

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 FFDCA section 408(d) 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 any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a 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* (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 FFDCA section 408(n)(4).

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: July 20, 2000.

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), (346a) and 371.

2. In § 180.515, by revising paragraph (a) to read as follows:

§ 180.515 Carfentrazone-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene propanoate) and its metabolite: carfentrazone-chloropropionic acid (alpha, 2-dichloro-5-[4-difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid) in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.20
Corn, sweet, forage	0.20
Corn, sweet, kernel plus cob with husk removed	0.10
Grain, cereal, forage (excluding corn and sorghum)	1.0
Grain, cereal, hay	0.30
Grain, cereal, group	0.10
Grain, cereal, stover	0.30
Grain, cereal, straw (excluding rice)	0.10
Rice, straw	1.0
Sorghum, forage	0.20

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301033; FRL-6599-2]

RIN 2070-AB78

Pymetrozine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pymetrozine 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene)amino] in or on cucurbit vegetables (Crop Group 8) at 0.05 parts per million (ppm) and fruiting vegetables (Crop Group 9) at 0.05 ppm. Novartis Crop Protection, Inc. of Greensboro, NC 27419 requested this

tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 9, 2000. Objections and requests for hearings, identified by docket control number OPP-301033, must be received by EPA on or before October 10, 2000.

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-301033 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel Peacock, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5407; e-mail address: peacock.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 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 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/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301033. 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 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

In the **Federal Register** of May 20, 1998 (63 FR 27723-27727) (FRL-5773-2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170) announcing the filing of a pesticide petition (PP) for tolerance by Novartis Crop Protection, Inc. of Greensboro, NC 27419. This notice included a summary of the petition prepared by Novartis Crop Protection, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.556 be amended by 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 hops at 5 ppm, fruiting vegetables at

0.05 ppm, and cucurbits and potatoes at 0.02 ppm.

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...."

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).

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of pymetrozine, 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene) amino] on cucurbit vegetables (Crop Group 8) at 0.05 parts per million (ppm) and fruiting vegetables at 0.05 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 pymetrozine, 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene)amino] are discussed in this unit or in a previous **Federal Register** notice.

1. *Acute toxicity.* In general, technical pymetrozine has low acute toxicity, being classified as Toxicity Category III for acute dermal and primary eye irritation studies and Toxicity Category IV for acute oral, acute inhalation and primary dermal studies. It is a slight sensitizer.

2. *Subchronic and chronic toxicity.* EPA's September 29, 1999, **Federal Register** notice (64 FR 52438-52450) (FRL-6385-6) summarized the results of the subchronic and chronic toxicity, metabolism, and dermal penetration studies in animals.

B. Toxicological Endpoints

EPA's September 29, 1999, **Federal Register** notice (64 FR 52438-52450) (FRL-6385-6) discussed the toxicological endpoints in detail and will not be repeated here.

C. Exposures and Risks

1. Current and proposed uses.

Pymetrozine is an insecticide of the pyridine azomethine type and was first registered in 1999. Pymetrozine controls aphids and suppression of whiteflies in a variety of crops. The mode of action of pymetrozine has not been precisely determined biochemically; physiologically, it appears to act by preventing these insects from inserting their stylus into the plant tissue.

Currently, EPA has registered pymetrozine for use on tuberous and corm vegetables (Subgroup 1-C) and tobacco under Fulfill® (EPA Reg. No. 100-912) and ornamental plants under Endeavor® (EPA Reg. No. 100-913). There are no homeowner applications for pymetrozine. However; postapplication (residential) exposure could occur due to contact with treated ornamental plants. For both Fulfill® and Endeavor®, pymetrozine is formulated as a water-dispersible granule containing 50% active ingredient.

Fulfill® may be applied by either ground or aerial broadcast equipment, in a minimum of 10 gallons of water per acre; chemigation is not permitted. Pymetrozine is applied to the foliage of affected plants where it is quickly absorbed. Potato and tobacco crops may be treated up to twice, each at a maximum rate of 0.09 lb active ingredient/acre (ai/A). The maximum seasonal use rate is 0.17 lb ai/acre. The retreatment and pre-harvest intervals are 7 and 14 days, respectively. The label for Fulfill® specifies a restricted-entry interval of 12 hours.

Endeavor® may be broadcast-applied to ornamentals at a rate not to exceed 10 ounce/acre/application (oz./A/application). Multiple applications may be made on a 7- to 14-day interval. For indoor use, the yearly application rate is not to exceed 100 oz./A/year; for outdoor use, the maximum rate is 48 oz./A/year.

Novartis Crop Protection has proposed that the use of pymetrozine be expanded on the Fulfill® label to include cucurbit and fruiting vegetables. The rates, number of applications, pre-harvest intervals, and restricted-entry interval will remain the same for these additional uses.

2. *From food and feed uses.* This Rule establishes two new tolerances for pymetrozine: in or on cucurbit vegetables (Crop Group 8) at 0.05 parts per million (ppm) and fruiting vegetables (Crop Group 9) at 0.05 ppm.

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.

Most of the dietary risk assessments performed on pymetrozine used a Tier

1 approach for fruiting vegetables, cucurbits, and potatoes, crops originally requested in the petition. That is, the Agency assumed 100% crop treated and tolerance level residues. For carcinogenicity risk assessment, the Agency used a Tier 3 chronic dietary exposure analysis for fruiting, cucurbit, and tuberous and corm vegetables. This was based on 6-20% of the crop treated and an anticipated residue of 0.0046 ppm to refine the cancer risk. Novartis supplied this estimate of PCT to the Agency. The Agency reviewed Novartis' estimate and found it reasonable.

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. EPA finds that the PCT information is reliable and has a valid basis. Before the petitioner can increase production of product for treatment of greater than 340,000 acres (20% of 1,700,000 total acres for fruiting, cucurbit, and the tuberous and corm subgroup), permission from the Agency must be obtained. 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 consumption of food in a particular area.

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.

The Tier 1 DEEM® analysis indicates that acute dietary (food only) exposure to pymetrozine from all existing and proposed uses (tuberous and corm, fruiting, and cucurbit vegetables) will be below EPA's level of concern (100% of the acute Population-Adjusted Dose (aPAD)) and will not occupy more than 7% of the aPAD for any population subgroup, including those of infants and children. For the maximum exposed subgroup, the 95th percentile of exposure (children ages 1-6 years) is

predicted to be 3.3% of the aPAD. Due to pymetrozine's lower acute endpoint for females 13–50 years (0.033 mg/kg) versus that of other population subgroups (0.14 mg/kg), the percentage of the aPAD occupied for females 13–50 years (6.5%) is slightly higher than that estimated for children 1–6 years. For a

Tier 1 analysis, EPA considers exposure at the 95th percentile of exposure. Even at the 99.9th percentile of exposure, the acute risk is well below EPA's level of concern.

ii. *Chronic exposure and risk.* The Tier 1 DEEM® chronic analysis indicates that exposure to pymetrozine from tuberous and corm vegetables,

cucurbits, and fruiting vegetables will occupy less than 74% of the chronic Population-Adjusted Dose (cPAD) for children ages 1–6 (the most highly exposed population subgroup). Chronic dietary risk to all other subgroups is less than that of children ages 1–6. See Table 1 below.

TABLE 1.—CHRONIC DIETARY (FOOD ONLY) TIER 1 EXPOSURE AND RISK ESTIMATES FOR PYMETROZINE USE ON CUCURBIT, FRUITING, AND TUBEROUS AND CORM VEGETABLES

Population Subgroup ¹	cPAD, mg/kg/day ²	Exposure, mg/kg/day	%cPAD ³
U.S. Population (total)	0.0038	0.000455	12
Hispanics	0.0038	0.000496	13
Children 1–6 yrs	0.0013	0.000958	74
Females 13–19 (not preg or nursing)	0.0013	0.48	37
Males 13–19 yrs	0.0038	0.0005	13

¹ Population subgroups shown include the U.S. general population and the maximally exposed subpopulation of adults, infants and children, and women of child-bearing age.

² cPAD values incorporate the different FQPA Safety Factors for the various population subgroups

³ %cPAD = Exposure (mg/kg) ÷ cPAD (mg/kg)100.

iii. *Cancer exposure and risk.* The Agency used a Tier 3 DEEM® analysis for cancer risk estimates to the U.S. population. Based on use of pymetrozine on tuberous and corm vegetables, fruiting vegetables, and cucurbits vegetables, the food only cancer risk is 1×10^{-7} , which is below the Agency's level of concern.

3. *From drinking water.* Pymetrozine is not persistent, breaking down in the environment through a number of mechanisms and degradation pathways including hydrolysis and aqueous and soil photolysis. Laboratory studies indicate that pymetrozine is a "low mobility" to "no mobility" chemical with respect to leaching. The environmental fate profile and application rates suggest that there should not be any notable concerns in the areas of soil mobility and persistence for pymetrozine resulting from its agriculture use to control aphids and whiteflies. Based on the low application rate, the field dissipation data, and the minimal concentrations relative to the parent (less than 10%, total), pymetrozine degrades should not enter ground and surface water to any appreciable extent.

EPA used the Screening Concentration In GROund Water (SCI-GROW) model to predict the Environmental Estimated Concentrations (EEC's) for pymetrozine in ground water. SCI-GROW is a regression model based on actual groundwater monitoring data. SCI-GROW appears to provide realistic

estimates of pesticide concentrations in shallow, highly vulnerable ground water sites. Using the highest application rate of 0.187 lb ai/A (hops), SCI-GROW estimates the concentration of pymetrozine in groundwater to be 0.015 µg/L. As there is relatively little temporal variation in ground water, this estimate can be used for both acute and chronic exposure scenarios.

In addition, EPA used the Tier 2 GENERIC Estimated Environmental Concentration (GENEEC) and Pesticide Root Zone Model-EXAMS (PRZM-EXAMS) model to obtain EEC's in surface water. The standard PRZM-EXAMS runoff modeling scenario is based on a 10 hectares (ha) field draining into a 1 ha by 2 meter deep small water body. This scenario represents a watershed drainage area: water volume ratio of 5 m²/m³. Each PRZM modeling scenario represents a unique combination of climatic conditions (e.g., rainfall), crop specific management practices, soil specific properties, site specific hydrology, and pesticide specific application and dissipation processes. Each PRZM simulation is conducted for multiple years to provide a probabilistic exposure characterization for a single site.

Based on the maximum use pattern for any of the requested crops (hops at 0.56 lb ai/A/season), the GENEEC-estimated 56-day surface water EEC is 2.29 µg/L. Actual chronic surface water concentrations are likely to be less than this estimated 56-day average. Because the DWLOC exceeds the chronic EEC,

the Agency believes that the aggregate risk from exposure to pymetrozine due to the proposed uses on tuberous and corm, fruiting, and cucurbit vegetables is not likely to exceed our level of concern. The DWLOCs for acute, short-term, and chronic exposure have not changed from those detailed in the risk assessment; all remain greater than the Tier 1 EEC values.

The EEC's for surface water (2.29 µg/L) are higher than those for groundwater (0.015 µg/L). Therefore, surface water EEC's will be used:

(1) To estimate actual concentrations of pymetrozine in water.

(2) To compare those concentrations with the Drinking Water Levels of Comparison (DWLOCs) in µg/L. DWLOCs are acceptable concentrations of pymetrozine in drinking water as theoretical upper limits in light of total aggregate exposure to that pesticide from food, water, and residential uses. The EPA calculates each DWLOC by subtracting the food and residential exposures (if appropriate) from the PAD or Cancer Dose and by converting this resulting dose, called the Maximum Water Exposure (in mg/kg/day), into a concentration of pymetrozine in water expressed in µg/L. Only pymetrozine was included in the drinking water assessment on the basis that the metabolites would not be found in drinking water. Table 2 shows the Drinking Water Levels of Comparison (DWLOC's) for acute, chronic, and cancer exposure.

TABLE 2.—DRINKING WATER LEVELS OF COMPARISON FOR AGGREGATED EXPOSURES

Scenario/Population Subgroup ^a	Population-Adjusted Dose, mg/kg/day	Exposure mg/kg/day ^b	Maximum Water Exposure mg/kg/day	DWLOC µg/L ^c
Acute Exposure				EEC = 4.0
U.S. Population	0.42	0.002	0.41802	15000
Hispanic	0.42	0.0023	0.417715	15000
Children (1–6 yrs)	0.14	0.0046	0.135444	1400
Females (13–19, not pregnant or nursing)	0.033	0.0021	0.030861	930
Males (13–19 yrs)	0.42	0.0021	0.417948	15000
Short-term Exposure^d				
Toddlers	0.033	0.001	0.03203	320
Chronic Exposure				EEC = 2.29
U.S. Population	0.0038	0	0.003345	2.6
Hispanic	0.00380	0	0.003304	120
Children (1–6 yrs)	0.0013	0.001	0.000342	3.4
Females (13–19, not pregnant or nursing)	0.0013	0	0.00082	25
Males (13–19)	0.0038	0.001	0.0033	120

^a Population subgroups shown include the U.S. general population and the maximally exposed subpopulation of adults, infants and children, and women of child-bearing age for each exposure scenario.

^b Exposure is the sum of dietary and non-dietary exposure. For the case of pymetrozine, only the short-term and cancer DWLOC have a non-dietary component. See section 5.4 for clarification.

^c DWLOC = Maximum Water Exposure (mg/kg/day) 1,000 µg/mg body weight (70 kg general population/males 13+ 60 kg females 13+, 10 kg infants and children) ÷ Water Consumption (2 L/day adults, 1 L/day infants and children). The acute EEC is 4.0 µg/L, the chronic and cancer EEC is 2.29 µg/L.

^d For short-term exposure, the short-term oral NOAEL was converted to a PAD by applying the 100x and 3x safety factors. Chronic food exposure for children ages 1–6 was used to estimate background food exposure.

i. *Acute exposure and risk.* For acute aggregate exposure scenarios, the DWLOC values (930–15,000 µg/L) are all in excess of the modeled acute EEC values (4.0 µg/L); thus, drinking water is not expected to be a significant contributor towards this type of exposure.

ii. *Chronic exposure and risk.* For chronic (non-cancer) aggregate exposure scenarios, the DWLOC values (3.4–120 µg/L) are all in excess of the modeled EEC values (2.29 µg/L); thus, drinking water is not expected to be a significant contributor towards this type of exposure.

iii. *Cancer exposure and risk.* For cancer aggregate exposure scenarios, the DWLOC value of 2.6 µg/L is in excess of the modeled EEC values (2.29 µg/L). EPA has calculated the cancer risk resulting from 2.29 µg/L in drinking water, a dose of 0.000654 mg/kg/day, to be 6.54×10^{-7} . Thus, drinking water alone does not exceed EPA's level of concern (in the range of 1×10^{-6}) and is not expected to be a significant contributor towards cancer risk.

4. *From non-dietary exposure.* As currently proposed, pymetrozine could be used on the following residential non-food sites: ornamentals (landscape, ground-covers, interiorscapes); home nurseries, non-bearing orchards, and greenhouses. The end-use product, Endeavor®, may not be applied by homeowners, but post-application exposure could occur. There are no intermediate-term exposure scenarios for which a risk assessment is required.

Short-term exposures are not applicable for adults but are applicable for toddlers.

Since there was no chemical specific data to determine dislodgeable residues, the EPA used its Standard Operating Procedures (SOPs) for Residential Exposure Assessment (Draft, December 18, 1997) to estimate postapplication exposure. This Standard Operating Procedure (SOP) does not include a scenario for ornamentals, landscapes and groundcover. Therefore, this assessment used the garden plants scenarios to determine postapplication exposures.

The postapplication scenarios and associated Margins of Exposure (MOEs) included:

- (1) Incidental non-dietary hand-to-mouth transfer of pesticide residues (770,000).
- (2) Incidental non-dietary ingestion of pesticide-treated plants (not significant).
- (3) Incidental non-dietary ingestion of soil from pesticide-treated areas (660,000).

The following assumptions were used for estimating postapplication for the three post-application scenarios.

(a) *Hand-to-mouth transfer (incidental non-dietary ingestion).*

- Maximum application rate of 0.3125 lbs ai per acre as specified on the label
- Twenty percent of the application rate are available on the foliage as dislodgeable residue
- Exposure is assessed on the same day the pesticide is applied

- Medium surface area of both hands is 350 cm² for a toddler (age 3 yrs old)
- Mean rate of hand-to-mouth activity is 1.56 events/hr
- Duration of exposure was assumed to be 0.18 hrs/day (10 mins) for toddlers
- A body weight of 15 kg was assumed for toddlers
- Short term NOAEL = 10 mg/kg/day (acute dietary);
- Hand-to-mouth exposure is not considered an intermediate-term exposure scenario

(b) *Accidental ingestion of plant material.*

- According to the HED SOP for Residential Exposure, exposure via this route is considered negligible.

(c) *Accidental ingestion of soil.*

- Maximum application rate of 0.3125 lbs ai per acre as specified on the label
- Twenty percent of the application rate are available on the foliage as dislodgeable residue
- Exposure is assessed on the same day the pesticide is applied
- The fraction of ai available in uppermost centimeter of soil is 1 cm
- The assumed soil ingestion rate for children (ages 1–6 yrs) is 100 mg/day
- A body weight of 15 kg was assumed for toddlers
- Short term NOAEL = 10 mg/kg/day (acute dietary);
- Exposure from soil ingestion is not considered an intermediate-term exposure scenario.

These exposure estimates are based on upper-percentile (i.e., maximum application rate, available residues and

duration of exposure) and some central tendency (i.e., transfer coefficient, surface area, hand-to-mouth activity, and body weight) assumptions and are considered to be representative of high-end exposures. The uncertainties associated with this assessment stem from the use of an assumed amount of pesticide available from gardens, and assumptions regarding dissipation, transfer of chemical residues, and hand-to-mouth activity. The estimated exposures are believed to be reasonable high-end estimates based on observations from chemical-specific field studies and professional judgement.

EPA determined that the FQPA Safety Factor to protect infants and children should be reduced to 3x and that the factor should apply to female (13–50 years), infant, and children population subgroups for all risk assessments. Thus, the levels of concern for these postapplication exposure scenarios are MOEs that are less than 100 for adult populations and less than 300 for female (13–50), infant, and children populations.

i. *Chronic exposure and risk.* Based on the proposed uses of pymetrozine, EPA does not believe there will be chronic non-occupational exposure to this insecticide.

ii. *Cancer exposure and risk.* The EPA has estimated the lifetime average daily dose for non-occupational exposure resulting from pruning and planting treated ornamental plants is 0.0000012 mg/kg/day.

A quantitative cancer risk assessment was performed for postapplication non-occupational exposure to treated ornamentals (e.g., a home garden). Exposures were estimated using EPA's default activity scenarios, transfer coefficients and input parameters as follows: The fraction of active ingredient retained on foliage is assumed to be 20% (0.2) on day zero (= percent dislodgeable foliar residue, DFR, after initial treatment). This fraction is assumed to further dissipate at the rate of 10% (0.1) per day on following days. These are EPA's default values for exposure.

- An application rate of 0.3125 lbs ai/acre (electrostatic spray, pulsfog and low volume systems) was used to represent the worst case scenario.

- Transfer coefficient of 4,500 was used to represent heaviest day of activity (planting, transplanting, and pruning) for contact with treated ornamental plants

- Assumed homeowner worked 0.67 hours per day (Residential SOP for Gardening)

- Assumed homeowner worked a total of 2 days per year performing heaviest activities (planting, pruning) at time points shortly after pymetrozine application

- Assumed homeowner would be exposed for 50 years of their life
- Dermal absorption = 1%
- Body weight = 70 kg
- Life expectancy = 70 years
- Cancer Q* (mg/kg/day) = 1.19×10^{-2}

The cancer risk estimate for this postapplication exposure is 1.4×10^{-8} and does not exceed EPA's level of concern (in the range of 1×10^{-6}) for the general population.

iii. *Short- and intermediate-term exposure and risk.* EPA did not calculate margins of exposure (MOEs) for adults since there are no short-term dermal exposure scenarios. However, short-term oral exposures and risks were calculated for toddlers. For toddlers, the MOEs for short-term postapplication exposure scenarios are 770,000 and 660,000 for hand-to-mouth and soil ingestion scenarios. These values are all greater than either of the threshold values; thus, short-term risks are below the Agency's level of concern.

5. *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."

According to our information, there are no other pesticides that have a common mechanism of toxicity with pymetrozine. 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).

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

1. *Acute risk.* The risk from aggregate acute exposure from food and drinking water from pymetrozine is below EPA level of concern for the following reasons. As indicated in Table 2, the

Tier 1 Dietary Exposure Evaluation Model (DEEM®) analysis indicates that acute dietary (food only) exposure to pymetrozine from fruiting vegetables, cucurbits, and tuberous and corm vegetables (Subgroup 1-C) will occupy less than 1/2% (0.001980/0.42) of the aPAD for the U.S. population, which is below EPA's level of concern of 100% of the aPAD. In addition, for drinking water, the DWLOC value (15,000 µg/L) for the U.S. population is greatly in excess of the modeled acute EEC value (1.9 µg/L); thus, drinking water is not expected to be a significant contributor towards this type of exposure.

2. *Chronic risk.* As indicated in Table 1, the Tier 1 DEEM analysis indicates that chronic dietary (food only) exposure to pymetrozine will utilize less than 12% (0.000455/0.0038) of the chronic Population-Adjusted Dose (cPAD) for the U.S. population. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. In addition, for drinking water, the DWLOC value (120 µg/L) for the U.S. Population is greatly in excess of the modeled EEC values (2.29 µg/L); thus, drinking water is not expected to be a significant contributor towards this type of exposure. Despite the potential for exposure in the diet, drinking water, and from non-dietary, non-occupational exposure, EPA does not expect the aggregate chronic exposure to exceed 100% of the cPAD.

3. *Aggregate cancer risk for U.S. population.* For fruiting vegetables, cucurbits, and tuberous and corm vegetables, EPA based its cancer risk assessment on a Tier 3 estimate of dietary exposure, which incorporates anticipated residues (0.0046 ppm) for pymetrozine and an estimate for percent crop treated. At this level of refinement, EPA's estimates of food exposure and cancer risk were 0.000008 mg/kg/day and 1×10^{-7} (in the range of 1×10^{-6}). The EPA also calculated a lifetime average daily dose of 0.0000012 mg/kg/day for non-occupational exposure resulting from pruning and planting treated ornamental plants, resulting in a cancer risk from this type of exposure of 0.143×10^{-7} . For drinking water, the cancer dose was 0.0000654 mg/kg/day, and the cancer risk was 8×10^{-7} .

The aggregate cancer risk for all exposures, even including water is 0.9×10^{-6} , which is below the Agency's level of concern.

4. *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 pymetrozine 1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-[(3-pyridinylmethylene) amino] 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 pymetrozine, EPA considered data from developmental toxicity studies in rabbit, an acute neurotoxicity study in the rat, and a chronic feeding study in the rat. See the Toxicological Profile (Unit III.A) for a discussion of these tests.

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 database 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 uncertainty factor (usually 100 for combined inter- and intra-species variability) and the additional 3-fold MOE/uncertainty factors, as described above, 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 these safety factors.

ii. *Conclusion.* EPA considered the available data and determined that the 10-fold FQPA factor could be reduced to 3.

2. *Acute risk.* The risk from aggregate acute exposure from food and drinking water from pymetrozine is below EPA level of concern for the following reasons. The Tier 1 Dietary Exposure Evaluation Model (DEEM®) analysis indicates that acute dietary (food only) exposure to pymetrozine from tuberous and corm vegetables (Subgroup 1-C), fruiting vegetables and cucurbits will occupy less than 4% (0.004556/0.14) of the aPAD for children (1 to 6 years old), which is below EPA's level of concern of 100% of the aPAD. In addition, for drinking water, the DWLOC value (1,400 µg/L) for children (1 to 6 years old) is greatly in excess of the modeled acute EEC values (1.9 µg/L); thus, drinking water is not expected to be a significant contributor towards this type of exposure.

3. *Chronic risk.* Using the residue concentration exposure assumptions described in this unit, the risk from aggregate chronic exposure from food and drinking water from pymetrozine is below EPA's level of concern for the following reasons. As indicated in Table 1 above, the Tier 1 DEEM analysis indicates that chronic dietary (food only) exposure to pymetrozine will utilize less than 74% (0.000958/0.0013) of the cPAD for children (1 to 6 years old). EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. In addition, for drinking water, the DWLOC value (3.4 µg/L) for children (1 to 6 years old) exceeds the modeled chronic EEC values (0.222 µg/L); thus, drinking water is not expected to be a significant contributor towards this type of exposure. Despite the potential for exposure from food, drinking water and non-dietary, non-occupational exposure, EPA does not expect the aggregate chronic exposure to exceed 100% of the cPAD.

4. *Short-term risk.* In aggregating short-term risk, EPA considered background average dietary exposure and short-term, non-dietary oral exposure. Non-dietary oral exposure may occur as hand-to-mouth transfer of residues from ornamental plants or incidental ingestion of surrounding soil. The lowest short-term MOE value is for toddlers. Combining this MOE (660,000) with that from dietary exposure (Short-term oral NOAEL/chronic dietary exposure = 10/0.00096 ≈ 10,000) results in an aggregate MOE of ≈ (approximately equal) 10,000. As this value is greater than 300, the short-term aggregate risk is below the Agency's level of concern. Aggregated short-term exposure results in a DWLOC of 320 µg/L. This value is in excess of the peak EEC for pymetrozine (1.9 µg/L; see Table 2).

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

IV. Other Considerations

A. Metabolism in Plants and Animals

Data concerning the metabolism of pymetrozine in plants and animals have been previously submitted. The nature of residues in plants and animals is adequately understood. The tolerance expression is for pymetrozine per se. The residues of concern for risk

assessment are pymetrozine; the plant metabolites GS-23199 [6-methyl-1,2,4-triazin-3,5 (2H,4H)-dione], CGA-215525 [4-amino-4,5-dihydro-6-methyl-1,2,4-triazin-3(2H)-one], CGA-249257 [4,5-dihydro-6-methyl-1,2,4-triazin-3(2H)-one], CGA-294849 [4-amino-6-methyl-1,2,4-triazin-3,5(2H,4H)-dione]; and the ruminant metabolite CGA-313124 [4,5-dihydro-6-hydroxymethyl-4-[(3-pyridinyl methylene)amino]-1,2,4-triazin-3(2H)-one] (free acid conjugated).

B. Analytical Enforcement Methodology

Adequate enforcement methodology for pymetrozine (Novartis Analytical Method AG-643) is currently being validated. Following validation, it will be available to enforce the tolerance expression. At that time the method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

The crop field trial data support the proposed tolerances for residues of "pymetrozine, per se."

D. International Residue Limits

There are no established European (CODEX), Canadian, or Mexican Maximum Residue Limits (MRL's) for pymetrozine. There are provisional MRLs in Germany for hops (10 ppm) and potatoes (0.02 ppm). The European Union is currently evaluating a proposed tolerance of 5 ppm on hops. At this time, international harmonization of residue levels is not an issue.

E. Rotational Crop Restrictions

The Fulfill® label reads as follows: "The rotational (plantback) restrictions for Fulfill are 30-days for all crops."

F. Pre-harvest Intervals

The pre-harvest interval for pymetrozine on the tuberous and corm, fruiting, and cucurbit vegetables is 14 days.

V. Conclusion

Therefore, EPA is establishing tolerances for residues of pymetrozine per se in cucurbit vegetables (Crop Group 8) at 0.05 ppm and fruiting vegetables (Crop Group 9) at 0.05 ppm.

VI. 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-301033 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 10, 2000.

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 Avenue, NW, 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 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, 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 VI.A., you should also send a copy of your request to the PIRB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket number OPP-301033, 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 PRIB 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 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 FFDCA section 408(d) 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 any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a 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* (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 FFDCA section 408(n)(4).

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 record keeping requirements.

Dated: August 1, 2000.

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), (346a), and 371.

2. Section 180.556 is revised 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
Tuberous and Corm Vegetables (Crop Group 1-C)	0.02
Cucurbit Vegetables (Crop Group 8)	0.05
Fruiting Vegetables (Crop Group 9)	0.05

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

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

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

[FR Doc. 00-20117 Filed 8-8-00; 8:45 a.m.]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301035; FRL-6736-8]

RIN 2070-AB78

Imidacloprid; Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for residues of the insecticide imidacloprid and its metabolites in or on turnip roots at 0.3 part per million (ppm), turnip tops at 3.5 ppm, beet roots at 0.3 ppm, and beet tops at 3.5 ppm for an additional 2-year period. These tolerances will expire and are revoked on June 30, 2002. This

action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on turnip greens and garden beets. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (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 the FIFRA.

DATES: This regulation is effective August 9, 2000. Objections and requests for hearings, identified by docket control number OPP-301035, must be received by EPA on or before October 10, 2000.

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 III. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301035 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9367; and e-mail address: ertman.andrew@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 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