ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0296; FRL–8876–4]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on aspirated grain fractions; carrot; chickpea; fruits, stone, group 12; soybean, hulls; soybean, seed; strawberry; and turnip greens. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also increases the existing tolerances for cattle, liver; goat, liver; hog, liver; horse, liver; sheep, liver; and decreases the existing tolererance for egg and revises the tolerance expression for animal commodities.

DATES: This regulation is effective June 15, 2011. Objections and requests for hearings must be received on or before August 15, 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–2010–0296. 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: Rose Mary Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–5611; *e-mail address: kearns.rosemary@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–2010–0296 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 August 15, 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–2010–0296, 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 4, 2010 (75 FR 46924) (FRL–8834–9), 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 9F7676) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.475 be amended by establishing tolerances for residues of the fungicide difenoconazole, in or on carrot at 0.45 parts per million (ppm); chickpeas at 0.05 ppm; fruits, stone, group 12 at 2.5 ppm; soybean, seed, at 0.2 ppm; soybean, aspirated grain fraction at 95 ppm; strawberry at 2.5 ppm; turnip greens at 35 ppm; and increasing the existing milk tolerance from 0.01 to 0.08 ppm. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has: Increased the proposed tolerance for carrot from 0.45 ppm to 0.50 ppm, and for chickpea from 0.05 ppm to 0.08 ppm; decreased the proposed soybean, seed tolerance from 0.20 ppm to 0.15 ppm; established a tolerance that was not proposed for soybean, hulls at 0.20 ppm; changed the proposed tolerance terminology for ''soybean, aspirated grain fractions'' to ''aspirated grain fractions;'' revised the tolerance

expression for animal commodities; increased the existing animal tolerances from 0.20 ppm to 0.40 ppm for the livers of cattle, goat, hog, horse, and sheep; decreased the existing tolerance for eggs from 0.10 ppm to 0.02 ppm; not granted the proposed tolerance increase for milk from 0.01 to 0.08 ppm. 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 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.

Difenoconazole possesses low acute toxicity by the oral, dermal and inhalation routes of exposure. It is not an eye or skin irritant and is not a sensitizer. Subchronic and chronic studies with difenoconazole in mice and rats showed decreased body weights, decreased body weight gains and effects on the liver. In an acute neurotoxicity study in rats, reduced fore-limb grip strength was observed on day 1 in males and clinical signs of neurotoxicity were observed in females at the limit dose of 2,000 milligrams/kilograms (mg/kg). In a subchronic neurotoxicity study in rats, decreased hind limb strength was observed in males only at the mid- and high-doses. However, the effects observed in acute and subchronic neurotoxicity studies are transient, and the dose-response is well characterized with identified no observed adverse effect level (NOAELs). No systemic toxicity was observed at the limit dose in the most recently submitted 28-day rat dermal toxicity study.

There is no concern for increased qualitative and/or quantitative susceptibility after exposure to difenoconazole based on developmental toxicity studies in rats and rabbits, and a reproduction study in rats as fetal/offspring effects occurred in the presence of maternal toxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by difenoconazole.

In accordance with the Agency's current policy, difenoconazole is classified as ''Suggestive Evidence of Carcingenic Potential'' and EPA is using the Margin of Exposure (MOE) approach to assess cancer risk. Difenoconazole is not mutagenic, and no evidence of carcinogenicity was seen in rats. Evidence for carcinogenicity was seen in mice (liver tumors), but these tumors were only induced at doses which were considered to be excessively high for carcinogenicity testing. Based on excessive toxicity observed at the two highest doses in the study, the absence of tumors at the study's lower doses, and the absence of genotoxic effects, EPA has concluded that the chronic point of departure (POD) from the chronic mouse study will be protective of any cancer effects. The POD from this study is the NOAEL of 30 ppm (4.7 and 5.6 mg/kg/day in males and females, respectively) which was chosen based upon only those biological endpoints which were relevant to tumor development (*i.e.,* hepatocellular hypertrophy, liver necrosis, fatty changes in the liver and bile stasis).

Specific information on the studies received and the nature of the adverse effects caused by difenoconazole as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Difenoconazole Human Health Risk Assessment for Amended Section 3 Registration to Add Uses on Carrots, Chickpeas, Soybeans, Stone Fruits (Group 12), Strawberries, Turnip Greens and Golf Course Turf Grass,'' pp. 13–19 in docket ID number EPA–HQ–OPP–2010–0296.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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 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 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 chemical name used for human risk assessment is shown in the Table of this unit.

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—General population including infants and children.	NOAEL = 25 mg/kg ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.25 mg/kg/day. aPAD = 0.25 mg/kg/day	Acute Neurotoxicity study in Rats LOAEL = 200 mg/kg/day 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	Chronic RfD = 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 based on cumulative decreases in body-weight gains.
Incidental oral short-term—1 to 30 days.	NOAEL= 1.25 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = < 100	Reproduction and fertility Study (rat; dietary) Parental/Offspring LOAEL = 12.5 mg/kg/day based on decreased pup weight in males on day 21 and reduction in body-weight gain of F_0 females prior to mating, gestation and lactation.
Inhalation short- and intermediate-term inhalation and oral absorption assumed equivalent.	Inhalation (or oral) study NOAEL = 1.25 mg/kg/day inhalation absorption rate = 100%. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = < 100	Reproduction and fertility study (rat; dietary) Parental/Offspring LOAEL = 12.5 mg/kg/day based on decreased pup weight in males on day 21 and reduction in body-weight gain of F_0 females prior to mating, gestation and lactation.
Cancer, Oral, dermal, inhalation.	Difenoconazole is classified ''Suggestive Evidence of Carcinogenic Potential'' with a non-linear (MOE) approach for human risk characterization.		

POD = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = No observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UFA = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. 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 (*i.e.,* anticipated residues) for the majority of commodities, and the available empirical or DEEM™ (ver. 7.81) default processing factors, and 100 PCT.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk difenoconazole. 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 and the cancer exposure assessment would not exceed the chronic exposure estimate. Therefore, the chronic dietary risk estimate will be protective of potential cancer risk.

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

iv. *Anticipated residue 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.* 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 surface water are estimated to be 15.8 parts per billion (ppb) for acute exposures and 10.4 ppb for chronic exposures. For ground water, the EDWCs are estimated to be 0.0128 ppb for both acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration of 15.8 ppb and 10.4 ppb were used to assess the contribution to drinking water in the acute and chronic dietary risk assessments, respectively.

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: Application to ornamentals. There is a potential for exposure to difenoconazole during mixing, loading, and application activities through the dermal and inhalation routes. Difenoconazole products are applied by homeowners using handheld spray equipment. Exposure duration is considered short-term (1–30 days). In addition, residential post-application exposure to treated golf course turf is possible for recreational golfers. 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 (EPA, 2002). With triazole type fungicides 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 reregistration docket at *http://www.regulations.gov,* docket 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 in body weight gain and decreased in 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 for difenoconazole is adequate for conducting a FQPA risk assessment. At this time, an immunotoxicity study is not available. However, the toxicology database for difenoconazole 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 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.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to difenoconazole will occupy 19% of the aPAD for children, 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to difenoconazole from food and water will utilize 49% of the cPAD for children 1–2 years old the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Difenoconazole 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 difenoconazole.

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 MOEs of 260. Because EPA's level of concern for difenoconazole is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A and the toxicological endpoints described in Unit III.B, EPA has concluded that the cPAD is protective of possible cancer effects; therefore, given the results of the chronic risk assessment described in this unit, cancer risk resulting from exposure to difenoconazole is not of concern.

5. *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 enforcement method, gas chromatography/nitrogen- phosphorus detection (GC/NPD) method AG–575B, is available for the determination of residues of difenoconazole *per* se in/on plant commodities. An adequate enforcement method, liquid chromatography mass spectrometry (LC/MS/MS) method REM 147.07b, is available for the determination of residues of difenoconazole and CGA–205375 in livestock commodities. Adequate confirmatory methods are also available. This is the first difenoconazole petition since the new livestock method (147.07b) was approved by the Agency and this new method has lower level of quantitation than the previous enforcement method.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; *telephone number:* (410) 305–2905; 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.

Codex maximum residue levels (MRLs) for residues of difenoconazole per se have been established at 0.2 ppm for carrot; 0.02 ppm for soya bean (dry); 0.2 ppm for cherries and plums (including prunes); and 0.5 ppm for nectarines and peaches. Canadian and Mexican MRLs have been established for difenoconazole; however, no MRLs have been established for the commodities included in the current petition. Codex MRLs for residues of difenoconazole and its metabolite CGA–205375, expressed as difenoconazole have been established at 0.2 ppm for edible offal (mammalian) and 0.01 for eggs. Also, Canadian MRLs have been established for difenoconazole at 0.05 ppm for meat byproducts of cattle, goats, hogs, and sheep and at 0.05 ppm in eggs. Based on the submitted/available magnitude of the residue data, harmonization with established Codex MRLs is not possible for carrots, soya bean (dry), cherries, plums (including prunes), nectarines, peaches, edible offal (mammalian), and eggs because the Codex MRLs are too low, due to differences in the use patterns, called Good Agricultural Practices or GAPs.

Harmonization with the established Canadian MRLs for eggs and meat byproducts of cattle, goats, hogs, and sheep is not possible due to differences in the regulated residue expression.

C. Response to Comments

One anonymous comment was received on August 7, 2010. This commenter opposes the establishment of any numerical tolerance other than zero. No information was submitted to support the commenter's position.

D. Revisions to Petitioned-For Tolerances

1. Tolerances for carrot, chickpea, and soybean, seed were corrected to use the recommendation from the EPA tolerance spreadsheet (January 2008 version).

2. No tolerance proposal was made for soybean, hulls, which is a regulated commodity. A tolerance is being established for this commodity, because difenoconazole residues concentrate in this commodity.

3. Commodity names for proposed tolerances are being corrected to be consistent with EPA's standard commodity vocabulary definitions: ''Chickpeas'' to ''Chickpea;'' ''Soybean, aspirated grain fractions'' to ''Aspirated Grain Fractions;'' ''Fruits, stone, group 12'' to ''Fruit, stone, group 12''.

4. The animal commodity tolerance expression is being changed slightly to express the metabolite CGA 205375 as a difenoconazole stoichoimetric equivalent.

5. There are a number of livestock feedstuffs associated with the proposed uses and currently established livestock tolerances were reassessed. Due primarily to the significant change in the beef diet from the proposed use on soybeans and the residues of difenoconazole found in/on soybean aspirated grain fractions, the tolerance levels for residues of concern in liver of cattle, goat, hog, horse, and sheep need to be increased from 0.20 ppm to 0.40 ppm.

6. Although there was little change in the poultry diet from the proposed new uses, due to the lower level of quantitation from the new animal commodity enforcement analytical method (method 147.07b), the tolerance level for residues of concern in egg needs to be decreased from 0.10 ppm to 0.02 ppm. Furthermore, the existing commodity name for ''eggs'' is being corrected to ''egg'' consistent with EPA's standard commodity vocabulary definition.

7. The proposed increased tolerance for milk is not needed because the calculations for changes in the dietary burden due to the new uses indicate no change is needed.

V. Conclusion

Therefore, tolerances are established for residues of difenoconazole, 1-([2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl]methyl)-1*H*-1,2,4-triazole, in or on: Aspirated grain fractions at 95 ppm; carrot at 0.50 ppm; chickpea at 0.08 ppm; fruit, stone, group 12 at 2.5 ppm; soybean, hulls at 0.20; soybean, seed at 0.15; strawberry at 2.5 ppm; turnip greens at 35 ppm. The existing animal commodity tolerance expression is being revised, and tolerances are being increased for liver of cattle/goat/hog/horse/sheep from 0.20 ppm to 0.40 ppm. The existing egg tolerance is being decreased from 0.10 ppm to 0.02 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: June 7, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.475 is amended as follows:

■ i. In the table to paragraph (a)(1), by alphabetically adding the following commodities; and

■ ii. In paragraph (a)(2), by revising the introductory text and the following commodities in the table.

The amendments read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Aspirated grain fractions	95
* * * * *	
Carrot	0.50
Chickpea	0.08
* * * * *	
Fruits, stone, group 12	2.5
* * * * *	
Soybean, hulls	0.20
Soybean, seed	0.15
Strawberry	2.5
Turnip, greens	35
* * * * *	

(2) Tolerances are established for residues of difenoconazole, including its metabolites and degradates, in the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring the sum of difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole, and its metabolite, CGA–205375, 1-[2-chloro-4-(4-chloro-phenoxy)phenyl]-2-[1,2,4]triazol-1-yl-ethanol, calculated as the stoichiometric equivalent of difenoconazole, in the following commodities:

Commodity	Parts per million
* * * * *	
Cattle, liver	0.40
* * * * *	
Egg	0.02
* * * * *	
Goat, liver	0.40
* * * * *	
Hog, liver	0.40
* * * * *	
Horse, liver	0.40
* * * * *	
Sheep, liver	0.40
* * * * *	

* * * * *

[FR Doc. 2011–14770 Filed 6–14–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–1081; FRL–8875–4]

Pesticide Tolerances; Technical Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA has reviewed its pesticide regulations and is making changes in a number of areas. These changes will correct cross-references, remove expired tolerances, ''reserve'' paragraphs within sections that no longer have any tolerances listed due to the removal of expired tolerances, and remove sections that no longer have any tolerances due to the removal of expired tolerances. These changes have no substantive impact on any requirements. As such, notice and public comment procedures are unnecessary.

DATES: This final rule is effective June 15, 2011.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–1081. All documents in the docket are listed in the docket index available in *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: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. 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