

the FFDCA. The Office of Management and Budget 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the [tolerances] 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. “Policies that have federalism implications” is defined in the Executive Order to include regulations that have

“substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**IX. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: August 14, 2003.

**Debra Edwards,**  
*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), 346(a) and 371.

■ 2. Section 180.565 is amended by adding text to paragraph (b) to read as follows:

**§ 180.565 Thiamethoxam; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the insecticide thiamethoxam [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine] and its metabolite CGA-322704 in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Bean, dried .....	0.02	12/31/06
Bean, succulent	0.02	12/31/06
Hops .....	0.10	12/31/06

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2003-0279; FRL-7323-1]

**Diflubenzuron; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for combined residues of diflubenzuron in or on wheat and barley commodities. This action is in response to treatment of these crops under section 18 of the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA). This regulation establishes maximum permissible levels for residues of diflubenzuron in these food commodities. The tolerances will expire and are revoked on December 31, 2005.

**DATES:** This regulation is effective August 27, 2003. Objections and requests for hearings, identified by docket (ID) number OPP-2003-0279, must be received on or before October 27, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9356; e-mail address: [conrath.andrea@epa.gov](mailto:conrath.andrea@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 producers (NAICS 111)
- Animal producers (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification ID number OPP-2003-0279. The official public docket consists of the documents specifically referenced in this action, any public comments received, and

other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

##### **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 tolerances for combined residues of the insecticide diflubenzuron, [N-[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide and its metabolites 4-chlorophenylurea and 4-chloroaniline (CPU) and (PCA)], in or on wheat and barley grain at 0.05 parts per million (ppm), wheat and barley straw at 0.50 ppm, wheat and barley hay at 1.0 ppm, wheat milled byproducts at 0.10 ppm, and aspirated grain fractions at 30 ppm. These tolerances will expire and are revoked on December 31, 2005. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

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 (FQPA) 1996. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

##### **III. Emergency Exemptions for Diflubenzuron on Wheat and Barley and FFDCA Tolerances**

The requesting States (Idaho, Montana, and Washington) are experiencing severe outbreaks of grasshoppers in their wheat and barley fields this year. In most areas, densities of grasshoppers have reached 40 or more per square yard, and without the use of diflubenzuron, the Applicants estimate that yield could drop by 50%,

resulting in severe crop devastation and significant economic impact to wheat and barley producers in these States. It is believed that the mild winters over the last several years have allowed grasshopper nymphs to survive the winter and multiply more rapidly in the spring, leading to population explosions of grasshoppers to levels of up to 60 grasshoppers per square foot in some cases. The Applicants state that materials registered for grasshopper control either are not effective with populations at the current levels, are toxic to beneficial insects, or provide insufficient residual control, given the outbreak levels of grasshopper infestation. Under the crisis provisions (40 CFR 166.40) of section 18 of FIFRA the Applicants used diflubenzuron on wheat and barley for control of grasshoppers.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of diflubenzuron in or on barley and wheat commodities. 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 will expire and is revoked on December 31, 2005, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on barley and wheat commodities after that date will not be unlawful, provided it is demonstrated pursuant to section 408(l)(5) that the residues are the result of the application or the use of a pesticide at a time and in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these tolerances at the time of that application or use. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues they allow are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether diflubenzuron meets EPA's registration requirements for use on barley and wheat or whether permanent tolerances for these uses would be

appropriate. Under these circumstances, EPA does not believe that these tolerances serve 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 States other than Montana, Washington, and Idaho 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 the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL-5754-7).

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 diflubenzuron and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for combined residues of diflubenzuron in or on wheat and barley grain at 0.05 ppm, wheat and barley straw at 0.50 ppm, wheat and barley hay at 1.0 ppm, wheat milled byproducts at 0.10 ppm, and aspirated grain fractions at 30 ppm.

EPA has received objections to a separate tolerance-setting involving the use of diflubenzuron on pears. These objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. Although that proceeding remains ongoing, EPA has considered whether it is appropriate to establish the emergency exemption tolerances for diflubenzuron on wheat and barley commodities while the objections are still pending.

Factors taken into account by EPA included how close the Agency is to concluding the proceedings on the objections, the nature of the current action, whether NRDC's objections raised non-frivolous issues, and the

extent to which the issues raised by NRDC had already been considered by EPA. Although NRDC's objections are not frivolous, the other factors all support establishing these tolerances at this time. First, the objections proceeding is unlikely to conclude prior to when action is necessary on this petition. [NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA initiated a 60 day public comment period on them in the **Federal Register** on June 19, 2002 (67 FR 41628) (FRL-7167-7). That comment period was extended until October 16, 2002 in the **Federal Register** of September 17, 2002 (67 FR 58536) (FRL-7275-3),] and EPA is now examining the extensive comments received. Moreover, NRDC itself submitted further information to the Agency in June 2003, and the Agency is in the process of evaluating that information as well. Second, the nature of the current actions are extremely time-sensitive as they address emergency situations. Third, the issues raised by NRDC are not new matters but questions that already have been the subject of considerable evaluation by EPA and comment by stakeholders. Accordingly, EPA is proceeding with establishing these tolerances for diflubenzuron. EPA has determined at this time that these tolerances rest on a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residues involved. As suggested above, if during the life of these tolerances EPA determines that any experience with, scientific data on, or other relevant information on this pesticide indicates that the residues these tolerances allow are not safe, EPA will take action to revoke the tolerances prior to their otherwise applicable expiration date. The action EPA is taking at this time should not be construed to constitute action on NRDC's aforesaid objections. The Agency continues to consider those objections and information concerning them, including the new information which NRDC submitted in June 2003.

The most recent estimated aggregate risks resulting from the use of diflubenzuron, are discussed in the **Federal Register** of September 19, 2002 (67 FR 59017) (FRL-7200-4), final rule establishing tolerances for residues of diflubenzuron in/on grass forage, fodder, and hay; peppers; stone fruits; and tree nuts. In that prior action, risk was estimated using anticipated residue (AR) information based on field trial data and percent crop treated (PCT) information for some commodities. Available residue data indicate that the

use pattern for these emergency exemptions will not result in residues of diflubenzuron in excess of the following levels: Wheat and barley grain at 0.05 ppm, wheat and barley straw at 0.50 ppm, wheat and barley hay at 1.0 ppm, wheat milled byproducts at 0.10 ppm, and aspirated grain fractions at 30 ppm.

Therefore, tolerances are being established for these commodities at these levels. The risk assessment related to incremental addition of these items at this level to dietary exposure is discussed below. Refer also to the September 19, 2002 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies in part upon that risk assessment and the findings made in that **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment.

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. A summary of the toxicological dose and endpoints for diflubenzuron for use in human risk assessment is discussed in the final rule mentioned above, published in the **Federal Register** of September 19, 2002 (67 FR 59017) (FRL-7200-4).

EPA assessed risk scenarios for diflubenzuron under chronic exposures only. Chronic risk estimates were calculated for the residues of toxicological concern, the parent compound of the insecticide diflubenzuron (*N*-[[4-chlorophenyl]amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, CPU and PCA. For the chronic analysis, ARs and PCT information for some commodities were also used. An acute dietary exposure analysis was not performed, because there were no acute toxicological endpoints identified (no effects of concern occurring as a result of a 1 day or single exposure). Short-term aggregate exposure, which takes into account residential exposure plus chronic exposure, was not assessed since diflubenzuron is not registered for use on any sites that would result in substantial residential exposure. Intermediate-term aggregate exposure, which takes into account residential exposure plus chronic exposure to food and water was not assessed, because intermediate-term exposure to diflubenzuron would not be expected from the registered and proposed use

patterns. Aggregate cancer risk for the U.S. population was assessed, since the metabolite, CPU, is of concern for aggregate cancer risk and could be found in drinking water.

A refined, chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups using the Dietary Exposure Evaluation Model (DEEM™) Version 1.3. software with the Food Commodity Intake Database (FCID). The chronic analysis was performed using ARs and PCT information for several registered plant and livestock commodities, and recommended tolerance-level residues and 100% CT information for all proposed commodities. The chronic dietary exposure estimates are below levels of concern (<100% of the chronic population adjusted dose (cPAD)) for that general U.S. population and all population subgroups. The most highly exposed population subgroups are all infants <1 year old and children 1–2 years old (both at 3% of the cPAD).

A cancer dietary exposure assessment from consumption of PCA and CPU was conducted in the previous risk assessment. Based on the submitted metabolism studies, there are two possible sources for dietary exposure to PCA and CPU: Residues in fungi (mushrooms), and residues in animal commodities (milk and liver). As the wheat and barley uses will not result in additional dietary exposure to PCA and CPU, an updated cancer dietary exposure assessment was not needed to support the current section 18 request. The results of the previous cancer analysis indicated that the estimated cancer dietary risk associated with the use of diflubenzuron is below the Agency's level of concern.

*Dietary exposure from drinking water.* For the current use on wheat and barley, a chronic aggregate exposure (food + drinking water) assessment was performed. Acute, short-term and intermediate-term aggregate risk assessments were not performed because an acute dietary endpoint was not selected and there are no registered or proposed non-food uses resulting in significant residential exposure, respectively. A cancer aggregate exposure (food + drinking water) assessment was not conducted because, as mentioned above, the current uses will not result in additional dietary exposure to CPU.

Since EPA does not have ground water and surface water monitoring data to calculate a quantitative aggregate exposure, Drinking Water Levels of Concern (DWLOCs) were calculated. A DWLOC is a theoretical upper limit on

a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses. Different populations will have different DWLOCs. EPA uses DWLOCs in the risk assessment process to assess potential concern for exposure associated with pesticides in drinking water. DWLOC values are not regulatory standards for drinking water. To calculate DWLOCs, the dietary food estimates (from DEEM™-FCID) were subtracted from the population adjusted dose (PAD) value to obtain the maximum water exposure level. DWLOCs were then calculated using the standard body weights and drinking water consumption figures: 70kg/2L (U.S. population and adult male), 60 kg/2L (adult female and youth), and 10kg/1L (infants and children). For chronic dietary exposure, EPA's level of concern is exceeded when estimated dietary risk exceeds 100% of the cPAD.

The chronic drinking water assessment resulted in chronic DWLOCs for the overall U.S. population of 690 parts per billion (ppb), and for all infants (<1 year old) and children (1–2 years) of 190 ppb (the population subgroups with the lowest DWLOC). All chronic DWLOCs were well above the chronic estimated environmental concentration (EEC) for ground water of 0.067 ppb. The chronic DWLOCs were also above the chronic EEC for surface water of 0.32 ppb.

Thus, results of the chronic analysis indicate that the estimated chronic dietary risk associated with the proposed use of diflubenzuron is below levels of concern, and chronic aggregate risk estimates are also below the level of concern.

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

Adequate methods are available for the analysis of diflubenzuron, PCA, and CPU in crops. Three enforcement methods for diflubenzuron are published in the Pesticide Analytical Method Volume II (PAM II) as Methods I, II, and III.

### B. International Residue Limits

There are no Codex proposals, Canadian, or Mexican limits for residues

of diflufenuron on wheat and barley commodities. Therefore there are no compatibility issues associated with the proposed tolerances.

### C. Conditions

One application per growing season may be made of the pesticide, diflufenuron, to wheat and barley, at a rate of 2.0 fl. oz. product (0.44 fl. oz. of active ingredient) per acre. Applications may be made by ground or aerial equipment. A preharvest interval of 45 days must be observed, and all label directions on the federally registered label, as well as the section 18 use directions must be followed.

## VI. Conclusion

Therefore, the tolerance is established for combined residues of diflufenuron, and its metabolites CPU and PCA, in or on wheat and barley grain at 0.05 ppm, wheat and barley straw at 0.50 ppm, wheat and barley hay at 1.0 ppm, wheat milled byproducts at 0.10 ppm, and aspirated grain fractions at 30 ppm.

## VII. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

### A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0279 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 October 27, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP-2003-0279, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

### B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

## VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFCA, such as the tolerances 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFCA. For these same reasons, the

Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**IX. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: August 18, 2003.

**Debra Edwards,**

*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), 346(a) and 371.

■ 2. Section 180.377 is amended by revising the table in paragraph (b) to read as follows:

**§ 180.377 Diflubenzuron; tolerances for residues.**

\* \* \* \* \*  
(b) \* \* \*

Commodity	Parts per million	Expiration/revocation date
Alfalfa, forage ...	6.0	6/30/04
Alfalfa, hay .....	6.0	6/30/04
Barley, grain .....	0.05	12/31/05
Barley, hay .....	1.0	12/31/05
Barley, straw .....	0.50	12/31/05
Wheat, aspirated grain fractions	30	12/31/05
Wheat, grain .....	0.05	12/31/05
Wheat, hay .....	1.0	12/31/05
Wheat, milled byproducts .....	0.10	12/31/05
Wheat, straw .....	0.50	12/31/05

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 272**

[FRL-7479-5]

**New Mexico: Incorporation by Reference of Approved State Hazardous Waste Management Program**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Immediate final rule.

**SUMMARY:** The Resource Conservation and Recovery Act (RCRA), allows the Environmental Protection Agency (EPA) to authorize States to operate their hazardous waste management programs in lieu of the Federal program. EPA uses the regulations entitled “Approved State Hazardous Waste Management Programs” to provide notice of the authorization status of State programs and to incorporate by reference those provisions of the State statutes and regulations that will be subject to EPA’s inspection and enforcement. The rule codifies in the regulations the prior approval of New Mexico’s hazardous waste management program and incorporates by reference authorized