In this case, x[1] is the largest number and x[n] is the smallest value.) The 98th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of table 1, determine the appropriate range (i.e., row) for the annual creditable number of samples for year y (cn_y). The corresponding ''n'' value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of daily site values for year y. Thus, $P_{0.98, y}$ = the nth largest value.

TABLE 1

Annual creditable number of samples for year "y" (cn_y)	$P_{0.98, y}$ is the nth maximum value of the year, where n is the listed number
1–50	1
51–100	2
101–150	3
151–200	4
201–250	5
251–300	6
301–350	7
351–366	8

(2) Formula for computing annual 98th percentile values when sampling frequencies are seasonal.

Procedure: Calculate the annual 98th percentiles by determining the smallest measured concentration, x, that makes W(x) greater than 0.98 using equation 5 of this appendix:

Equation 5

$$W(x) = \frac{d_{High}}{d_{High} + d_{Low}} F_{High}(x) + \frac{d_{Low}}{d_{High} + d_{Low}} F_{Low}(x)$$

Where:

d_{High} = number of calendar days in the ''High'' season;

d_{Low} = number of calendar days in the ''Low'' season;

$d_{High} + d_{Low}$ = days in a year; and

$$F_a(x) = \frac{\text{number of daily values in season a that are } \leq \times}{\text{number of daily values in season a}}$$

Such that ''a'' can be either ''High'' or ''Low''; ''x'' is the measured concentration; and ''$d_{High}/(d_{High} + d_{Low})$ and $d_{Low}/(d_{High} + d_{Low})$'' are constant and are called seasonal ''weights.''

(b) The 24-hour standard design value is then calculated by averaging the annual 98th percentiles using equation 6 of this appendix:

Equation 6

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98, y}}{3}$$

(c) The 24-hour standard design value (3-year average 98th percentile) is rounded according to the conventions in section 4.3 of this appendix before a comparison with the standard is made.

[FR Doc. 07–5954 Filed 1–8 –08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0541; FRL–8343–5]

Difenoconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes, increases, and removes tolerances for residues of difenoconazole and also establishes tolerances for combined residues of difenoconazole and its metabolite, CGA-205375, in or on various commodities. In addition, this regulation revokes tolerances for secondary residues in poultry, fat, meat, and meat byproducts. Syngenta Crop Protection, Inc., requested these tolerances under the Federal, Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 9, 2008. Objections and requests for hearings must be received on or before March 10, 2008, 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–2007–0541. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Janet Whitehurst, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6129; e-mail address: *whitehurst.janet@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0541 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before March 10, 2008.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0541, 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'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. Petition for Tolerance

In the **Federal Register** of August 22, 2007 (72 FR 47010–47012) (FRL–8142-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 6E7120 and PP 6F7115) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. The petitions requested that 40 CFR 180.475 be amended by establishing a tolerance for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole, in or on fruit, pome, group 11 at 0.6 parts per million (ppm) (PP 6F7115); vegetable, fruiting, group 8 at 0.5 ppm (PP 6F7115); vegetables, tuberous and corm, subgroup 1C at 0.02 ppm (PP 6F7115); sugar beet roots at 0.3 ppm (PP 6F7115); sugar beet tops at 7.0 ppm (PP 6F7115); and imported whole papaya fruit at 0.3 ppm (PP 6E7120). That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. 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 determined that several of the proposed tolerances need to be raised, lowered, or revoked. Additionally, EPA also determined that the pesticide uses for the proposed tolerances would result in residues of difenoconazole and CGA-205375 in or on the egg; milk; fat, meat, meat byproducts; and liver of ruminants that need tolerances.

The need to revise the tolerance expression for livestock is based on the previously submitted ruminant metabolism studies, the new foliar uses, and the need to include CGA 205375 in the risk assessment. The uses on pome fruit, sugar beets, and tuberous and corm vegetables included potential cattle feedstuffs (cull potatoes, processed potato waste, sugar beet molasses, sugar beet pulp, and wet apple pomace), and therefore resulted in a greater potential for the transfer of residues to meat and milk.

For poultry, based on the calculated dietary burdens and the submitted feeding study data, the Agency concluded that the currently established tolerances for secondary residues in poultry, meat, fat and meat byproducts should be removed. Additionally, the tolerance for residues of difenoconazole in eggs should be altered to include residues of CGA-205375 and the tolerance level should be increased to 0.10 ppm (to account for CGA-205375).

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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data

and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of difenoconazole as revised by EPA. EPA's assessment of exposures and risks associated with establishing the tolerances 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. Specific information on the studies received and the nature of the adverse effects caused by difenoconazole 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*. The referenced document is available in the docket established for this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2007–0541 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for difenoconazole used for human risk assessment can be found at *http://www.regulations.gov* in the document entitled ''Difenoconazole in/on Fruiting Vegetables, Pome Fruit, Sugar Beets, Tuberous and Corm Vegetables, and Imported Papaya,'' Health Effects Division (HED) Risk Assessment on page 13 in docket ID number EPA–HQ–OPP–2007–0541.

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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) insert 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

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 all foods for which there are tolerances were treated and contain tolerance-level residues.

iii. *Cancer*. A cancer dietary exposure assessment was not conducted for difenoconazole because the cancer NOAEL is higher than the chronic NOAEL; therefore, the chronic dietary risk estimate is more protective.

iv. *Anticipated residue and percent crop treated (PCT) information*. The Agency did not use anticipated residue estimates or PCT information.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for difenoconazole in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 environmental concentrations (EECs) of difenoconazole are 0.00128 parts per billion (ppb) for acute groundwater and 0.00108 ppb for chronic groundwater. The EECs for surface water are estimated to be 13.3 ppb and 9.43 ppb for 1-in-10 year annual peak and 1-in-10 year annual average concentrations respectively.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. In this assessment, 1-in-10–year annual peak (13.3 ppb) and 1-in10–year annual mean (9.43 ppb) residue values were used for acute and chronic dietary exposure 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 residential non-dietary sites: Ornamentals. EPA assessed residential exposure using the following assumptions: Residential pesticide handlers will 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. A MOE of 100 is adequate to protect residential pesticide handlers from exposures to difenoconazole. MOEs are >100; therefore are not of concern. With respect to residential

postapplication exposures, no significant postapplication exposure is anticipated from ornamentals by residents; therefore, no residential postapplication assessment was conducted.

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 website 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 UFs) 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 ID number EPA–HQ–OPP–2005–0497.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (10X) tenfold 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 when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, and pre-/postnatal exposure in the 2–generation reproduction toxicity study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre-/postnatal studies.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for difenoconazole is complete.

ii. There is no indication that difenoconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that difenoconazole 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. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. Conservative ground and surface water modeling estimates were used. Similarly conservative residential SOPs were used to assess postapplication exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by difenoconazole.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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 8% of the aPAD for the population group all infants (<1 year old) receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to difenoconazole from food and water will utilize 56% of the cPAD for the population group (children 1–2). Based on the use pattern, chronic residential exposure to residues of difenoconazole is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account 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 food and water and short-term exposures for difenoconazole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of

greater than or equal to 170, and are therefore not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The Agency believes residential pesticide handlers will be exposed to short-term duration (1–30 days) only. Therefore, intermediate-and long-term aggregate risk are not of concern.

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

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

Adequate enforcement methodology: liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method 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; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for difenoconazole.

C. Response to Comments

One comment was received from B. Sachau. Ms. Sachau's comments regarding general exposure to pesticides contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to difenoconazole, including all anticipated dietary exposures and other exposures for which there is reliable information. This comment as well as her comments regarding animal testing have been responded to by the Agency on several occasions. For examples, see the **Federal Register** issues of January 7, 2005 (70 FR 1349) (FRL–7691–4) and October 29, 2004 (69 FR 63083) (FRL–7681–9).

V. Conclusion

Therefore, tolerances are established for residues of difenoconazole in or on vegetable, fruiting, group 8 at 0.60 ppm; vegetable, tuberous and corm, subgroup 1C at 0.01 ppm; beet, sugar at 0.01 ppm; papaya (imported) at 0.30 ppm; apple, wet pomace 4.5 ppm; beet, sugar, dried pulp at 1.9 ppm; and potato, processed waste at 0.04 ppm. The tolerance for fruit, pome group 11 is increased from 0.6 ppm to 1.0 ppm. Tolerances for pome fruit, group 11 and barley, grain are established for domestic use. Tolerances for secondary residues in poultry, meat, fat, and meat byproducts are revoked. Tolerances as listed in the table of paragraph (a) in 40 CFR 180.475 are removed for milk, meat of cattle, hog, goat, horse, and sheep; meat byproduct (except liver) of cattle, hog, goat, horse, and sheep; fat of cattle, hog, goat, horse, and sheep; liver of cattle, hog, goat, horse, and sheep; and eggs. Tolerances for combined residues of CGA-205375 are established in or on milk at 0.01 ppm; meat of cattle, hog, goat, horse, and sheep at 0.05 ppm; meat byproduct (except liver) of cattle, hog, goat, horse, and sheep at 0.10 ppm; fat of cattle, hog, goat, horse, and sheep at 0.10 ppm; liver of cattle, hog, goat, horse, and sheep at 0.20 ppm; and eggs at 0.10 ppm; and are listed in a table in newly created paragraph (a)(2) of 40 CFR 180.475.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 rule. In addition, This 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) (Public Law 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: December 28, 2007.

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 by revising paragraph (a) to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	4.5
Banana[1]	0.2
Barley, grain	0.1
Barley, hay	0.05
Barley, straw	0.05
Beet, sugar	0.01
Beet, sugar, dried pulp	1.9
Canola, seed	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01
Cotton, gin byproducts	0.05
Cotton, undelinted seed	0.05
Fruit, pome group 11	1.0
Grape[1]	0.10
Papaya[1]	0.30
Potato, processed waste	0.04
Rye, grain[1]	0.1
Vegetable, fruiting, group 8	0.60
Vegetable, tuberous and corm, subgroup 1C	0.01

[1] There are no U.S. registrations.

(2) Tolerances are established for residues of the fungicide 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, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, liver	0.20
Cattle, meat	0.05
Cattle, meat byproduct (except liver)	0.10
Eggs	0.10
Goat, fat	0.10
Goat, liver	0.20
Goat, meat	0.05
Goat, meat byproduct (except liver)	0.10
Hog, fat	0.10
Hog, liver	0.20
Hog, meat	0.05
Hog, meat byproduct (except liver)	0.10
Horse, fat	0.10
Horse, liver	0.20
Horse, meat	0.05
Horse, meat byproduct (except liver)	0.10
Milk	0.01
Sheep, fat	0.10
Sheep, liver	0.20
Sheep, meat	0.05
Sheep, meat byproduct (except liver)	0.10

* * * * *

[FR Doc. E8–15 Filed 1–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0093]; FRL–8344–3]

Mesotrione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mesotrione in or on berry, group 13; flax, seed; cranberry; lingonberry; millet, grain; millet, forage; millet, hay; and millet, straw. Syngenta Crop Protection requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 9, 2008. Objections and requests for hearings must be received on or before March 10, 2008, 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–2006–0093. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1243; e-mail address: *montague.kathryn @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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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