calculating annual gas consumption for each fluorinated GHG and N_2O used at your facility and emissions from the use of each fluorinated heat transfer fluid.

* * * * *

(3) Ensure that the inventory at the beginning of one reporting year is identical to the inventory reported at the end of the previous reporting year. This requirement does not apply to the end-of-the-year inventory of fluorinated heat transfer fluids in 2011 and the beginning-of-the-year inventory of the same in 2012.

* * * * *

■ 7. Section 98.95 is amended by revising paragraph (b) to read as follows:

§ 98.95 Procedures for estimating missing data.

* * * * *

(b) If you use fluorinated heat transfer fluids at your facility and are missing data for one or more of the parameters in Equation I–16 of this subpart, you must estimate fluorinated heat transfer fluid emissions using the arithmetic average of the emission rates for the reporting year immediately preceding the period of missing data and the months immediately following the period of missing data. Alternatively, you may estimate missing information using records from the fluorinated heat transfer fluid supplier. You must document the method used and values used for all missing data values.

■ 8. Section 98.96 is amended by:
■ a. Revising paragraph (c)(4).
■ b. Revising paragraph (r).
■ c. Revising paragraph (s).
■ d. Adding paragraph (u).
■ e. Adding paragraph (v).

§ 98.96 Data reporting requirements.

* * * * *

(c) * * *

(4) Each fluorinated heat transfer fluid emitted as calculated in Equation 1–16 of this subpart.

* * * * *

(r) For fluorinated heat transfer fluid emissions, inputs to the fluorinated heat transfer fluid mass balance equation, Equation I–16 of this subpart, for each fluorinated heat transfer fluid used.

(s) Where missing data procedures were used to estimate inputs into the fluorinated heat transfer fluid mass balance equation under § 98.95(b), the number of times missing data procedures were followed in the reporting year, the method used to estimate the missing data, and the estimates of those data.

* * * * *

(u) For each fluorinated heat transfer fluid used, whether the emission estimate includes emissions from all applications or from only the applications specified in the definition of fluorinated heat transfer fluids in § 98.98.

(v) For reporting year 2012 only, the date on which you began monitoring emissions of fluorinated heat transfer fluids whose vapor pressure falls below 1 mm Hg absolute at 25 °C. This is either January 1, 2012 or March 23, 2012.

■ 9. Section 98.98 is amended by removing the definition of ''Heat transfer fluids'' and adding the definition of ''Fluorinated heat transfer fluids'' in alphabetical order to read as follows:

§ 98.98 Definitions.

* * * * *

Fluorinated heat transfer fluids means fluorinated GHGs used for temperature control, device testing, cleaning substrate surfaces and other parts, and soldering in certain types of electronics manufacturing production processes. Fluorinated heat transfer fluids do not include fluorinated GHGs used as lubricants or surfactants. For fluorinated heat transfer fluids under this subpart I, the lower vapor pressure limit of 1 mm Hg in absolute at 25 °C in the definition of *Fluorinated greenhouse gas* in § 98.6 shall not apply. Fluorinated heat transfer fluids used in the electronics manufacturing sector include, but are not limited to, perfluoropolyethers, perfluoroalkanes, perfluoroethers, tertiary perfluoroamines, and perfluorocyclic ethers.

* * * * *

■ 10. Table I–2 to Subpart I is revised to read as follows:

TABLE I–2 TO SUBPART I OF PART 98—EXAMPLES OF FLUORINATED GHGS AND FLUORINATED HEAT TRANSFER FLUIDS USED BY THE ELECTRONICS INDUSTRY

Product type	Fluorinated GHGs and fluorinated heat transfer fluids used during manufacture
Electronics	CF_4, C_2F_6, C_3F_8, c-C_4F_8, c-C_4F_8O, C_4F_6, C_5F_8, CHF_3, CH_2F_2, NF_3, SF_6, and fluorinated HTFs (CF_3-(O-$CF(CF_3)$-$CF_2)_n$-(O-$CF_2)_m$-O-CF_3, C_nF_{2n+2}, $C_nF_{2n+1}(O)C_mF_{2m+1}$, $C_nF_{2n}O$, $(C_nF_{2n+1})_{3N}$).

[FR Doc. 2012–3769 Filed 2–21–12; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0168; FRL–9333–4]

Metaflumizone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metaflumizone in or on citrus fruit, tree nuts, almond hulls; and grape. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 22, 2012. Objections and requests for hearings must be received on or before April 23, 2012, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0168. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Julie Chao, Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8735; email address: *chao.julie@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/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–2008–0168 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 April 23, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2008–0168, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of August 10, 2011 (76 FR 49396) (FRL–8882–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7260) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide metaflumizone, in or on: Fruit, citrus, group 10 at 0.04 ppm; nut, tree, group 14 at 0.04 ppm; almond, hulls at 0.04 ppm; and grape at 0.04 ppm. That notice 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.

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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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. 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 (HDT) 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 the document entitled ''Metaflumizone. Revised Human-Health Risk Assessment Associated with a Section 3 Registration for a Fire Ant Bait for Application to Citrus, Tree Nuts, and Grape, and a new Section 3 Registration for a Fly Bait for Application around Industrial, Commercial, Agricultural, and Recreational Facilities/Structures and Premises'' in docket ID number EPA–HQ–OPP–2008–0168.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for metaflumizone used for human risk assessment is provided in this unit:

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 in which no toxicity was observed at any dose including the HDT, which is the limit dose (1,000 milligrams/kilograms/day (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 body/weight/day (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 HDT of 120 mg/kg bw/day metaflumizone. A combined uncertainty factor of 300 was applied to account for interspecies (10X) and intraspecies (10X) extrapolation and a Food Quality Protection Act (FQPA) safety factor of 3X. 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, leading to increased plasma bilirubin, increased urinary urobilinogen, and increased hemosiderin in the liver. A combined uncertainty factor of 300 was applied to account for interspecies (10X) and intraspecies (10X) extrapolation and an FQPA safety factor of 3X. 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 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 level of concern for this scenario is 300 based on a 10X intraspecies factor, a 10X interspecies factor, and an FQPA safety factor of 3X.

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 level of concern 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 for this exposure scenario. There was no NOAEL identified for female rats. At the LOAEL of 0.10 mg/Liter (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 Agency's level of concern for this scenario is 1,000 based on a 10X interspecies factor, a 10X intraspecies factor, and an FQPA safety factor of 10X. Route-specific toxicity studies were selected for assessment of

short-intermediate-term dermal, inhalation, and oral exposures. Short-intermediate-term dermal and inhalation exposures can be aggregated based on the immunotoxic effects seen at the LOAEL in the selected studies. Short/intermediate-term oral, dermal, and inhalation exposures can be aggregated based on the decreased body weight or decreased body-weight gain effects seen at the LOAEL in the selected oral and dermal studies and at doses above the LOAEL in the selected inhalation study.

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. 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) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). 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 1994–1996 and 1998 CSFII. 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 PCT 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 to drinking water. For chronic dietary risk assessment, the water concentration of value 0.597 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). Metaflumizone is currently registered for the following uses that could result in residential exposures: Pet spot-on products to control fleas on dogs and cats; fire ant bait products for application to lawns, landscapes, golf courses, and other non-cropland area. In addition, a pending fly bait product is proposed for use in areas where people may be present; therefore, a residential exposure assessment was performed for this use.

EPA assessed residential exposure using the following assumptions: For the pet spot-on products, residential handler exposure is not expected, because the product is applied directly from a tube to the pet. Pet spot-on applications are expected to result in short- and intermediate-term post-application dermal exposure to all populations, and incident oral exposure (i.e., hand-to-mouth) for children 3 to <6 years of age. For the 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, landscapes, golf-courses, and other non-cropland areas are expected to result in short-term, post-application dermal exposure to adults, adolescents, and children 3 to <6 years old, and incident oral exposure for children 3 to <6 years old. For the pending fly bait product, residential handler exposure is not expected, because the product is applied by commercial handlers. The pending fly bait product is expected to result in short-term, post-application dermal exposure to adults and children 3 to <6 years old, and incident oral exposure to children 3 to <6 years old.

For residential handlers, dermal and inhalation exposures are combined since the endpoints are similar for these routes. For children (3 to <6 year olds), post-application hand-to-mouth and dermal exposures are combined. Since the levels of concern (LOCs) for the dermal, inhalation and incidental oral routes are not the same (dermal LOC = 100, inhalation LOC = 1,000, 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. 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 prenatal 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 safety factor 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 *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 analyses assumed tolerance-level residues, 100 PCT, and modeled drinking water estimates. Therefore, HED concludes that while the submission of data/information by the petitioner addressing the residue chemistry deficiencies 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 and, thus, can potentially lead to toxicity at 2-fold lower levels of exposure. Applying a FQPA safety factor 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 safety factor 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 safety factor of 10X is adequate due to the severity of lymphocyte necrosis being minimal to slight and not exhibiting a strong dose dependence.

vii. The FQPA safety factor 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% of the aPAD for females 13–49 years old. An acute dietary exposure estimate was generated for females 13–49 years old, but not for the remaining population subgroups since an endpoint attributed to a single dose was not identified for those populations.

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 <1% 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 level of concern (LOC) is different for dermal and oral exposures (100 and 300, respectively), 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 3 for the general population, and 2 for children 1–2 years old. Since the LOCs for the dermal, inhalation and incidental oral routes are not the same (dermal LOC = 100, inhalation LOC = 1,000, and incidental oral LOC = 300), these routes were combined using the aggregate risk index approach. Because EPA's LOC for metaflumizone is an aggregate risk index less than 1, the aggregate risks are not of concern. These aggregate risk indices utilize residential exposure estimates from the pet spot-on products, which represent the worst-case exposure scenario. However, it should be noted that all registered pet spot-on products containing metaflumizone are pending voluntary cancellation; therefore, these aggregate risk indices can be considered conservative.

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 longer-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 U.N. 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 metaflumizone.

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: Fruit, citrus, group 10 at 0.04 ppm; nut, tree, group 14 at 0.04 ppm; almond, hulls at 0.04 ppm; and grape at 0.04 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Pub. L. 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: February 3, 2012.

Steven Bradbury,

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. Section 180.657 is added to subpart C to read as follows:

§ 180.657 Metaflumizone; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide metaflumizone, 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 the sum 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, calculated as the stoichiometric equivalent of metaflumizone, in or on the following commodities:

Commodity	Parts per million
Almond, hulls	0.04
Fruit, citrus, group 10	0.04
Grape	0.04
Nut, tree, group 14	0.04

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

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

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

[FR Doc. 2012–3795 Filed 2–21–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[EPA–HQ–SFUND–2011–0965; FRL–9635–9]

Designation of Hazardous Substances; Designation, Reportable Quantities, and Notification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to reinstate the maximum observed constituent concentrations for several listed hazardous wastes that were inadvertently removed from the regulations by a November 8, 2000 final rule.

DATES: This rule is effective on April 23, 2012 without further notice, unless EPA receives adverse comment by March 23, 2012. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–2011–0965, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: superfund.docket@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* Environmental Protection Agency, EPA Docket Center (EPA/DC), Superfund Docket, Mailcode: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20460. Attention Docket ID No. *EPA–HQ–SFUND–2011–0965.* Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–2011–0965. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the EPA–HQ–SFUND–2011–0965 docket. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Superfund Docket telephone number is (202) 566–0276. EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: For general information, contact the Superfund, TRI, EPCRA, RMP and Oil Information Center at (800) 424–9346 or TDD (800) 553–7672 (hearing impaired). In the Washington, DC metropolitan area, call (703) 412–9810 or TDD (703) 412–3323. For more detailed information on specific aspects of this direct final rule, contact Lynn Beasley at (202) 564–1965 (*beasley.lynn@epa.gov*), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460–0002, Mail Code 5104A.

SUPPLEMENTARY INFORMATION:

I. Why is EPA using a direct final rule?

EPA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. This action merely reinstates the maximum observed constituent concentrations for several listed hazardous wastes that were inadvertently removed from regulations by a November 8, 2000 final rule. However, in the ''Proposed Rules'' section of today's **Federal Register,** we are also publishing a separate proposed rule to reinstate these same maximum observed constituent concentrations for several listed hazardous wastes that were inadvertently removed from the regulations if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document.

If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect until EPA addresses all public comments in any subsequent final rule based on the proposed rule.

II. Does this action apply to me?

Type of entity	Examples of affected entities
Federal Agencies	National Response Center and any Federal agency that may release or respond to releases of hazardous substances.