantitative sensitivity/susceptibility resulting from pre- and/or postnatal exposures. In the rat prenatal development toxicity study, there was no offspring toxicity reported at any dose tested whereas in the rabbit study a maltransformation based on an absent subclavian artery was noted to occur only in the presence of severe maternal toxicity. Similarly, offspring mortality in the 2-generation reproductive toxicity occurred only in the presence of a poor maternal health state. Thus, there is no evidence for increased susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced from 10x to 3x for all oral exposure scenarios; retained at 10x for inhalation exposure scenarios; and reduced to 1x for dermal exposures. That decision is based on the following findings:

i. The toxicity database for metaflumizone is complete.

ii. There is no indication that metaflumizone directly affects the nervous system. Clinical signs consisting of piloerection and body temperature variations were observed only in the absence of neuropathology and in the presence of a poor general state. There is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. There is no evidence that metaflumizone results in increased susceptibility in the prenatal developmental studies in rats and rabbits or in developing rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases.

The dietary analyses assumed tolerance-level residues, 100% CT, and modeled drinking water estimates. Therefore, EPA concludes that while the submission of data/information by the petitioner addressing the residue chemistry deficiencies identified in a previous petition may conceivably result in adjustment of the maximum theoretical residue estimate, actual metaflumizone dietary exposure estimates will not be greater than those generated in the current risk assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to metaflumizone in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by metaflumizone.

v. Dietary exposures (which are more relevant for human exposures) exhibited an approximately 2-fold greater absorption into the systemic circulation as compared to oral gavage and, thus,

can potentially lead to toxicity at 2-fold lower levels of exposure. Applying a FQPA SF of 3x for all oral exposure scenarios is adequate to protect against any greater toxicity that might occur in dietary exposures (absorption was noted to be 2-fold greater in dietary versus oral gavage studies).

vi. The FQPA SF of 10x is being retained for inhalation exposure scenarios for the use of a LOAEL instead of a NOAEL (no NOAEL achieved) for histopathological lesions consisting of lymphocyte necrosis in the mesenteric lymph node. The FQPA SF of 10x is adequate because the effect (lymphocyte necrosis) is considered minimal to slight and does not exhibit a strong dose dependence.

vii. The FQPA SF for dermal exposure scenarios is being reduced from 10x to 1x since there is a route-specific study with a clear NOAEL.

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 metaflumizone will occupy 1.6% of the aPAD for females 13–49 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to metaflumizone from food and water will utilize 5.8% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of metaflumizone is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Metaflumizone is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to metaflumizone. Since the LOC and toxicological points of departure for the short-term dermal and oral routes of exposure differ, the aggregate risk index method was used to determine aggregate risk (aggregate risk indices >1 are not a risk of concern).

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate risk indices of 43 for the general population, and 27 for children 1–2 years old. Because EPA's LOC for metaflumizone is an aggregate risk index less than 1, the aggregate risks are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Metaflumizone is currently registered for uses that could result in intermediate-term residential exposure; however, since the PODs for the short- and intermediate-term durations are the same for metaflumizone, the short-term aggregate assessment is protective of intermediate-term exposures.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatograph/mass spectrometer/mass spectrometer (LC/MS/MS) Method 531/0) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for metaflumizone in or on tomato at 0.6 ppm. This MRL is the same as the tolerance established for metaflumizone in or on tomato in the United States. The Codex has established MRLs for metaflumizone in or on eggplant at 0.6 ppm and pepper at 0.6 ppm. These MRLs are different than the tolerances established for metaflumizone in the United States.

The currently established Codex MRLs are based on the 2009 Joint Food and Agricultural Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues (JMPR) metaflumizone report, and this report was utilized in the Agency's residue chemistry review. The difference in the United States tolerances and the Codex MRLs is thus due to the following issues:

i. The United States metaflumizone tolerance expression for crops includes metaflumizone (E and Z isomers) and the metabolite M320I04. The Codex MRL expression differs in that it does not include M320I04. The Agency determined that M320I04 should be included as a residue of concern for risk assessment and tolerance enforcement purposes as it is identified at significant concentrations in the submitted metabolism study and is the primary residue in some processed commodities.

ii. Harmonization with the Codex MRLs for pepper and eggplant is not appropriate because the U.S. residue data for pepper (and eggplant by translation) indicate maximum residues of in excess of 0.6 ppm. The 1.5 ppm tolerances for both pepper and eggplant are based on the Organisation for Economic Co-operation and Development (OECD) tolerance-calculation procedure. The current Codex MRLs were established using the North American Free Trade Agreement (NAFTA) tolerance-calculation procedure which allowed the establishment of tolerances less than the

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