

3. Section 63.1344 is amended by revising paragraph (a)(3) to read as follows:

**§ 63.1344 Operating limits for kilns and in-line kiln/raw mills.**

(a) \* \* \*

(3) If the in-line kiln/raw mill is equipped with an alkali bypass, the applicable temperature limit for the alkali bypass specified in paragraph (b) of this section and established during the performance test, with or without the raw mill operating, is not exceeded.

\* \* \* \* \*

4. Section 63.1349 is amended by adding new paragraph (e)(3) to read as follows:

**§ 63.1349 Performance testing requirements.**

\* \* \* \* \*

(e) \* \* \*

(3) In preparation for and while conducting a performance test required in paragraph (e)(1) of this section, a source may operate under the planned operational change conditions for a period not to exceed 360 hours, provided that the conditions in paragraphs (e)(3)(i) through (iv) of this section are met. The source shall submit temperature and other monitoring data that are recorded during the pretest operations.

(i) The source must provide the Administrator written notice at least 60 days prior to undertaking an operational change that may adversely affect compliance with an applicable standard under this subpart, or as soon as practicable where 60 days advance notice is not feasible. Notice provided under this paragraph shall include a description of the planned change, the emissions standards that may be affected by the change, and a schedule for completion of the performance test required under paragraph (e)(1) of this section, including when the planned operational change period would begin.

(ii) The performance test results must be documented in a test report according to paragraph (a) of this section.

(iii) A test plan must be made available to the Administrator prior to testing, if requested.

(iv) The performance test must be conducted, and it must be completed within 360 hours after the planned operational change period begins.

\* \* \* \* \*

5. Section 63.1350 is amended by:

a. Adding paragraphs (a)(4)(v) through (vii);

b. Revising paragraph (c)(2)(i);

c. Revising paragraph (d)(2)(i); and

d. Revising paragraph (e) introductory text.

The revisions and additions read as follows:

**§ 63.1350 Monitoring requirements.**

(a) \* \* \*

(4) \* \* \*

(v) The requirement to conduct Method 22 visible emissions monitoring under this paragraph shall not apply to any totally enclosed conveying system transfer point, regardless of the location of the transfer point. "Totally enclosed conveying system transfer point" shall mean a conveying system transfer point that is enclosed on all sides, top, and bottom. The enclosures for these transfer points shall be operated and maintained as total enclosures on a continuing basis in accordance with the facility operations and maintenance plan.

(vi) If any partially enclosed or unenclosed conveying system transfer point is located in a building, the owner or operator of the portland cement plant shall have the option to conduct a Method 22 visible emissions monitoring test according to the requirements of paragraphs (a)(4)(i) through (iv) of this section for each such conveying system transfer point located within the building, or for the building itself, according to paragraph (a)(4)(vii) of this section.

(vii) If visible emissions from a building are monitored, the requirements of paragraphs (a)(4)(i) through (iv) of this section apply to the monitoring of the building, and you must also test visible emissions from each side, roof and vent of the building for at least 1 minute. The test must be conducted under normal operating conditions.

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(i) Perform daily visual opacity observations of each stack in accordance with the procedures of Method 9 of appendix A to part 60 of this chapter. The Method 9 test shall be conducted while the affected source is operating at the representative performance conditions. The duration of the Method 9 test shall be at least 30 minutes each day.

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(i) Perform daily visual opacity observations of each stack in accordance with the procedures of Method 9 of appendix A to part 60 of this chapter. The Method 9 test shall be conducted while the affected source is operating at

the representative performance conditions. The duration of the Method 9 test shall be at least 30 minutes each day.

\* \* \* \* \*

(e) The owner or operator of a raw mill or finish mill shall monitor opacity by conducting daily visual emissions observations of the mill sweep and air separator PMCD of these affected sources in accordance with the procedures of Method 22 of appendix A to part 60 of this chapter. The Method 22 test shall be conducted while the affected source is operating at the representative performance conditions. The duration of the Method 22 test shall be 6 minutes. If visible emissions are observed during any Method 22 visible emissions test, the owner or operator must:

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2002-0237; FRL-7274-8]

**Cyromazine; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of cyromazine in or on bean, dry at 3.0 parts per million (ppm). The 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 (FQPA) of 1996.

**DATES:** This regulation is effective December 6, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0237, must be received on or before February 4, 2003.

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

**FOR FURTHER INFORMATION CONTACT:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@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:

- Industry (NAICS 111, 112, 311, 32532), e.g., Crop production, Animal production, Food manufacturing, and 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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0237. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet

under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the appropriate docket ID number.

## II. Background and Statutory Findings

In the **Federal Register** of July 17, 2002 (67 FR 4697) (FRL-7185-6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 0E6219) by IR-4. The notice included a summary of the petition prepared by Novartis Crop Protection Inc., Greensboro, NC 27419, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.414 be amended by establishing a tolerance for residues of the insecticide cyromazine, (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine), in or on dry bean (except cowpea) at 3.0 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) of the FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is

reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

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

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of cyromazine on dry bean at 0.3 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 their 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 cyromazine are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents—rat	NOAEL = 3.0 (milligram/kilogram/day (mg/kg/day)) LOAEL = 30 mg/kg/day based on alteration in the liver weight changes in males

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3150	90-Day oral toxicity—dog	NOAEL = 7.5 mg/kg/day LOAEL = 25 mg/kg/day based on alteration in liver weight in males
870.3200	21-Day dermal toxicity	NOAEL = > 2,010 mg/kg/day LOAEL = > 2,010 mg/kg/day. No dermal irritation was noted. No treatment related systemic toxicity was noted.
870.3700	Developmental toxicity in rodents—rat	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on clinical signs (red or clear nasal discharge) and decrease body weights Developmental NOAEL = 300 mg/kg/day LOAEL = 600 mg/kg/day highest dose tested (HDT) based on increased incidence of minor skeletal variations
870.3700	Developmental toxicity in non-rodents—rabbit	Maternal NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on reduced body weight Developmental NOAEL = > 60 mg/kg/day (HDT) LOAEL was not established
870.3800	2-Generation reproduction—rat	Parental/Systemic NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on based on decreased body weights that were associated with decreased food efficiency Reproductive NOAEL = > 150 mg/kg/day LOAEL = Not determined. No effects were noted on reproductive parameters at HDT Offspring NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on based on decreased body weights at birth and through weaning
870.4100	Chronic oral toxicity—dogs	NOAEL = 7.5 mg/kg/day LOAEL = 75.0 mg/kg/day based on alteration in the hematological parameters (hemoglobin and hematocrit)
870.4300	Combined chronic/carcinogenicity—rats	NOAEL = 0.75 mg/kg/day LOAEL = 7.5 mg/kg/day based on based on decreased body weight There is no evidence of carcinogenicity.
870.4200	Carcinogenicity—mice	NOAEL = 7.5 mg/kg/day LOAEL = 50.0 mg/kg/day based on decreased body weight There is no evidence of carcinogenicity
	Mammalian chromosomal aberration	Negative for mutagenicity in Chinese hamster study
870.5100	Mutagenic—point mutation <i>Salmonella typhimurium</i>	Negative results for point mutations in TA1537, TA98, TA100, with and without activation
870.5450	Mutagenic—dominant lethal—mouse	Negative mutagen

### 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 intra species differences.

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or

chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

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 is expressed as  $1 \times 10^{-6}$  or one in a million). Under certain specific

circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value

derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ( $MOE_{cancer} = \text{point of departure/exposures}$ ) is calculated. A summary of the toxicological endpoints for cyromazine used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYROMAZINE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary General population including infants and children	Not Applicable (NA)	NA	An appropriate end point attributable to a single dose (exposure) was not observed in oral toxicity studies.
Chronic dietary All populations	NOAEL = 7.5 mg/kg/day UF = 100 Chronic RfD = 0.075 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD/FQPA SF = 0.075 mg/kg/day	6-Month Feeding—dog LOAEL = 75 mg/kg/day based on alterations in hematological parameters [hematocrit, and hemoglobin (males)], body weight and body weight gain decreases and increase in several organ weights
Incidental oral Short-term (1 to 30 days) (Residential)	NOAEL = 10	LOC for MOE = 100 (Residential)	Developmental toxicity—rabbit study. LOAEL = 30 mg/kg/day based on decreases in body weight gain and food consumption.
Incidental Oral Intermediate-term (1 to 6 months) (Residential)	NOAEL = 7.5 mg/kg/day	LOC for MOE = 100 (Residential)	6-Month feeding—dog LOAEL = 75 mg/kg/day based on alterations in hematological parameters [hematocrit, and body weight gain decreases and increase in several organ weights].
Dermal (any time period) (Residential)	NA	NA	Dermal risk assessments were not performed since no hazard was identified via dermal exposure; there are no concerns for pre-/post-natal toxicity and dermal exposure is not expected since there are no registered residential uses.
Short-term inhalation (1 to 30 days) (Residential)	Oral NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental toxicity—rabbit study LOAEL = 30 mg/kg/day based on decreases in body weight gain and food consumption
Intermediate-term inhalation (1 to 6 months) (Residential)	Oral study NOAEL = 7.5 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	6-Month feeding—dog study LOAEL = 75.0 mg/kg/day based on alterations in hematological parameters [hematocrit, and hemoglobin (males)], body weight and body weight gain decreases and increase in several organ weights.
Long-term inhalation (>6 months) (Residential)	Oral study NOAEL = 7.5 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	6-Month feeding—dog study LOAEL = 75.0 mg/kg/day based on alterations in hematological parameters [hematocrit, and hemoglobin (males)], body weight and body weight gain decreases and increase in several organ weights.
Cancer	NA	NA	Based on weight-of-the-evidence, classified in Category E "no evidence of carcinogenicity in humans"

\* The reference to the Food Quality Protection Act Safety Factor (FQPA SF) refers to any additional SF retained due to concerns unique to the FQPA.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.414) for the residues of cyromazine, in or on a variety of raw agricultural commodities.

There are currently tolerances for cyromazine use on a number of food crops including cucurbits, leafy vegetables, onions, lima beans, pepper, potato, and tomato. Tolerances exist as well for livestock commodities.

Cyromazine is generally used on terrestrial crops as a foliar spray throughout the growing season, although for onions it is used as a seed treatment and for poultry it is used as a feed-through to control flies breeding

in poultry waste. There are no existing or pending residential uses of cyromazine. Risk assessments were conducted by EPA to assess dietary exposures from cyromazine in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. An endpoint was not identified for acute dietary exposure and risk assessment because no effects were observed in oral toxicity studies including developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, an acute dietary exposure assessment was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Chronic dietary exposure estimates are based on tolerance level residues for plant and poultry commodities and on anticipated residue estimates for ruminant commodities. Dietary exposure estimates are also factored by the estimated (weighted average) usage of cyromazine, or “percent crop treated” (PCT) data.

iii. *Cancer.* Cyromazine is classified into Group E (non-carcinogen) based on carcinogenicity studies in rats and mice following long-term dietary administration. A quantified carcinogenic risk estimate is not appropriate for cyromazine.

iv. *Anticipated residue and 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 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) of the FFDCA, 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) of the 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 the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows.

Cantaloupe 0.3%; cucurbits 0.1%; lettuce 2.6%; leafy vegetables, other 9.4%; celery 14.2%; spinach 6.0%; onions 2.4%; pepper 5.3%; peppers, bell 9.0%; tomatoes 5.8%; tomatoes, fresh 22.2%; and watermelon 1.5%.

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

and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cyromazine 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 cyromazine 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 cyromazine.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would exceed human health levels of concern.

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

Based on the FIRST and SCI-GROW models the EECs of cyromazine for chronic exposures are estimated to be 16 parts per billion (ppb) for surface water and 5.0 ppb for ground water.

3. *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).

Cyromazine is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to 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."

Cyromazine is a member of the triazine class of chemicals. EPA evaluated available scientific evidence to determine whether a common mechanism of toxicity exists among certain triazine-containing pesticides. Based on the available weight-of-evidence, cyromazine can not be grouped with other triazines based on a common mechanism of toxicity. EPA determined that only atrazine, simazine, propazine, and their specified degradants could be grouped based on a common mechanism of toxicity for disruption of the hypothalamic-pituitary-gonadal (HPG) axis. For purposes of this tolerance action, EPA has concluded that cyromazine does not have a common mechanism of toxicity with other triazine-containing compounds. If additional data become available to support its inclusion in a common mechanism group, these data

will be considered. 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. Safety Factor for Infants and Children*

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for pre-natal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Pre-natal and post-natal sensitivity.* The developmental and reproductive toxicity data from a pre-natal developmental study in rats, a pre-natal developmental study in rabbits, and a 2-generation reproductive toxicity study in rats, did not indicate increased susceptibility of young rats on rabbits to *un urero* and/or post-natal exposure.

3. *Conclusion.* There is a complete toxicity data base for cyromazine and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10x safety factor to protect infants and children should be reduced to 1x. The FQPA factor was reduced based on reliable data supporting the following weight-of-evidence considerations:

i. There are no data deficiencies and hence there are no residual uncertainties for pre- and/or post-natal exposure, and no additional traditional SFs are needed with regard to the completeness of the cyromazine toxicity data base;

ii. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with cyromazine;

iii. There is no evidence of increased susceptibility of young rats in the reproduction study with cyromazine; and

iv. There are also no residual uncertainties identified in the exposure data bases.

#### *E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + 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 USEPA 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). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* There were no toxicological effects attributable to a single exposure (dose) observed in the oral toxicity studies. A dose and an endpoint for an acute RfD was not selected. Therefore, acute risk from exposure to cyromazine is not expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyromazine from food will utilize 2.0% of the cPAD for both males and females of the U.S. population, and 4.0% of the cPAD for children 1–6 years old, subpopulation at

greatest exposure. There are no residential uses for cyromazine that result in chronic residential exposure to cyromazine. Based on the use pattern, chronic residential exposure to residues of cyromazine is not expected. In addition, there is potential for chronic dietary exposure to cyromazine in

drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Males	0.075	2.0	16	5	2,550
Female	0.075	2.0	16	5	2,200
Children	0.075	4.0	16	5	700

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).

Cyromazine is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Cyromazine has been classified as a chemical showing "no evidence of carcinogenicity in humans." The Agency concludes that pesticidal uses of cyromazine are not likely to pose a carcinogenic risk to humans.

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 cyromazine residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Analytical methods, AG-408 and AG-417, as listed in the Food and Drug Administration's Pesticide Analytical Manual (PAM) II, are adequate for tolerance enforce purposes.

##### B. International Residue Limits

There are currently no codex, Canadian or Mexican limits for residues of cyromazine on dry bean.

#### V. Conclusion

Therefore, the tolerance is established for residues of cyromazine, (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine), in or on dry bean (except cowpea) at 3.0 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0237 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 February 4, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in

connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

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

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

of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit 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 Unit I.B.1. Mail your copies, identified by docket ID number OPP–2002–0237, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. 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. Regulatory Assessment Requirements**

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive

Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 the 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 the FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### **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: November 15, 2002.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### **PART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.414 is amended by alphabetically adding a commodity to the table in paragraph (a)(1) to read as follows:

#### **§ 180.414 Cyromazine, tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
Bean, dry, except cowpea .....	3.0
* * * * *	*

[FR Doc. 02-30839 Filed 12-5-02; 8:45 am]

BILLING CODE 6560-50-S

#### **FEDERAL EMERGENCY MANAGEMENT AGENCY**

#### **44 CFR Part 64**

[Docket No. FEMA-7797]

#### **Suspension of Community Eligibility**

**AGENCY:** Federal Emergency Management Agency, FEMA.

**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

**EFFECTIVE DATES:** The effective date of each community's suspension is the third date ("Susp.") listed in the third column of the following tables.

**ADDRESSES:** If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

#### **FOR FURTHER INFORMATION CONTACT:**

Edward Pasterick, Division Director, Risk Communication Division, Federal Insurance and Mitigation Administrator, 500 C Street, SW.; Room 411, Washington, DC 20472, (202) 646-3098.

**SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas

(section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

**National Environmental Policy Act.** This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

**Regulatory Flexibility Act.** The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

**Regulatory Classification.** This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

**Paperwork Reduction Act.** This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

**Executive Order 12612, Federalism.** This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp.; p. 252.

**Executive Order 12778, Civil Justice Reform.** This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp.; p. 309.

#### **List of Subjects in 44 CFR Part 64**

Flood insurance, Floodplains.