person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. of this preamble. You may also send an electronic copy of your request via e-mail to: *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 file format 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408(d) of the 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). 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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues 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 require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(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). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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.

VIII. Submission to Congress and the Comptroller General

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 rule in the **Federal Register**. This 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: September 23, 1999.

Susan B. Hazen,

Acting Director, 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 180.556 is added to read as follows:

§ 180.556 Pymetrozine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide pymetrozine [1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene) amino]] in or on the following raw agricultural commodities. The tolerance level for each commodity is expressed in terms of the parent insecticide only, which serves as an indicator or the use of pymetrozine on these raw agricultural commodities.

Commodity	Parts per million	Expiration/Revocation Date
Corm and Tuberous Vegetables Subgroup 1-C.	0.02	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 99–25313 Filed 9–28–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300921; FRL–6382–1]

RIN 2070–AB78

Diflubenzuron; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of diflubenzuron (*N*-[[4-

chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites PCA (4-chloroaniline) and CPU (4-chlorophenylurea), expressed as parent compound in or on pears. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pears. This regulation establishes a maximum permissible level for residues of diflubenzuron in this food commodity. The tolerance will expire and is revoked on March 31, 2001.

DATES: This regulation is effective September 29, 1999. Objections and requests for hearings, identified by docket control number OPP–300921, must be received by EPA on or before November 29, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the ''SUPPLEMENTARY INFORMATION'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300921 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail:Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703)308-9356; and e-mail address: beard.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 categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*.You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''Federal Register--Environmental Documents.'' You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300921. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall ı2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the insecticide diflubenzuron and its metabolites PCA and CPU, expressed as parent compound, in or on pears at 0.5 part per million (ppm). This tolerance will expire and is revoked on March 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerance 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 and the new safety standard to other tolerances and exemptions.

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) 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) 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 Federal Insecticide, Fungicide, and Rodenticide Act (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 Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Diflubenzuron on Pears and FFDCA Tolerances

The Oregon and Washington Departments of Agriculture requested use of diflubenzuron on pears, for control of pear psylla, which had developed resistance to currently available pesticides, and was expected to cause significant economic loss if not adequately controlled. EPA has authorized under FIFRA section 18 the use of diflubenzuron on pears for

control of pear psylla in Oregon and Washington. After having reviewed the submission, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of diflubenzuron in or on pears. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) 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). Although this tolerance will expire and is revoked on March 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on pears 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 pears 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 Oregon and Washington to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing 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 the ''ADDRESSES'' section.

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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

Consistent with 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 diflubenzuron and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of diflubenzuron and its metabolites PCA and CPU, expressed as parent compound on pears at 0.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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. The nature of the toxic effects caused by diflubenzuron are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. A risk assessment for acute (1-day) dietary exposure is not necessary. One day single dose oral studies in rats and mice indicated only marginal effects on methemoglobin levels at a dose level of 10,000 milligrams/kilogram/day (mg/kg/day).

2. *Short- and intermediate-term toxicity.* The toxicological endpoint for short-term occupational or residential exposure (1-7 days) is sulfhemoglobinemia observed in the 14-day subchronic oral study in mice dosed with technical grade diflubenzuron. The no observed adverse effect level (NOAEL) in this study was 40 mg/kg/day, and the lowest observed adverse effect level (LOAEL) was 200 mg/kg/day.

The toxicological endpoint for intermediate-term occupational or residential exposure (1 week to several months) is methemoglobinemia observed in the 13-week subchronic feeding study in dogs. For the purpose of risk assessments, the NOAEL of 1.64 mg/kg/day in this study should be rounded up to 2 mg/kg/day, so as to be consistent with the NOAEL of 2 mg/kg/day in the chronic study used to calculate the Reference Dose (RfD). The LOAEL in this study was 6.24 mg/kg/day. Since an oral NOAEL was selected for a dermal endpoint, a dermal absorption factor of 0.5% should be used for this risk assessment when converting dermal exposure to oral equivalents. Therefore, the dermal equivalent dose producing a NOAEL by the oral route is calculated to be 400 mg/kg/day (2.0 mg/kg/day divided by 0.005 = 400 mg/kg/day).

3. *Chronic toxicity*. EPA has established the RfD for diflubenzuron at 0.02 mg/kg/day, based on the NOAEL of 2.0 mg/kg/day from the 52- week chronic oral study in dogs. Increases in methemoglobin and sulfhemoglobin were observed at the next higher dose level (LOAEL) of 10.0 mg/kg/day. An uncertainty factor of 100 was applied to account for the interspecies extrapolation and intraspecies variability. Diflubenzuron has been reviewed by the FAO/WHO joint committee on pesticide residues and an Acceptable Daily Intake (ADI) of 0.02 mg/kg/day was established in 1985. The ADI was based upon the 1- year oral toxicity study in dogs with a NOAEL of 2.0 mg/kg/day, with a safety factor of 100 applied to account for inter- and intra- species variability.

4. *Carcinogenicity*. Based on the available evidence, which included adequate carcinogenicity studies in rats and mice, and a battery of negative mutagenicity studies, diflubenzuron *per se* has been classified as Group E (evidence of non- carcinogenicity for humans). However, p-chloroaniline (PCA), a metabolite of diflubenzuron, was classified as a Group B2 carcinogen (probable human carcinogen). The classification for PCA was based on the results of a National Toxicology Program (N.T.P.) study reported in July 1989, in which PCA-HCL was administered by gavage to rats and mice for 2 years. In rats, clearly increased incidences of uncommon sarcomas (fibrosarcomas, hemangiosarcomas, and/or osteosarcomas) of the spleen were observed in males. In females, two additional sarcomas of the spleen were also found. Pheochromocytomas of the adrenal gland may also have been associated with the test material in male and female rats. In mice, increased incidences of hepatocellular neoplasms in the liver and of hemangiosarcomas in the spleen and/or liver were observed in males. In females, no evidence of carcinogenic activity was observed. The results of several mutagenicity studies on PCA were also included in the same N.T.P. Report. PCA was mutagenic in *Salmonella* strains TA98 and TA100 with metabolic activation. Gene

mutations were induced by PCA in cultured mouse lymphoma cells with and without metabolic activation. In cultured Chinese Hamster Ovary (CHO) cells, treatment with PCA produced significant increases in sister chromatic exchanges (SCEs) with and without metabolic activation. Chromosomal aberrations were also significantly increased in CHO cells in the presence of metabolic activation.

For the purpose of calculating dietary risk assessments, the following procedure was used:

i. P-chlorophenylurea (CPU) and p-chloroacetanilide (PCAA), additional metabolites of diflubenzuron that are closely related to PCA and for which there are no adequate carcinogenicity data available, should be considered to be potentially carcinogenic and to have the same carcinogenic potency (Q_1*) as PCA.

ii. The sum of PCA, CPU, and PCAA residues in ingested food should be used to estimate the dietary exposure of humans to the carcinogenic metabolites of diflubenzuron.

iii. In addition to ingested residues of these three metabolites, amounts of PCA, CPU, and/or PCAA formed in vivo following ingestion of diflubenzuron should also be included when estimating the total exposure of humans to the carcinogenic metabolites of diflubenzuron. The in vivo conversion of ingested diflubenzuron to PCA and/or CPU was estimated to be 2.0%, based on data in the rat metabolism study.

The Q_1* (estimated unit risk) for PCA, based upon spleen sarcoma rates in male rats, was calculated to be 6.38 x 10^{-2} $(mg/kg/day)^{-1}$ in human equivalents. It has been determined that PCAA does not occur in animal or plant tissues in significant amounts.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.377) for the residues of diflubenzuron per se, in or on citrus, artichokes, walnuts, mushrooms, cottonseed, soybean, rice, and associated livestock commodities. Existing tolerances range from 0.05 ppm in/on soybeans, to 6.0 ppm in/on artichokes. Tolerances of 0.05 ppm have also been established for residues of diflubenzuron in animal commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from diflubenzuron as follows:

i. *Acute exposure and risk.* 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. One day single dose oral studies in rats and mice indicated only marginal effects on methemoglobin levels at a dose level of 10,000 mg/kg/day. Therefore, this risk assessment is not needed, as there are no significant acute effects observed.

ii. *Chronic exposure and risk.* For conducting the chronic dietary risk assessment, refined residue estimates were used for all commodities except for pears. Percent of crop treated figures were also used for certain commodities. The percent of RfD utilized for Non-Nursing Infants <1 Yr. Old (the most highly exposed subgroup) was 6.1%. For Nursing Infants, this figure was 2.2%, and for all other population subgroups, including the overall U.S. Population, the ARC utilized less than 1% of the RfD.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of crop treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 1% for grass/rangeland; 3% for cottonseed; 8% for grapefruit; 3.1% for mushrooms; 2% for oranges; 4% for tangerines; 1% for soybean; and 5% for cattle bolus. Other commodities were assumed to be 100% treated.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which diflubenzuron may be applied in a particular area.

2. *From drinking water.* The Agency currently lacks sufficient water- related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for diflubenzuron. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on the models GENEEC and PRZM/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond; and SCI-GROW, which predicts pesticide concentrations in groundwater. None of these models include consideration of the impact that processing of raw water, for distribution as drinking water, would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely

that drinking water concentrations would ever exceed human health levels of concern.

In the absence of monitoring data for pesticides, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits for a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to diflubenzuron they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Diflubenzuron is a restricted use pesticide and therefore not available for use by homeowners, although it is possible that non- agricultural uses of diflubenzuron may expose people in residential locations. However, based on the low dermal absorption rate (0.5%), and the extremely low dermal and inhalation toxicity, these uses are expected to result in insignificant risks.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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.''

Diflubenzuron is structurally similar to other substituted benzoylurea insecticides including triflumuron and flucycloxuron. However, EPA does not have, at this time, available data to determine whether diflubenzuron has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 more 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Since one day single dose oral studies in rats and mice indicated only marginal effects, this risk assessment is not needed, as there were no significant acute effects observed.

2. *Chronic risk.* Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to diflubenzuron from food will utilize <1 of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Non-nursing infants, <1 year old, for which 6.1% of the RfD was utilized. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The Agency does not have monitoring data available to perform a quantitative drinking water risk assessment for diflubenzuron at this time. Based on PRZM/EXAMS modeling, the average annual mean concentration of diflubenzuron in surface water sources is not expected to exceed 0.05 ppb. Estimated concentrations of CPU in surface water sources is not expected to exceed 0.73 ppb. These values reflect the maximum concentrations for any of the crops treated with diflubenzuron (including pears). The DWLOCs for chronic (non-cancer) exposure to diflubenzuron in drinking water for the U.S. population and Non Nursing Infants (< 1 yr. old), and Females (13+ yrs. old/nursing) are 700, 190, and 600 ppb, respectively. The estimated maximum concentration of diflubenzuron in surface and ground water (0.05 ppb) is lower than the DWLOCs as a contribution to chronic aggregate exposure. Therefore, EPA concludes that residues of diflubenzuron and its metabolites in drinking water would not result in an unacceptable estimate of chronic, non-cancer risk. Despite the potential for exposure to diflubenzuron in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

As stated earlier, although residential exposure has been considered possible from, for example, area-wide gypsy moth or mosquito control, this contribution is anticipated to be negligible. Thus, it was determined that this risk assessment is not necessary.

4. *Aggregate cancer risk for U.S. population.* A cancer risk assessment was conducted for the metabolites of diflubenzuron, PCA and CPU. As a conservative measure, EPA assumes that PCA/CPU occupied 2% of diflubenzuron tolerance levels, based upon metabolism studies. Based upon the ARC estimates described above, the cancer risk for the overall U.S. population from dietary (food only) was calculated to be 5×10^{-7}, which does not exceed EPA's levels of concern. The DWLOC for cancer risk for the U.S. population is 0.26 ppb. Estimated drinking water concentrations from PCA/CPU (0.73 ppb) are greater than the DWLOC of 0.26, for cancer risk. However, EPA believes these estimates are significantly overstated for several reasons. The PRZM/EXAMS model used to derive these estimates was designed for ecological risk assessments, and uses a scenario of a body of water approximating the size of a 2.5 acre pond. This tends to overstate chronic drinking water exposure levels for the following reasons. First, surface water source drinking water generally comes from bodies of water that are substantially larger. Second, the scenario assumes that the whole basin receives an application of the pesticide, but in virtually all cases, basins used for drinking water will contain a substantial portion of the area that does not receive pesticide application. Third, there is often at least some flow or turnover of the water, so the persistence of the pesticide near the drinking water facility is usually overestimated. Fourth, even assuming that the reservoir is directly adjacent to an agricultural field, the field may not be used to grow a crop on which the pesticide in question is registered for use. Fifth, the PRZM/EXAMS scenario does not take into account reductions in residue-loading due to applications less than the maximum application rate or no treatment of the crop at all. Considering these uncertainties associated with the modeled water estimates noted above, and the fact that the estimated concentrations are within close range of the DWLOCs, EPA concludes with reasonable certainty that residues of diflubenzuron in drinking water will

not contribute significantly to the aggregate cancer human health risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to diflubenzuron residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of diflubenzuron, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the developmental study in rats, the maternal (systemic) and the developmental (fetal) NOAEL were both 1,000 mg/kg/day. No LOAELs were achieved, as no maternal or developmental toxicity was observed.

In the developmental toxicity study in rabbits, both the maternal (systemic) and the developmental (fetal) NOAELs were both 1,000 mg/kg/day. As with the rat study, mentioned above, no LOAELs were achieved, as no maternal or developmental toxicity was observed.

iii. *Reproductive toxicity study*. In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOAEL was considered to be less than 36 mg/kg/day for males, and less than 42 mg/kg/day for females based on hematological effects at all dose levels tested. For offspring effects, the NOAEL was equal to 427 mg/kg/day, and the LOAEL was equal to 4,254 mg/kg/day, based on statistically significant decreases in F-1 pup weight on days 4, 8, and 21 of lactation.

iv. *Pre- and post-natal sensitivity*. The toxicological database for evaluating pre- and post-natal toxicity for diflubenzuron is completed with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based upon the result of the developmental and reproductive studies mentioned above.

v. *Conclusion*. The OPP FQPA Safety Factor Committee recommended that the 10X factor for increased susceptibility of infants and children be reduced to 1X, for diflubenzuron. This decision was based on the determination that there was no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to diflubenzuron, and because exposure assessments do not indicate a concern for potential risk to infants and children. There is a complete toxicity database for diflubenzuron and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. Since one day single dose oral studies in rats and mice indicated only marginal effects, this risk assessment is not needed, as there are no significant acute effects observed.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to diflubenzuron from food will utilize 6.1% of the RfD for Non-Nursing Infants < 1 year old, the most highly exposed infant/children population subgroup. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to diflubenzuron in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. As stated earlier, although residential exposure has been considered possible from, for example, area-wide gypsy moth or mosquito control, this contribution is anticipated to be negligible. Thus, it was determined that this risk assessment is not necessary.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to diflubenzuron residues.

V. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residue of concern is diflubenzuron and its metabolites p-chloroaniline (PCA) and p- chlorophenylurea (CPU), expressed as the parent compound.

B. Analytical Enforcement Methodology

Adequate methodology for the analysis of diflubenzuron is available to enforce the tolerance expression. Three analytical methods for diflubenzuron are published in PAM, Vol. II as Methods I, II, and III. All three methods have undergone successful Agency validations and are acceptable for enforcement purposes.

C. Magnitude of Residues

Residues of diflubenzuron and its metabolites are not expected to exceed 0.5 ppm in/on pears as a result of this use.

D. International Residue Limits

There is a Codex maximum residue limit (MRL) for pears at 1 mg/kg, a MRL for Mexico at 1.0 mg/kg, and no limits set for Canada for pears. This tolerance is to be set at a lower level than the MRLs. This is a time-limited tolerance, established solely in support of this section 18 use. In considering permanent tolerances for pears in the future, the Agency will take these circumstances into account.

E. Rotational Crop Restrictions

Available data for diflubenzuron indicate that tolerances for residues in rotational crops will not be required, provided the label specifies a restriction for the planting of rotational crops of at least 30 days.

VI. Conclusion

Therefore, the tolerance is established for combined residues of diflubenzuron and its metabolites PCA and CPU, expressed as parent compound in pears at 0.5 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–300921 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 November 29, 1999.

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 (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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 be 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.'' (cite). 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, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A. of this preamble, 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.2. of this preamble. Mail your copies, identified by the docket number OPP–300921, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. of this preamble. You may also send an electronic copy of your request via e-mail to: 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 5.1/6.1 file format 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. Regulatory Assessment Requirements

This final rule establishes a tolerance 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). 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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues 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 require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the FFDCA, 21 U.S.C. 346a(n)(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). In addition, since tolerances and exemptions that are established under FFDCA section 408(l)(6), 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.

IX. Submission to Congress and the Comptroller General

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 rule in the **Federal Register**. This 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: September 14, 1999 .

Peter Caulkins,

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), 346(a), and 371.

2. In § 180.377, by adding text to paragraph (b) to read as follows:

§ 180.377 Diflubenzuron; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions*. Time-limited tolerances are established for residues of diflubenzuron and its metabolites, PCA (4-chloroaniline) and CPU (4-chlorophenylurea), expressed as the parent diflubenzuron, in connection with use of this pesticide under a section 18 emergency exemption granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Pears	0.5	3/31/00

* * * * *

[FR Doc. 99–25312 Filed 9–28–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300923; FRL–6383–6]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of Tebufenozide benzoic acid, 3,5-dimethyl-,1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide in or on turnips and canola. The Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 1999. Objections and requests for hearings, identified by docket control number OPP–300923, must be received by EPA on or before November 29, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the ''SUPPLEMENTARY INFORMATION'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300923 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja @epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300923. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents