Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 15, 2005.

Lois Rossi,

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 180.434 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.434 Propiconazole; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/ revocation date
* * *	* *	* *
Soybean	2.0	December 31, 2009
Soybean, forage.	10.0	December 31, 2009
Soybean, hay	25	December 31, 2009

* * * * *

[FR Doc. 05–14599 Filed 7–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0106; FRL–7724–5]

Pymetrozine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pymetrozine in or on asparagus. Interregional Research Project Number 4 (IR-4) 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 July 27, 2005. Objections and requests for hearings must be received on or before September 26, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0106. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers, and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers, greenhouse, nursery, and floriculture workers; ranchers, pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers, greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of June 9, 2004 (69 FR 32346) (FRL–7360–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E6467) by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.556 be amended by establishing a tolerance for residues of the insecticide pymetrozine, [4,5-dihydro-6-methyl-4-[(E)-(3-pyridinylmethylene)amino]-1,2,4-triazin-3(2H)-one], in or on asparagus at 0.02 parts per million (ppm). The petition was subsequently amended to establish a tolerance of 0.04 ppm. That notice included a summary of the

petition prepared by Syngenta, the registrant. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of pymetrozine on asparagus at 0.04 ppm. EPA's assessment of 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, as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of December 27, 2001 (66 FR 66786) (FRL–6804–1).

B. 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 level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}, one in a million (1×10^{-6}), or one in ten million (1×10^{-7})). 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_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for pymetrozine used for human risk assessment is shown in the Table of this unit:

SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYMETROZINE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-49 years of age)	NOAEL = 10 mg/kg/day UF = 1,000 Acute RfD = 0.01 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/Special FQPA SF = 0.01 mg/kg/day	Rabbit development study LOAEL = 75 mg/kg/day based on reduced body weight gain, food consumption and feed efficiency. Also, increased incidence of skeletal anomalies in pups.
Acute dietary (General population including infants and children)	LOAEL = 125 mg/kg/day UF = 1,000 Acute RfD = 0.125 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/Special FQPA SF = 0.125 mg/kg/day	Rat acute neurotoxicity study LOAEL = 125 mg/kg/day based on decreased body temperature, decreased motor activity and FOB parameters associated with decreased activity.
Chronic dietary (all populations)	NOAEL= 0.377 mg/kg/kg/day UF = 100 Chronic RfD = 0.0038 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.0038 mg/kg/day	Rat chronic feeding study LOAEL = 3.76 mg/kg/day based on liver hypertrophy pathology supported by chronic feeding and multi-generation reproduction studies and dog sub-chronic and chronic studies.
Cancer	Cancer Classification: ''Likely to be carcinogen to humans'' (Q* of 0.0119 mg/kg/day)		

C. Exposure Assessment

1. *Dietary exposure from food, and drinking water*. Tolerances have been established (40 CFR 180.556) for the residues of pymetrozine, in or on a variety of raw agricultural commodities. In conducting the acute and chronic dietary risk assessments, EPA used the LifeLine™ Model software. This LifeLine assessment was conducted using the same consumption data as the DEEM-FCID™ (CSFII, 1994–1996 and 1998). LifeLine™ models the individual's dietary exposures over a season by selecting a new CSFII diary each day from a set of similar individuals. Lifeline organizes groups, or ''bins,'' of CSFII diaries based on the respondents' age and the season during which the food diary was recorded. Both age and season were found to be the critical determinants of dietary patterns.

Modeled estimates of drinking water concentrations were directly entered into the exposure model (LifeLine™) to assess the contribution from drinking water. 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 1–day or single exposure. The following assumptions were made for the acute exposure assessment: A Tier 1 analysis was utilized; which assumes tolerance-level residues of pymetrozine *per se* in/on all commodities (along with additional residues, calculated and summed with the parent compound to account for plant metabolites), and also assumes 100 percent crop treated (PCT). Actual PCT and/or anticipated residues were not used. Aggregate acute food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The Agency used the acute water concentration (16.3 ppb) derived from surface water modeling results, which was significantly higher than the modeled ground water concentration, and therefore protective of potential exposures via ground water sources of drinking water.

ii. *Chronic exposure*. The following assumptions were made for the chronic exposure assessment: A Tier 3 analysis was utilized; tolerance-level residues of pymetrozine (plus metabolites) and 100 PCT were assumed for asparagus. For all other commodities, anticipated residues were derived from average crop field trial residue values, and PCT data were taken from prior risk assessments. Actual PCT and/or anticipated residues were used. Aggregate chronic food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The Agency used the chronic water concentration (10.1 ppb) derived from surface water modeling results, which was significantly higher than the modeled ground water concentration, and therefore protective of potential exposures via ground water sources of drinking water.

iii. *Cancer*. The following assumptions (identical to those for the chronic exposure assessment) were made for the cancer exposure assessment: A Tier 3 analysis was utilized; tolerance-level residues of pymetrozine (plus metabolites) and 100 PCT were assumed for asparagus. For all other commodities, anticipated residues were derived from average crop field trial residue values, and PCT data for existing uses were taken from prior risk assessments. Actual PCT and/or anticipated residues were used. Aggregate cancer food and water exposure was determined by including modeled estimates of drinking water concentrations in the dietary model. The Agency used the average water concentration (6.0 ppb) derived from surface water modeling results, which was significantly higher than the modeled ground water concentration, and therefore protective of potential exposures via ground water sources of drinking water.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA 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, pursuant to section 408(f)(1), 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. For the present action, EPA will issue such Data Call-

Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA 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) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Cucumbers 10%; squash (winter and summer) 8%; cantaloupes 25%; pumpkins 10%; watermelons 20%; potatoes 20%; cotton 6%; tomatoes 12%; peppers 8%; spinach 16%; leaf lettuce 25%; head lettuce 25%; celery 25%; cabbage 12%; and broccoli 25%.

The Agency believes that the three conditions listed in Unit III.B., 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 an average PCT for chronic dietary exposure estimates. The average PCT figure is derived by combining available federal, state, and private market survey data, averaging by year, averaging across all years, and rounding up to the nearest multiple of five. 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.

2. *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 used Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground water (SCI-GROW), which predicts pesticide concentrations in ground water. 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.

Pymetrozine is not generally considered to be persistent. It tends to break down relatively quickly in the environment through a variety of degradation mechanisms such as acidic hydrolysis, aqueous photolysis, and soil photolysis. In aerobic soils, it exhibits a strong bi-phasic degradation pattern consisting of a rapid initial breakdown of the available pymetrozine, followed by a much slower degradation process which could be possibly due to the strong binding of this chemical to the soil matrix. Approximately 35% of the pymetrozine and 40% of the pymetrozine plus CGA-359009 remained at the end of the aerobic soil metabolism studies. Furthermore, based on its high soil/water partitioning coefficients, pymetrozine is expected to have a low potential to leach. Laboratory studies conducted to assess the mobility of pymetrozine on a variety of soils classify this chemical as a ''low mobility to no mobility'' chemical.

Fifteen degradates were observed in laboratory studies. Because CGA-359009 is structurally similar to the parent, the Agency concluded that CGA-359009 should be included in the drinking water assessment in addition to the parent. CGA-359009 is expected to be more mobile than the parent due to the addition of the hydroxyl group and therefore more likely to reach to drinking water.

Based on the PRZM/EXAMS model, the estimated environmental concentrations (EECs) of pymetrozine for acute, chronic, and cancer exposures are estimated to be 16.3 parts per billion (ppb), 10.1 ppb and 6.0 ppb for surface water respectively. Based on the SCI-GROW model, the EEC of pymetrozine for the acute and chronic exposure is estimated to be 0.038 ppb for ground water. The acute, chronic, and cancer estimated water concentrations derived from surface water modeling results were significantly higher than the modeled ground water concentrations, and therefore protective of potential exposures via ground water sources of drinking water when incorporated into aggregate exposure estimates. The pymetrozine EEC's were incorporated into LifeLine version 2.0 to determine aggregate pesticide exposures from pesticide residues in the diet.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fulfill® is the pymetrozine pesticide product for use on ornamentals. Application of this product must be by a licensed pesticide applicator. Currently, there are no applications for registration of a homeowner use of pymetrozine. EPA believes that there is a low likelihood of adults and children engaging in activities in and/or around treated or landscaped areas and/or ornamentals that could lead to any meaningful exposure. As a result, dermal and oral post-application exposures are expected to be negligible.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to

pymetrozine and any other substances, and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *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.

3. *Conclusion*. Due to the lack of a required developmental neurotoxicity study, EPA is retaining the additional 10X FQPA safety factor for the protection of infants and children. Evaluation of the pymetrozine database indicates that the DNT has the potential to lower regulatory endpoints for pymetrozine and therefore the 10X factor is being retained.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated environmental concentrations (EECs). The DWLOC values are not regulatory standards for drinking water, but 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 + residential 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). 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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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. When new uses are added EPA reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

There are no existing or proposed uses for pymetrozine that would result in residential non-dietary exposure, therefore aggregate acute, chronic and cancer risks are based solely on exposure from food and water, which are as follows:

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pymetrozine will occupy 2.3% of the aPAD for the U.S. population, 31% of the aPAD for females 13 years and older, 2.5% of the aPAD for all infants < 1 years old, and 3.4% of the aPAD for children 1-2 years old. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

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 5.1% of the cPAD for the U.S. population, 16% of the cPAD for all infants < 1 year old, and 8.9% of the cPAD for children 1-2 years old. There are no residential uses for pymetrozine that result in chronic residential exposure to pymetrozine. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pymetrozine is not registered for use on any sites that would result in significant residential exposure. Although postapplication non-occupational exposure could occur as a result of contact with treated ornamental plants, EPA believes that there is a low likelihood of adults and children engaging in activities in and/or around treated or landscaped areas and/or ornamentals that could lead to any meaningful exposure. As a result, dermal and oral post-application exposures are expected to be negligible.

4. *Aggregate cancer risk or U.S. population*. Under the reasonable certainty of no harm standard in FFDCA section 408(b)(2)(A)(ii), cancer risks must be no greater than negligible. EPA has consistently interpreted negligible cancer risks to be risks within the range of an increased cancer risk of 1 in 1 million (1×10^{-6}). Risks as high as 3 in

1 million have been considered to be within this risk range. The estimated chronic cancer exposure of the general U.S. population to pymetrozine is 0.000137 mg/kg/day. Applying the Q1* of 0.0119 $(mg/kg/day)^{-1}$ to the exposure value results in a cancer risk estimate of 1.6×10^{-6}, which is within the negligible risk range of 1×10^{-6}. The exposure value of 0.000137 mg/kg/day, although somewhat refined, is a high-end estimate. Use of food monitoring data, if available, would likely result in a significant reduction in the exposure estimate since residues would be from actual pymetrozine use patterns and not from trials designed to maximize residues for tolerance-setting purposes. It is EPA's experience that monitoring data from sources such as the USDA's Pesticide Data Program show that residues in foods are significantly less than those produced from field trials. In addition, default processing factors were used with no adjustments made to account for consumer practices such as washing and peeling. Based on those factors, the Agency is confident that actual dietary exposure to pymetrozine in food and drinking water will be much less than our estimate of 0.000137 mg/kg/day and that the actual cancer risk will be correspondingly lower than 1×10^{-6}.

5. *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.

IV. Other Considerations

A. Analytical Enforcement Methodology

The HPLC/UV methods, AG-643A and AG-647, are adequate for collecting data on residues of pymetrozine and GS-23199, respectively, in/on the following commodities: Undelinted cottonseed, cotton gin byproducts, cottonseed processed commodities, broccoli, cabbage (with and without wrapper leaves), celery, hops (green and dried cones), lettuces, mustard greens, spinach, pecans, cucurbits, and fruiting vegetables. The validated limit of quantitation (LOQ) is 0.02 ppm for each analysis in each matrix with the exception of pymetrozine in dried hops cones. The Agency's Analytical Chemistry Branch (ACB) validated Method AG-643A on tomatoes, hops, and cottonseed. This method is considered adequate for enforcement purposes on plant commodities.

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no MRLs or Codex limits for pymetrozine on asparagus.

V. Conclusion

Therefore, the tolerance is established for residues of pymetrozine, [4,5-dihydro-6-methyl-4-[(E)-(3-pyridinylmethylene)amino]-1,2,4-triazin-3(2H)-one], in or on asparagus at 0.04 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0106 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 26, 2005.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0106, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 18, 2005.

Lois Rossi,

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 amended by alphabetically adding the commodity to the table in paragraph (a) to read as follows:

§ 180.556 Pymetrozine; tolerances for residues.

(a) * * *

Commodity	Parts per million
Asparagus	0.04
* * *	* *

* * * * *

[FR Doc. 05–14598 Filed 7–26–05; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0038; FRL–7726–8]

2,4-D; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of 2,4-dichlorophenoxyacetic acid (2,4-D) in or on hop, soybean, and wild rice . Interregional Research Project Number 4 (IR-4) and the Industry Task Force II on 2,4-D Research Data (Task Force) and its registrant members and affiliates on behalf of IR-4 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 July 27, 2005. Objections and requests for