

and pests, Reporting and recordkeeping requirements.

Dated: July 17, 2007.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 174 is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

■ 2. Section 174.501 is revised to read as follows:

§174.501 *Bacillus thuringiensis* Vip3Aa19 protein in cotton; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa19 protein in cotton are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant (PIP) in the food and feed commodities of cotton; vegetative-insecticidal protein in cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when treated in accordance with the provisions of the experimental use permit (EUP) 67979–EUP–7, which is being issued in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked May 1, 2008. However, if the EUP is revoked, or if any experience with or scientific data on this pesticide indicate that the temporary tolerance exemption is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time. [FR Doc. E7–14373 Filed 7–24–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0446; FRL–8136–7]

Diflubenzuron; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for diflubenzuron and its metabolites p-chlorophenylurea and p-chloroaniline in or on lemon. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on lemon. This regulation establishes a maximum permissible level for combined residues of diflubenzuron and its metabolites p-chlorophenylurea and p-chloroaniline, in this food commodity. The tolerance expires and is revoked on December 31, 2010.

DATES: This regulation is effective July 25, 2007. Objections and requests for hearings must be received on or before September 24, 2007, 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–2007–0446. 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 www.regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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: Libby Pemberton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:

(703) 308–9364; e-mail address: pemberton.libby@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:

- 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 provides 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 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 the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2007-0446 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 on or before September 24, 2007.

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 your copies, identified by docket ID number EPA-HQ-OPP-2007-0446, 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. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for of the insecticide, diflubenzuron and its metabolites p-chlorophenylurea and p-chloroaniline, in or on lemon at 0.8 parts per million (ppm). This tolerance expires and is revoked on December 31, 2010. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the

application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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. . . ."

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

EPA is also revising the tolerance expression in § 180.377(b) to be consistent with the preferable wording as expressed in § 180.377(a)(2).

III. Emergency Exemption for Diflubenzuron on Lemon and FFDCA Tolerances

In the fall of 2005 and spring of 2006, active infestations of Diaprepes root weevil were detected including one lemon orchard (28 acres) in commercial sites in Long Beach, Newport Beach, Carlsbad, Encinitas, and La Jolla, California. The California Department of Food and Agriculture (CDFA) has quarantined these sites and has already initiated eradication treatments using products that impact various life stages of this insect. The emergency use of diflubenzuron is needed to treat the egg stage of the weevil when they are detected in lemon. The overall program involves treatment for larval and adult

stages as well. EPA has authorized under FIFRA section 18 the use of diflubenzuron on lemon for control of Diaprepes root weevil in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of diflubenzuron in or on lemon. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance expires and is revoked on December 31, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on lemon after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether diflubenzuron meets EPA's registration requirements for use on lemon or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of diflubenzuron by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for diflubenzuron, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

Consistent with section 408(b)(2)(D) of the 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 diflubenazuron and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of diflubenazuron in or on lemon at 0.8 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>. A summary of the toxicological endpoints for diflubenazuron used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 19, 2002 (67 FR 59006) (FRL-7200-4).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances for residues of

diflubenazuron are established under 40 CFR 180.377. Tolerances listed in 40 CFR 180.377(a)(1) are expressed in terms of diflubenazuron *per se*. Under this section, tolerances of 0.05–6.0 ppm are established for residues in/on eggs; milk; fat and meat of cattle, goat, hog, horse, poultry, and sheep; poultry meat byproducts; cottonseed; mushroom; grapefruit, orange (sweet); tangerine; soybean hulls; and globe artichoke. Tolerances listed in 40 CFR 180.377(a)(2) are expressed in terms of the combined residues of diflubenazuron and its metabolites 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA). Under this section, tolerances of 0.02–55.0 ppm are established for residues in/on rice grain and straw; barley grain, straw, and hay; oat, forage, grain, hay, and straw; wheat forage, grain, hay, and straw; grain aspirated fractions; brassica, leafy greens, subgroup 5B; grass, forage, fodder, and hay, group 17; tree nuts (group 14); peanut, peanut hay and refined oil; pistachios; fruit, stone (group 12) except cherry; meat byproducts of cattle, goat, hog, horse, and sheep; pear; pepper; pummelo; turnip greens; and almond hulls. Time-limited tolerances listed in 40 CFR 180.377(b) are expressed in terms of the combined residues of diflubenazuron and its metabolites CPU and PCA, expressed as the parent diflubenazuron, in connection with use of the pesticide under Section 18 Emergency Exemptions granted by EPA. Risk assessments were conducted by EPA to assess dietary exposures from diflubenazuron in food as follows:

i. *Acute exposure.* Acute dietary 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. The diflubenazuron toxicology studies indicated no possibility of such an effect for either the general U.S. population (including infants and children) or the females 13–50 years old population subgroup for diflubenazuron; therefore, an acute dietary exposure analysis was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM-FCID™) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic dietary-exposure

assessment was conducted using the established/recommended tolerances for all food commodities, 100% CT information for all proposed and existing uses, and DEEM(™) Version 7.81 default processing factors for some processed commodities.

iii. *Cancer.* The Agency has classified diflubenazuron as “Group E,” evidence of non-carcinogenicity for humans, based on lack of evidence of carcinogenicity in rats and mice. There are also two metabolites of diflubenazuron; PCA and CPU. PCA tested positive for splenic tumors in male rats and hepatocellular adenomas/carcinomas in male mice in a National Toxicology Program (NTP) study. Therefore, EPA classified PCA as a “Group B2” probable human carcinogen. The Agency determined for those commodities that contained PCA and CPU, the Q1* of PCA should be used to calculate the cancer risk from the sum of these two metabolites.

Based on the submitted metabolism studies, there are two possible sources for dietary exposure to PCA and CPU: Residues in mushrooms and residues in milk and liver. Because human exposure to PCA and CPU will not be affected by the proposed new uses, and EPA has previously concluded that exposure to these compounds is safe, therefore, the cancer dietary risk from PCA and CPU will not be addressed in this document. For a detailed discussion on the exposure and risks to PCA and CPU, please refer to the September, 2002 **Federal Register** document titled *Diflubenazuron; Pesticide Tolerances* (September 19, 2002, FR 67 59006); <http://www.epa.gov/fedrgstr/EPA-PEST/2002/September/Day-19/p23818.htm>.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to assess dietary exposure to diflubenazuron in drinking water based on measured drinking water concentrations. 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 physical characteristics of diflubenazuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppfed1/models/water/index.htm>. Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentrations in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of diflubenazuron and the major degradate CPU for chronic exposures are estimated

to be 2.76 parts per billion (ppb) for surface water and 0.208 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™, Version 2.03). For chronic dietary risk assessment, the annual average concentration of 2.76 ppb was used to represent the drinking water contribution to chronic dietary exposure for diflubenzuron.

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). Although there are no registered homeowner uses, there are registered uses for professional applications to outdoor residential and recreational areas to control mosquitoes, moths, and other insects. In addition, certain residential use sites will be treated in association with this emergency exemption for the control of the Diaprepes root weevil. However, EPA considers the potential for post-application residential exposure to be low. Further, diflubenzuron has a low dermal absorption rate (0.5%) and will be only applied to the tree canopy.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to diflubenzuron and any other substances and diflubenzuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that diflubenzuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

C. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional 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 that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* Based on the developmental and reproductive toxicity studies, there is no indication of increased susceptibility of rats or rabbits to *in utero* or postnatal exposure.

3. *Conclusion.* There is a complete toxicity database for diflubenzuron and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the additional FQPA 10X safety factor to protect infants and children was not needed. This decision was based on the following:

- i. There is a complete toxicity database for diflubenzuron;
- ii. There is no indication of increased susceptibility of rats or rabbits to *in utero* or postnatal exposure;
- iii. A developmental neurotoxicity study (DNT) with diflubenzuron is not required;
- iv. Food and drinking water exposure assessments will not underestimate the potential exposure for infants and children; and
- v. The potential for post-application residential exposures are expected to be limited. Due to the low dermal absorption rate (0.5%) of diflubenzuron, and since it is only applied to the tree canopy to control gypsy moths and mosquitoes, minimal bystander contact is expected.

D. Aggregate Risks and Determination of Safety

1. *Acute risk.* Because there were no toxic effects attributable to a single dose of diflubenzuron, it is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to diflubenzuron from food will utilize 12% of the cPAD for the U.S. population, 12% of the cPAD for all infants less than 1 year old and 38% of the cPAD for children 1–2 years old. There are no residential uses for

diflubenzuron that result in chronic residential exposure to diflubenzuron. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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).

The aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

The aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Based on the available evidence, which included adequate carcinogenicity studies in rats and mice, and battery of negative mutagenicity studies, diflubenzuron has been classified as "Group E," evidence of non-carcinogenicity for humans, by the Agency. As noted in Unit III.C.1.iii. of this document, the Agency has concluded that human exposure to PCA and CPU (metabolites of diflubenzuron) will not be affected by the proposed new uses. EPA has previously found aggregate exposure to these compounds to be safe. (September 19, 2002, 67 FR 59006); <http://www.epa.gov/fedrgstr/EPA-PEST/2002/September/Day-19/p23818.htm>.

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, and to infants and children from aggregate exposure to diflubenzuron residues.

V. Other Considerations

A. Analytical Enforcement Methodology

There are adequate enforcement methods, published in the Pesticide Analytical Manual (PAM, Vol. II), for determining diflubenzuron residues of concern. In addition, a new analytical methodology for plant commodities was successfully validated by an independent laboratory as well as by Agency chemists at the Analytical Chemistry Branch (ACB)/Biological and Economics Analysis Division (BEAD) in conjunction with an approved rice petition (PP 8F4925). The new methods were forwarded to the Food and Drug Administration (FDA) for publication in PAM Vol. II as Roman Numeral Methods. These methods can separately determine residues of diflubenzuron by

gas chromatography/electron-capture detection (GC/ECD), CPU by GC/ECD, and PCA by GC/mass spectrometry (MS).

B. International Residue Limits

The Codex Alimentarius has established maximum residue limits (MRL), expressed in terms of diflubenzuron *per se*, for many commodities including: Apple (5 ppm), citrus fruits (0.5 ppm), edible offal (mammalian) (0.1 ppm), eggs (0.05 ppm), meat (from mammals other than marine mammals) (0.1 ppm), milks (0.02 ppm), mushrooms (0.3 ppm), pear (5 ppm), pome fruits (5 ppm), poultry meat (0.05 ppm), rice (0.01 ppm), and rice straw and fodder (dry) (0.7 ppm). As the U.S. residue definition includes CPU and PCA, compatibility is not possible with the proposed tolerance.

VI. Conclusion

Therefore, the tolerance is established for of the insecticide diflubenzuron, (N-[[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide and its metabolites 4-chlorophenylurea and 4-chloroaniline in or on lemon at 0.8 ppm.

VII. 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 6, 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).

VIII. 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: July 6, 2007.

Donald R. Stubbs,

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 180.377, paragraph (b) is amended by:

i. Revising the introductory text and

ii. Alphabetically adding the commodity "Lemon" to the table to read as follows:

§180.377 Diflubenzuron; tolerances for residues.

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for of the insecticide diflubenzuron, (N-[[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide and its metabolites 4-chlorophenylurea and 4-chloroaniline, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table, and will expire and are revoked on the dates specified.

Commodity	Parts per million	Expiration/revocation date
Lemon	0.8	12/31/2010

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2006-0076; FRL-8137-7]

Penoxsulam (2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide; Pesticide Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues or residues of penoxsulam (2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide) in or on fish; fish, shellfish, mollusc; and fish, shellfish, crustacean. Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 25, 2007. Objections and requests for hearings must be received on or before September 24, 2007, 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-2006-0076. 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 web site 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:

Philip V. Errico, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6663; e-mail address: errico.philip@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 the 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-2006-0076 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 September 24, 2007.

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-2006-0076, 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 April 14, 2006 (72 FR Page 19507) (FRL-8063-4), 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 5F7012) by Dow AgroSciences LLC, Dow AgroSciences