

Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior special consultations 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* (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 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. 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* (August 10, 1999 64 FR 43255). 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 FFDCA section 408(n)(4). 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.

**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 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: February 26, 2001.

**James Jones,**  
*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.

**§ 180.458 Clethodim ((E)-(-)-2-[1-[[[3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one); tolerances for residues.**

2. Section 180.458 is amended by revising the table in paragraph (a)(3), removing paragraphs (a)(4) and (a)(6), and redesignating paragraph (a)(5) as paragraph (a)(4) to read as follows:

(a) \* \* \*  
(3) \* \* \*

Commodity	Parts per million
Beet, sugar, molasses	1.0
Beet, sugar, roots	0.20
Beet, sugar, tops	1.0
Carrot	0.50
Cranberry	0.50
Clover, forage	10.0
Clover, hay	20.0
Fruiting group, vegetable	1.0
Leaf petioles subgroup	0.60
Melon subgroup	2.0
Onion, dry bulb	0.20
Potato, granules/flakes	2.0
Radish, roots	0.50
Radish, tops	0.70
Squash/cucumber subgroup	0.50
Strawberry	3.0
Sunflower, meal	10.0
Sunflower, seed	5.0
Vegetable, tuberos and corm group	1.0

\* \* \* \* \*  
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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-301106; FRL-6766-9]

RIN 2070-AB78

**Pymetrozine; Pesticide Tolerances for Emergency Exemptions**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of pymetrozine in or on pecans. 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 pecans. This regulation establishes a maximum permissible level for residues of pymetrozine in this food commodity.

The tolerance will expire and is revoked on December 31, 2002.

**DATES:** This regulation is effective March 14, 2001. Objections and requests for hearings, identified by docket control number OPP-301106, must be received by EPA on or before May 14, 2001.

**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**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301106 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6463; and e-mail address: madden.barbara@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 Codes	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 under **FOR FURTHER INFORMATION CONTACT**.

*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," "Regulations and Proposed Rules," 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/>. 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.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301106. 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, Mall #2, 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 section 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the insecticide pymetrozine, 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene)amino], in or on pecans at 0.020 part per million (ppm). This tolerance will expire and is revoked on December 31, 2002. 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(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) 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 the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

**III. Emergency Exemption for Pymetrozine on Pecans and FFDCA Tolerances**

The Applicant, the Georgia Department of Agriculture, states that aphids have developed resistance to all labeled products (all chlorinated hydrocarbons, organophosphates, carbamates, or synthetic pyrethroids), except for imidacloprid and aldicarb,

which still provide some suppression of the yellow aphid complex (comprised of the yellow pecan and the blackmargined aphid). Resistance to the organophosphates has also developed in the black pecan aphid, which until recently, had been controlled with this class of chemicals. Unfortunately, the two materials which still retain some effectiveness (imidacloprid and aldicarb) must be used at high rates, performance is often inconsistent, and frequently they fail to provide adequate control. Furthermore, the Applicant states that many growers cannot use aldicarb at all due to its high toxicity.

Growers employ cultural control practices, such as the use of legume ground cover crops to provide alternate hosts for aphids within the orchards. This management of ground cover on orchard floors has been very effective in maintaining lady beetle populations, which have greatly enhanced natural aphid suppression, especially early in the season. However, this practice alone does not provide adequate control, particularly late in the season.

Pecan aphids reproduce parthenogenetically, with up to 32 generations per year, and develop populations which are resistant to chemicals very rapidly. The Applicant states that resistance to a chemical or a chemical class can develop after only three or four applications, as has been seen with the synthetic pyrethroids. High, uncontrolled populations of the yellow aphid complex, especially late in the season, cause damage by removing large amounts of carbohydrates from the trees, reducing the current crop, as well as the bloom the following year. This may reduce yields by 50–75% over a 5–year period. The black pecan aphid causes more serious and immediate damage, by injecting a toxin during feeding which causes leaflet abortion. Heavy infestations can defoliate entire orchards in 7–10 days, with devastating effects lasting at least 2 years.

The Applicant states that pymetrozine is necessary to control aphids and avoid significant economic losses in pecan production. The available materials do not provide adequate control, and pymetrozine has the added benefit of providing another mode of action to help forestall complete resistance development. The Applicant also states that without newer efficacious materials, the black pecan aphid will ultimately threaten the long-term economic viability of commercial pecan production.

EPA has authorized under FIFRA section 18 the use of pymetrozine on pecans for control of yellow pecan aphids, Blackmargined aphids and black

pecan aphids in Georgia. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of pymetrozine in or on pecans. 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 December 31, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on pecans 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 pymetrozine meets EPA's registration requirements for use on pecans 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 pymetrozine 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 Georgia 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 pymetrozine, 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 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 pymetrozine and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of pymetrozine in or on pecans at 0.020 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

##### *A. Toxicological Endpoints*

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. To estimate the acute dietary risk from the exposure of pymetrozine for infants, children and the general population, an UF of 300 is appropriate due to the use of a LOAEL to estimate the toxicological endpoint.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100.

To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q\* is calculated and used to estimate

risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10<sup>-6</sup> or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an

endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE<sub>cancer</sub> = point of departure/exposures) is calculated. A summary of the toxicological endpoints for pymetrozine used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYMETROZINE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF*1 and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary Females 13–50 years of age	NOAEL = 10 mg/kg UF = 100 Acute RfD = 0.10 mg/kg	FQPA SF = 3 aPAD = 0.033 mg/kg	Rabbit developmental study LOAEL = 75 mg/kg based on increased incidence of skeletal anomalies
Acute dietary Infants, children	LOAEL = 125 mg/kg UF = 300 Acute RfD = 0.42 mg/kg	FQPA SF = 3 aPAD = 0.14 mg/kg	Acute neurotoxicity study LOAEL = 125 mg/kg based on decreased body temperature, decreased motor activity and functional observational battery (FOB) parameters associated with decreased activity
Acute dietary General population	LOAEL = 125 mg/kg UF = 300 Acute RfD = 0.42 mg/kg	FQPA SF = 1 aPAD = 0.42 mg/kg	Acute neurotoxicity study LOAEL = 125 mg/kg based on decreased body temperature, decreased motor activity and functional observational battery (FOB) parameters associated with decreased activity
Chronic dietary Females 13–50 years of age, infants, and children	NOAEL = 0.377 mg/kg/day UF = 100 Chronic RfD = 0.0038 mg/kg/day	FQPA SF = 3 cPAD = 0.0013 mg/kg/day	Rat chronic feeding study LOAEL = 3.76 mg/kg/day based on liver hypertrophy and pathology supported by the rat chronic feeding and multigeneration reproduction studies and dog subchronic and chronic studies
Chronic dietary General population	NOAEL = 0.377 mg/kg/day UF = 100 Chronic RfD = 0.0038 mg/kg/day	FQPA SF = 1 cPAD = 0.0038 mg/kg/day	Rat chronic feeding study LOAEL = 3.76 mg/kg/day based on liver hypertrophy and pathology supported by the rat chronic feeding and multigeneration reproduction studies and dog subchronic and chronic studies
Short-term dermal (1 to 7 days)	None	None	Rat dermal toxicity - no effects at the highest dose tested (HDT)
Intermediate-term dermal (1 week to several months)	None	None	Rat dermal toxicity - NOAEL at the HDT
Long-term dermal (several months to life-time)	None	None	None
Short-term inhalation (1 to 7 days) (residential)	Oral study NOAEL = 10 mg/kg/day Inhalation absorption rate = 100%	LOC for MOE = 100 (residential)	Rabbit developmental study LOAEL = 75 mg/kg based on reduced body weight gain, food consumption, and feed efficiency. Also increased skeletal anomalies in pups
Intermediate-term inhalation (1 week to several months) (residential)	Oral study NOAEL = 0.377 mg/kg/day Inhalation absorption rate = 100%	LOC for MOE = 100 (residential)	Rat chronic feeding study LOAEL = 3.76 mg/kg/day based on liver hypertrophy and pathology supported by the rat chronic feeding and multigeneration reproduction studies and dog subchronic and chronic studies
Long-term inhalation (several months to life-time)	None	None	None

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYMETROZINE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF*1 and Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	$Q_1^* = 0.0119 \text{ (mg/kg/day)}^{-1}$	$LOC = 1 \times 10^{-6}$	“Likely human carcinogen” based on combined (benign hepatoma and/or carcinomas) liver tumors

\* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.556) for the residues of pymetrozine, in or on tuberous and corm vegetables (crop group 1), cucurbit vegetables (crop group 8) and fruiting vegetables (crop group 9). Risk assessments were conducted by EPA to assess dietary exposures from pymetrozine in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: it was assumed that 100% of the all crops were treated resulting in tolerance level residues on all crops.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 –nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: it was assumed that 100% of the all crops were treated resulting in tolerance level residues on all crops.

iii. *Cancer.* In conducting this cancer dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the cancer exposure assessments: use of average field trial residue values and percent crop treated (PCT) data were used for tuberous and

corm vegetables, cucurbit vegetables, and fruiting vegetables.

iv. *Anticipated residue and PCT information.* 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 food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, 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: Tuberous and corm vegetables, 20%; cucurbit vegetables, 16% except cucumbers (10%); squash (8%); melons (25%); pumpkins (10%); zucchini (10%); and fruiting vegetables, 11% except, tomatoes (12%); peppers (8%); eggplant (6%). It was assumed that 100% of the pecan crop was treated.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, 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 pymetrozine may be applied in a particular area.

a. *Dietary exposure from drinking water.* The Agency lacks sufficient

monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pymetrozine in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of pymetrozine.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) 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.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOC) 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 on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and from residential uses. Since DWLOCs address total aggregate exposure to pymetrozine, they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models, the EECs of pymetrozine for acute exposures are estimated to be 4.0 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 2.3 ppb for surface water and 0.02 ppb for ground water.

b. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Currently, pymetrozine is not registered for use on any sites that would result in residential exposure.

c. *Cumulative exposure to substances with a 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."

EPA does not have, at this time, available data to determine whether pymetrozine 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, pymetrozine 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 pymetrozine has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

### C. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* FFDC 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in

calculating a dose level that poses no appreciable risk to humans.

ii. *Developmental toxicity studies.* In the rat, developmental toxicity was observed only at maternally toxic dose levels: maternal NOAEL: 30 mg/kg/day, LOAEL: 100 mg/kg/day (reduced body weight gains and food consumption); developmental NOAEL: 100 mg/kg/day, LOAEL: 300 mg/kg/day (increased incidence of skeletal anomalies). In the rabbit, developmental toxicity was also observed only at maternally toxic dose levels: (maternal NOAEL: 10 mg/kg/day, LOAEL: 75 mg/kg/day reduced body weight gains and reduced food consumption and efficiency); developmental NOAEL: 10 mg/kg/day, LOAEL: 75 mg/kg/day (increased incidence of skeletal anomalies).

iii. *Reproductive toxicity study.* In the rat reproduction study, systemic/developmental toxicity was observed in the pups at parentally toxic dose levels (parental systemic NOAEL: 1.4 mg/kg/day for males, 1.6 mg/kg/day for females, LOAEL: 13.9 mg/kg/day for males, 16.0 mg/kg/day for females (liver effects in the F0 and F1 males); offspring systemic/developmental NOAEL: 13.9 mg/kg/day for males, 16.0 mg/kg/day for females, LOAEL: 136.9 mg/kg/day for males, 151.6 mg/kg/day for females (decreased pup weight and delay in eye opening in both F1 and F2 litters). There was no reproductive toxicity at dose levels up to 136.9 mg/kg/day for males and 151.6 mg/kg/day for females.

iv. *Prenatal and postnatal sensitivity.* Based on the results of the developmental and reproduction studies, there is no indication of increased sensitivity in rats or rabbits to *in utero* and/or postnatal exposure to pymetrozine.

v. *Neurotoxicity.* Acute and subchronic neurotoxicity studies are available for pymetrozine. The acute neurotoxicity study did not establish a NOAEL for effects on body temperature, FOB parameters or motor activity. In the subchronic neurotoxicity study, stereotypy in males and tiptoe gate or walking on toes in females were observed. The frequency and magnitude of these effects were low. Before any regulatory decision based on the conclusion that pymetrozine exerts a direct effect on the nervous system, a confirmatory study that more definitively establishes that pymetrozine causes stereotypy in males (head moving and excessive sniffing) and tiptoe gait in females is needed. The Agency has requested a developmental neurotoxicity study in rats be conducted.

vi. *Conclusion.* Although there was no indication of increased susceptibility in the existing prenatal and postnatal studies, the 10x FQPA safety factor has been reduced to 3x because there is a data gap for a developmental neurotoxicity study. The FQPA safety factor for pymetrozine is applicable to females aged 13–50 years, infants, children aged 1–6 years, and children aged 7–12 years for all exposure scenarios.

*D. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water

exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to pymetrozine in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable

levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of pymetrozine on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to pymetrozine will occupy 2% of the aPAD for the U.S. population, 5% of the aPAD for females 13 years and older, 1% of the aPAD for all infants and 3% of the aPAD for children 1–6 years old, the children subpopulation at greatest exposure. In addition, despite the potential for acute dietary exposure to pymetrozine in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of pymetrozine in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PYMETROZINE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. population	0.42	2	4.0	0.02	15,000
Females aged 13–50 years	0.033	5	4.0	0.02	940
All infants	0.14	1	4.0	0.02	1,400
Children aged 1–6 years	0.14	3	4.0	0.02	1,400

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pymetrozine from food will utilize 12% of the cPAD for the U.S. population, 29% of the cPAD for females 13 years and older, 23% of the cPAD for all infants, and 74% of the

cPAD for children 1–6 years, the children subpopulation with greatest exposure. There are no residential uses for pymetrozine that result in chronic residential exposure to pymetrozine. In addition, despite the potential for chronic dietary exposure to pymetrozine in drinking water, after calculating

DWLOCs and comparing them to conservative model EECs of pymetrozine in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYMETROZINE

Population subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0038	12	2.3	0.02	120
Females aged 13–50	0.0013	29	2.3	0.02	30
All infants	0.0013	23	2.3	0.02	10
Children aged 1–6 years	0.0013	74	2.3	0.02	3

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pymetrozine is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-

occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Pymetrozine is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for cancer exposure, EPA has concluded that exposure to pymetrozine from food

will result in an estimated risk of  $1.2 \times 10^{-7}$  for the U.S. population. There are no residential uses for pymetrozine that result in residential exposure to pymetrozine. In addition, despite the potential for dietary exposure to pymetrozine in drinking water, after calculating a DWLOC and comparing it to conservative model EECs of pymetrozine in surface and ground water, EPA does not expect the aggregate exposure to exceed  $1 \times 10^{-6}$ , as shown in the following Table 4:

TABLE 4.—AGGREGATE CANCER RISK ASSESSMENT FOR PYMETROZINE

Population Subgroup	Q1*(mg/kg/day)-1	Estimated Cancer Risk (Food + Non-dietary)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Cancer Risk DWLOC (ppb)
General U.S. population	0.0119	$1.2 \times 10^{-7}$	2.3	0.02	3

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

**V. Other Considerations**

*A. Analytical Enforcement Methodology*

The Agency has evaluated and accepted Method AG-643 (HPLC/UV) as a tolerance enforcement method for a number of plant commodities, including cucurbit vegetables, fruiting vegetables, and tuberous and corm vegetables. This method has a limit of quantitation (LOQ) of 0.02 ppm. In data submitted to support a pending petition to establish tolerances of pymetrozine in cotton commodities (PP 8F4984), the registrant has indicated that this method produces acceptable recovery of pymetrozine from refined cottonseed oil. Based on this, the Agency will assume that Method AG-643 is adequate for enforcement of tolerances for residues of pymetrozine in pecan nutmeat for purposes of this section 18 only.

The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

*B. International Residue Limits*

There are no Codex maximum residue levels (MRLs) established for pymetrozine. There are provisional MRLs in Germany for hops (10 ppm) and potatoes (0.02 ppm), and the

European Union is currently evaluating a proposed tolerance of 5 ppm on hops. There are no international residue limits that affect this section 18 exemption.

*C. Conditions*

Maximum application rate per application is 0.125 lbs active ingredient per acre. A maximum of 0.25 lbs active ingredient per acre may be applied per year. A minimum of 7 days between applications is required. A 14-day pre-harvest interval (PHI) is required. For the proposed section 18 use on pecans there are no rotational crop issues since pecans are not rotated to another crop.

**VI. Conclusion**

Therefore, the tolerance is established for residues of pymetrozine, 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene)amino], in or on pecans at 0.020 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-301106 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 May 14, 2001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You

may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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 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, 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.

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.

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.2. Mail your copies, identified by the docket control number OPP-301106, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 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 time-limited tolerance under FFDC section 408. 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 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 other 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 FFDC section 408, 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. 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 FFDC section 408(n)(4). 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. 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 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: March 2, 2001.

**James Jones,**

*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 180.556 is amended by revising paragraph (b) to read as follows:

**§ 180.556 Pymetrozine; tolerance for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the insecticide pymetrozine, 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene)amino] in connection with use of the pesticide under the section 18 exemption granted by EPA. The time-limited tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/Revocation Date
Pecan	0.020	December 31, 2002

\* \* \* \* \*

[FR Doc. 01-6328 Filed 3-13-01; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-301108; FRL-6774-9]

**RIN 2070-AB78**

**Imazethapyr; Time-Limited Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for the combined residues of imazethapyr, as its ammonium salt, and its metabolite in or on rice, grain; rice, straw; rice hulls, and rice, bran. BASF requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDC), as amended by the Food Quality Protection Act (FQPA) of 1996. These tolerances will expire on January 1, 2003.

**DATES:** This regulation is effective March 14, 2001. Objections and requests for hearings, identified by docket control number OPP-301108, must be received by EPA on or before May 14, 2001.

**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**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301108 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Daniel J. Rosenblatt, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5697; e-mail address: rosenblatt.dan@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 Codes	Examples of Potentially Affected Entities
Industry	111 ..... 112 ..... 311 .....	Crop production Animal production Food manufacturing

Categories	NAICS Codes	Examples of Potentially Affected Entities
	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 under **FOR FURTHER INFORMATION CONTACT**.

*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," "Regulations and Proposed Rules," 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/>. 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.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301108. 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 #2, 1921 Jefferson