of potassium hypochlorite in or on all commodities.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0823; FRL–8864–9]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on mango and wax jambu. Syngenta Crop Protection, Incorporated requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 2, 2011. Objections and requests for hearings must be received on or before May 2, 2011, 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–2009–0823. 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: Tony Kish, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 308–9443; e-mail address: *kish.tony@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://www.gpoaccess.gov/ecfr.*

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–2009–0823 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 May 2, 2011. 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–2009–0823, 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 Tolerances

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL–8801–5), 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 9E7573) by Syngenta Crop Protection, Inc., P. O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.475 be amended by establishing tolerances for residues of the fungicide, difenoconazole, [1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H–1,2,4-triazole], in or on mango at 0.09 parts per million(ppm) and waxapple at 1.5 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., 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 revised the proposed tolerance for mango, fruit from 0.09 ppm to 0.07 ppm to reflect the Agency's recommended tolerance level. Additionally, EPA corrected commodity definitions from "mango, fruit" to "mango" and "waxapple" to "wax jambu" to reflect prescribed terminology. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with 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 difenoconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with difenoconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

Difenoconazole possesses low acute toxicity by the oral, dermal and inhalation routes of exposure. It is not considered to be an eye or skin irritant and is not a dermal sensitizer.

In an acute neurotoxicity study in rats, reduced fore-limb grip strength was observed on day 1 in males and clinical signs of neurotoxicity in females at the limit dose of 2,000 milligrams/kilogram (mg/kg). This effect in males is considered as transient since it was not observed at later observation points and toxicity in females was observed only at doses exceeding the limit dose. In a subchronic neurotoxicity study in rats decreased hind limb strength was observed only in males, which was considered as nonspecific in nature.

Difenoconazole is not a developmental or reproductive toxicant. Chronic effects in mice and rat studies are seen as cumulative decreases in body weight gains.

Difenoconazole is not mutagenic. Evidence for carcinogenicity was seen only in the mice study, where liver tumors were induced at excessively high doses for carcinogenicity testing. Liver tumors were observed in mice at 300 ppm and higher. Based on excessive toxicity observed at the two highest doses of 2,500 and 4,500 ppm, the absence of tumors at two lower doses of 10 and 30 ppm, as well as, the absence of genotoxic effects, the Agency classified difenoconazole as a Group C, possible human carcinogen with a non-linear margin-of-exposure (MOE) approach for human risk characterization.

Specific information on the studies received and the nature of the adverse effects caused by difenoconazole as well as the no-observed-adverse-effects-level (NOAEL) and the lowest-observed-adverse-effects-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document entitled, "Difenoconazole FQPA Human Health Risk Assessment to Support the Establishment of Import Tolerances on Mango and Waxapple (also known as Wax jambu)," at pages 28–35, dated January 28, 2010, Document No. EPA–HQ–OPP–2009–0823–003.

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 difenoconazole used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DIFENOCONAZOLE 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 (All populations).	NOAEL = 25 mg/kg/day .... UF_A = 10x UF_H = 10x FQPA SF = 1x	aRfD = 0.25 mg/kg/day ..... aPAD = 0.25 mg/kg/day	Acute Neurotoxicity Study in rats LOAEL = 200 mg/kg/day in males based on reduced fore-limb grip strength in males on day 1.
Chronic dietary (All populations).	NOAEL = 0.96 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	cRfD = 0.01 mg/kg/day ..... cPAD = 0.01 mg/kg/day	Combined chronic toxicity/carcinogenicity (rat; dietary) LOAEL = 24.1/32.8 mg/kg/day (M/F) based on cumulative decreases in body-weight gains.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Oral NOAEL = 1.25 mg/kg/day (dermal absorption factor = 15.3%). UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = < 100.	Reproduction and fertility effects (rat; dietary) Offspring LOAEL = 12.5 mg/kg/day based on reduction in body weight of F_0 females prior to mating, gestation and lactation.
Inhalation short-term (1 to 30 days) and Intermediate-term Inhalation (1 to 6 months).	Oral NOAEL= 1.25 mg/kg/day inhalation absorption rate = assumed as 100% UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE < 100.	Reproduction and fertility effects (rat; dietary) Offspring LOAEL = 12.5 mg/kg/day based on reduction in body weight of F_0 females prior to mating, gestation and lactation.
Cancer (Oral, dermal, inhalation).	Difenoconazole is classified as a Group C, possible human carcinogen with a non-linear (MOE) approach for human risk characterization.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to difenoconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing difenoconazole tolerances in 40 CFR 180.475. EPA assessed dietary exposures from difenoconazole 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 difenoconazole. 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, 100 percent crop treated (PCT), and the available empirical or Dietary Exposure Evaluation Model (DEEM™) (ver. 7.81) default processing factors.

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 for some commodities, average field trial residues for the majority of commodities, the available empirical or DEEM™ (ver. 7.81) default processing factors, and 100 PCT.

iii. *Cancer.* No evidence of carcinogenicity was seen in rats. Evidence for carcinogenicity was seen in mice, where liver tumors were induced at doses which were considered to be excessively high for carcinogenicity testing. Liver tumors were observed in mice at 300 ppm and higher; however, based on excessive toxicity observed at the two highest doses of 2,500 and 4,500 ppm (females terminated after 2 weeks due to excessive toxicity resulting in moribundity and death), the absence of tumors at two lower doses of 10 and 30 ppm and the absence of genotoxic effects, the Agency classified difenoconazole as a Group C, possible human carcinogen with a non-linear MOE approach for human risk characterization. A MOE approach in risk assessment was chosen utilizing the NOAEL of 30 ppm (4.7 and 5.6 mg/kg/day in males and females, respectively) and the LOAEL of 300 ppm (46 and 58 mg/kg/day in males and females, respectively) from the mouse study using only those biological endpoints which were relevant to tumor development (*i.e.,* hepatocellular hypertrophy, liver necrosis, fatty changes in the liver and bile stasis). However, EPA determined that a quantitative cancer exposure assessment is unnecessary since the NOAEL (4.7 and 5.6 mg/kg/day in males and females, respectively) to assess cancer risk is higher than the NOAEL (0.96 and 1.27 mg/kg/day in males and females, respectively) to assess chronic risks. Therefore, the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residues and percent crop treated (PCT) information.* EPA did not use PCT information in the dietary assessment of difenoconazole. EPA used anticipated residues including average field trial residues for the majority of commodities, the available empirical or DEEM™ (ver. 7.81) default processing factors; and 100 PCT information in the chronic dietary assessment for difenoconazole.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require, pursuant to FFDCA section 408(f)(1), that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* Although the subject petition is for import tolerances and therefore does not result in drinking water exposure, there are existing uses of difenoconazole registered in the United States. The drinking water assessment was conducted for parent compound only. The fate and transport database for difenoconazole were sufficient to conduct the drinking water assessment.

The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for difenoconazole in drinking water. These simulation models take into

account data on the physical, chemical, and fate/transport characteristics of difenoconazole. 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 difenoconazole for acute exposures are estimated to be 15.8 parts per billion (ppb) for surface water and 0.0128 ppb for ground water.

Chronic exposures for non-cancer assessments are estimated to be 10.4 ppb for surface water and 0.0128 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 15.8 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 10.4 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).

Difenoconazole is currently registered for the following uses that could result in residential exposures: Ornamentals. EPA assessed residential exposure using the following assumptions: Adults may be exposed to difenoconazole from its currently registered use on ornamentals. Residential pesticide handlers may be exposed to short-term duration (1–30 days) only. The dermal and inhalation (short-term) residential exposure was assessed for "homeowners" mixer/loader/applicator wearing short pants and short-sleeved shirts as well as shoes plus socks using garden hose-end sprayer, "pump-up" compressed air sprayer, and backpack sprayer.

No post-application exposure is expected. 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."

Difenoconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, *see* EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

Difenoconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including difenoconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (*e.g.,* use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (*i.e.,* high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov,* Docket Identification (ID) Number EPA–HQ–OPP–2005–0497.

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.* EPA determined that the available data indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to difenoconazole. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals. In the prenatal developmental toxicity study in rats, maternal toxicity was manifested as decreased body weight gain and food consumption at the LOAEL of 85 mg/kg/day; the NOAEL was 16 mg/kg/day. The developmental toxicity was manifested as alterations in fetal ossifications at 171 mg/kg/day; the developmental NOAEL was 85 mg/kg/day. In a developmental toxicity study in rabbits, maternal and developmental toxicity were seen at the same dose level (75 mg/kg/day). Maternal toxicity in rabbits were manifested as decreased body weight gain and decreased food consumption, while developmental toxicity was manifested as decreased fetal weight. In a 2-generation reproduction study in rats, there were decreases in maternal body weight gain and decreases in body weights of F_1 males at the LOAEL of 12.5 mg/kg/day; the parental systemic and off spring toxicity NOAEL was 1.25 mg/kg/day.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF

were reduced to 1x. That decision is based on the following findings:

i. The toxicity database is adequate for conducting a FQPA risk assessment. At this time, an immunotoxicity study is not available. However, the toxicology database for difenocanazole does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. An immunotoxicity study is now required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower point of departure (POD) than that currently in use for overall risk assessment, and therefore, a database uncertainty factor (UFDB) is not needed to account for lack of this study.

ii. The acute and subchronic neurotoxicity studies in rats are available. These data show that difenoconazole exhibits some evidence of neurotoxicity in the database, but the effects are transient or occur at doses exceeding the limit dose. EPA concluded that difenoconazole is not a neurotoxic compound. Based on the toxicity profile, and lack of neurotoxicity, a developmental neurotoxicity study in rats is not required nor is an additional database uncertainty factor needed to account for the lack of this study.

iii. There is no evidence that difenoconazole results in increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data.

iv. There are no residual uncertainties identified in the exposure databases. A conservative dietary food exposure assessment was conducted. Acute dietary food exposure assessments were performed based on tolerance-level residues, 100 PCT, and the available empirical or DEEM™ (ver. 7.81) default processing factors. Chronic dietary exposure assessments were based on tolerance-level residues for some commodities, average field trial residues for the majority of commodities, the available empirical or DEEM™ (ver. 7.81) default processing factors, and 100 PCT. These are conservative approaches and are unlikely to understate the residues in food commodities.

EPA also made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to difenoconazole in drinking water. Post-application exposure of children as well as incidental oral exposure of toddlers is not expected. These assessments will not underestimate the exposure and risks posed by difenoconazole.

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. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., "chronic exposure."

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to difenoconazole will occupy 16% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to difenoconazole from food and water will utilize 45% of the cPAD for children 1 to 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 difenoconazole 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).

Difenoconazole is currently registered for ornamentals 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 difenoconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures result in aggregate MOEs of 180 or greater. Because EPA's level of concern for difenoconazole is a MOE of 100 or below, these MOEs resulting from short-termed exposure to difenoconazole 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).

An intermediate-term adverse effect was identified; however, difenoconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for difenoconazole.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.C.1.iii., the chronic dietary risk assessment is protective of any potential cancer effects.

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 difenoconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate tolerance enforcement method, method AG–575B, is available to enforce the tolerance expression. The method determines residues of difenoconazole *per se* in or on crop commodities by gas chromatography with nitrogen-phosphorus detection (GC/NPD). The method's limits of quantitation (LOQs) are 0.01–0.05 ppm. A confirmatory GC method with mass-selective detection (MSD) is also available for crop commodities. Samples from the submitted crop field trials were analyzed for residues of difenoconazole using a high performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS), Syngenta REM 147.08, or a similar method. The methods are adequate for data collection based on acceptable concurrent method recoveries. The LOQ was 0.01 ppm for difenoconazole in mango and wax jambu.

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; *e-mail 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 established a MRL for difenoconazole in or on mango at 0.07 ppm. This MRL is the same as the tolerance established by this action for difenoconzole in the United States. Canadian and Mexican MRLs have been established for difenoconazole; however, no MRLs have been established for mango. No Codex, Canadian, and Mexican MRLs have been established for residues of difenoconazole in or on wax jambu.

C. Response to Comments

There were no public comments received on the Notice of Filing.

D. Revisions to Petitioned-For Tolerances

EPA has revised the tolerance levels proposed in the notice of filing for mango from 0.09 ppm to 0.07 ppm. The modification was made based on the available data supporting the use of difenoconazole on mango and to achieve harmonization with the established Codex MRL of 0.07 ppm residues in or on mango.

Also, the Agency corrected the commodities named in the notice from "mango fruit" to "mango" and "waxapple" to "wax jambu" to reflect EPA's prescribled terminology for these crops.

V. Conclusion

Therefore, tolerances are established for residues of difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, in or on mango at 0.07 ppm and wax jambu at 1.5 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 18, 2011.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.475 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.475 Difenoconazole; tolerance for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Mango [1]	0.07
* * * * *	
Wax jambu [1]	1.5

* * * * *

[FR Doc. 2011–4370 Filed 3–1–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1994–0001; FRL–9274–1]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the AT&SF Albuquerque Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 announces the deletion of the northern 62-acre parcel of the AT&SF Albuquerque Superfund Site (Site) located in Albuquerque, Bernalillo County, New Mexico, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This partial deletion pertains to the soil and ground water associated with the northern 62-acre parcel. After this deletion, these 62 acres will no longer be part of the Site. The other 27 acres will remain on the NPL and are not being considered for deletion as part of this action. The EPA and the State of New Mexico, through the New Mexico Environment Department (NMED), have determined that all appropriate response actions for this parcel under CERCLA, other than operation, maintenance, and five-year reviews, have been completed. However, the deletion of these parcels does not preclude future actions under Superfund.

DATES: *Effective Date:* This action is effective March 2, 2011.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–1994–0001. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information 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 either electronically through *http://www.regulations.gov* or in hard copy at the site information repositories. Locations, contacts, and phone numbers are:

- U.S. EPA Region 6 Library, 7th Floor, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733, (214) 665–6424;
- Albuquerque Public Library, Main Downtown Branch, 501 Copper Avenue, NW., Albuquerque, New Mexico 87102, Contact: John Vittal; and,
- New Mexico Environment Department, Harold Runnels Building, 1190 St. Francis Drive, Santa Fe, New Mexico 87505.

FOR FURTHER INFORMATION CONTACT: Katrina Higgins-Coltrain, Remedial Project Manager (RPM), U.S. EPA Region 6 (6SF–RL), 1445 Ross Avenue, Dallas, TX 75202–2733, (214) 665–8143 or 1–800–533–3508 (*coltrain.katrina@epa.gov*).

SUPPLEMENTARY INFORMATION:

The portion of the site to be deleted from the NPL is: Northern 62-acre parcel of the AT&SF Albuquerque Superfund Site, located in Albuquerque, Bernalillo County, New Mexico. A Notice of Intent for Partial Deletion for this Site was published in the **Federal Register** on January 5, 2011 (76 FR 510).

The closing date for comments on the Notice of Intent for Partial Deletion was February 4, 2011. One anonymous public comment was received and supported the partial deletion of the Site. EPA, in conjunction with the NMED, believes the partial deletion action remains appropriate.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion of a site from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of portions of a site from the NPL does not affect responsible party liability, in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: February 16, 2011.

Al Armendariz,

Regional Administrator, Region 6.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by revising the entry under NM for "AT&SF (Albuquerque)" to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/County	Notes (a)
* * * * * * *			
NM	AT&SF Albuquerque	Albuquerque	P
* * * * * * *			

(a) * * *

P = Sites with partial deletion(s).