Rules and Regulations

Federal Register
Vol. 68, No. 185
Wednesday, September 24, 2003

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0269; FRL–7326–5]

Cyromazine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyromazine in or on leek; onion, green; onion, potato; onion, tree; onion, welsh; shallot, fresh leaves; garlic, bulb; garlic, great-headed, bulb; onion, dry bulb; rakkyo, bulb; shallot, bulb; vegetable, brassica, leafy, group 5, except broccoli; broccoli; turnip, greens; cabbage, abyssinian; cabbage, seakale; hanover salad, leaves; kidney of cattle, goat, hog, horse, and sheep; and meat byproducts, except kidney, of cattle, goat, hog, horse, and sheep. The petitioner has requested that existing tolerances for residues of cyromazine in/on dry bulb onion at 2.0 ppm, green onion at 0.1 ppm, and mustard greens and cabbage, Chinese at 3.0 ppm be deleted. Interregional Research Project Number 4 (IR–4) requested these tolerances 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 September 24, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0269, must be received on or before November 24, 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: 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 an are agricultural producer, food manufacturer, and pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Industry (NAICS 111), e.g., Crop production.
- Industry (NAICS 112), e.g., Animal production.
- Industry (NAICS 311), e.g., Food manufacturing.
- Industry (NAICS 32532), e.g., 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–2003–0269. 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*, 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. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of August 6, 2003 (68 FR 46616) (FRL–7319–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 2E6507 and 2E6510) by IR–4, 681 US Highway #1 South, New Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Syngenta Crop Protection Incorporated, the registrant.

The petitions requested that 40 CFR 180.414 be amended by establishing tolerances for residues of the insecticide, cyromazine, (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine), in or on the following commodities: leek; onion, green; onion, potato; onion, tree; onion, welsh; and shallot, fresh leaves at 3.0 parts per million (ppm) (2E6507), garlic, bulb; garlic, great-headed, bulb; onion, dry bulb; rakkyo, bulb; and shallot, bulb at 0.2 ppm (2E6507), vegetable, brassica,

leafy, group 5, except broccoli at 10.0 ppm (2E6510), broccoli at 1.0 ppm, turnip, greens; cabbage, abyssinian; cabbage, seakale; and hanover salad, leaves at 10.0 ppm, and kidney of cattle, goat, hog, horse, and sheep at 0.2 ppm, and meat byproducts, except kidney, of cattle, goat, hog, horse, and sheep at 0.05 ppm (2E6510).

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 tolerances for residues of cyromazine on leek; onion, green; onion, potato; onion, tree; onion, welsh; and shallot, fresh leaves at 3.0 ppm, garlic, bulb; garlic, great-headed, bulb; onion, dry bulb; rakkyo, bulb; and shallot, bulb at 0.2 ppm, vegetable, brassica, leafy, group 5, except broccoli at 10.0 ppm, broccoli at 1.0 ppm, turnip, greens; cabbage, abyssinian; cabbage, seakale; and hanover salad, leaves at 10.0 ppm, and kidney of cattle, goat, hog, horse, and sheep at 0.2 ppm, and meat byproducts, except kidney, of cattle, goat, hog, horse, and sheepat 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

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 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	Subchronic oral-Dog	The systemic toxicity LOAEL is 1,000 ppm (25 mg/kg/day) based on alteration in liver weight in males. The systemic toxicity NOAEL is 300 ppm (7.5 mg/kg/day).
870.3100	Subchronic oral-Rat	The systemic toxicity LOAEL is 300 ppm (30 mg/kg/day), based on alteration in the liver weight changes in males. The systemic toxicity NOAEL is 30 ppm (3 mg/kg/day).
870.3200	21-day dermal toxicity-Rabbit	No treatment related systemic toxicity was noted. The systemic toxicity NOAEL > 2,000 mg/kg/day. The systemic toxicity LOAEL > 2,000 mg/kg/day. No dermal irritation was noted. The dermal toxicity NOAEL > 2,000 mg/kg/day. The dermal toxicity LOAEL > 2,000 mg/kg/day.
870.3200	21-day dermal toxicity-Rabbit	No treatment related systemic toxicity was noted. The systemic toxicity NOAEL > 2,010 mg/kg/day. The systemic toxicity LOAEL > 2,010 mg/kg/day. No dermal irritation was noted. The dermal toxicity NOAEL > 2,010 mg/kg/day. The dermal toxicity LOAEL > 2,010 mg/kg/day.
870.4100	Chronic oral (6–months)-Dog	The systemic toxicity LOAEL is 3,000 ppm (75 mg/kg/day) based on alteration in hematological parameters (hemoglobin, and hematocrit). The systemic toxicity NOAEL is 300 ppm (7.5 mg/kg/day).
870.4300	Combine Chronic/Carcinogenicity-Rat	The systemic toxicity LOAEL is 300 ppm (15 mg/kg/day) based on decreased body weight. The systemic toxicity NOAEL is 30 ppm. (1.5 mg/kg/day). There is no evidence of carcinogenicity.
870.4200	Carcinogenicity-Mouse	The systemic toxicity LOAEL is 1,000 ppm (150 mg/kg/day) based on decreased body weight. The systemic toxicity NOAEL is 50 ppm. (7.5 mg/kg/day). There is no evidence of carcinogenicity.

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

Guideline No.	Study Type	Results
870.3700	Developmental toxicity-Rabbit	The maternal toxicity LOAEL is 30 mg/kg/day, based on reduced body weight gain and food consumption. The maternal toxicity NOAEL is 10 mg/kg/day. The developmental toxicity LOAEL was not established. The developmental toxicity NOAEL > 60 mg/kg/day (HDT).
870.3700	Developmental toxicity-Rat	The maternal toxicity LOAEL is 300 mg/kg/day, based on clinical signs (red or clear nasal discharge) and decreased body weights. The maternal toxicity NOAEL = 100 mg/kg/day. The developmental toxicity LOAEL is 600 mg/kg/day (HDT), based on increased incidence of minor skeletal variations. The developmental toxicity NOAEL is 300 mg/kg/day.
870.3800	Two-generation reproduction-Rat	The parental systemic toxicity LOAEL is 3,000 ppm (150 mg/kg/day) based on decreased body weights that were associated with decreased food efficiency. The parental systemic toxicity NOAEL is 1,000 ppm (50 mg/kg/day). The offspring systemic/developmental toxicity LOAEL is 3,000 ppm (150 mg/kg/day), based on decreased body weights at birth and through weaning. The systemic/developmental toxicity NOAEL is 1,000 ppm (50 mg/kg/day). No effects were noted on reproductive parameters and no reproductive toxicity LOAEL was determined. The reproductive toxicity NOAEL is ≥ 3,000 ppm (150 mg/kg/day).
870.7485	Metabolism-Rat	Cyromazine was well absorbed after oral administration. Excretion was rapid at the dose (3 mg/kg), but an apparent delay in excretion occurred at the high dose (300 mg/kg). Fecal elimination was equivalent among dose groups except the high dose males, where a greater percentage was eliminated by this route. The origin of fecal radioactivity was via biliary elimination. Residual radioactivity in tissues was minimal in all dose groups. Urinary and fecal metabolites of ^{14}C-cyromazine were isolated and identified by TLC, HPLC, and GC/MS. The major compounds were the N-dealkylated product melamine, hydroxycyromazine, and unmetabolized cyromazine identified.
870.7600	Dermal Absorption-Rat	Absorption at 10 hrs = 13 %. Cyromazine apparently rapidly absorbed into the skin in an inverse dose related manner. The absorption into the skin is followed by a slower release into the body. The main route of excretion is apparently by the urine. There is no evidence that the compound is sequestered in the skin. Mean absorption based on blood, urinary/fecal excretion, and carcass, ranged from 0.6 to 7% for animals sacrificed at the end of the exposure periods. For animals exposed for 10 and 24 hours and followed for 48 hours post-exposure, mean absorption ranged from 8 to 14.5%. Total radioactivity absorbed generally decreased as dose increased indicating saturation of absorption with increasing dose. Amounts remaining in/on the skin at termination ranged from 4.5% (10 mg dose/2 h exposure) to 24% (0.1 mg dose/24 hour exposure). The majority of the absorbed radioactivity was found in the urine and carcass. Most of the unabsorbed radioactivity was found in the skin washes from each dose/duration.
870.7600	Dermal Absorption-Rat	Absorption at 10 hrs = 10%. Mean total recoveries of applied radioactivity from all dose groups ranged from 85 to 101%. Mean absorption based on blood, urinary/fecal excretion, and carcass, ranged from 2% to 11%. Total radioactivity absorbed generally increased with increasing exposure time but decreased with increasing dose indicating saturation of penetration with increasing dose. The majority of the absorbed radioactivity was found in the urine and carcass. Most of the unabsorbed radioactivity was found in the skin washes from each dose/duration (35–90%). However, based on measurements of skin absorption, a significant amount of radioactive dose was also found in the skin itself (9–40%). Mean absorption with inclusion of radioactivity in dissolved skin ranged from 10 to 45%. The ratio of the amount of radioactive dose in the skin wash to the radioactivity in the skin itself decreased with time indicating penetration into the subsurface of the skin with time after treatment.
870.5395	Gene mutation in Hamster (Chinese)-Mutagenic-Nucleus Anomaly	Negative mutagen.
870.5100	Mutagenic-Point Mutation Salmonella typhimurium	Negative results for point mutations in TA1537, TA1537, TA98, and TA100 with and without activation.
870.5450	Mutagenic-Dominant lethal test species: 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 factors (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 1×10^{-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} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for cyromazine used for human risk assessment is shown 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	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All populations)	NA	NA	An appropriate endpoint attributable to a single dose (exposure) of cyromazine was not observed in oral toxicity studies. Thus, an acute dietary endpoint was not chosen.
Chronic Dietary (All populations)	NOAEL= 7.5 mg/kg/day UF = 100 Chronic RfD = NOAEL/UF = 0.075 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD ÷ FQPA SF = 0.075 mg/kg/day	Chronic Oral Toxicity in Dogs. LOAEL = 75 mg/kg/day based on alterations in hematological parameters [hematocrit and hemoglobin (males)], decreased body weight/body weight gain and increases in several organ weights.
Short-Term Incidental Oral (1–30 days)	NOAEL = 10 mg/kg/day	Residential LOC for MOE = 100	Developmental Toxicity study in rabbits. LOAEL = 30 mg/kg/day based on decreases in body weight gain and food consumption.
Intermediate-Term Incidental Oral (1–6 months)	NOAEL = 7.5 mg/kg/day	Residential LOC for MOE = 100	Chronic Oral Toxicity in Dogs. LOAEL = 75 mg/kg/day based on alterations in hematological parameters [hematocrit and hemoglobin (males)], decreased body weight/body weight gain and increases in several organ weights.
Short-, Intermediate- and Long-Term Dermal	NA	NA	No hazard was identified via the dermal route of exposure.
Short-Term Inhalation (1 to 30 days)	Inhalation (oral) study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100	Chronic Oral Toxicity in Dogs. LOAEL = 75 mg/kg/day based on alterations in hematological parameters [hematocrit and hemoglobin (males)], decreased body weight/body weight gain and increases in several organ weights.
Intermediate-Term Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL = 7.5 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100	Chronic Oral Toxicity in Dogs. LOAEL = 75 mg/kg/day based on alterations in hematological parameters [hematocrit and hemoglobin (males)], decreased body weight/body weight gain and increases in several organ weights.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-Term Inhalation (> 6 months)	Inhalation (or oral) study NOAEL = 7.5 mg/kg/day (inhalation absorption rate = 100%)	Occupational LOC for MOE = 100 Residential LOC for MOE = 100	Chronic Oral Toxicity in Dogs. LOAEL = 75 mg/kg/day based on alterations in hematological parameters [hematocrit and hemoglobin (males)], decreased body weight/body weight gain and increases in several organ weights.
Cancer (oral, dermal, inhalation)	NA	NA	Group E carcinogen - evidence of non-carcinogenicity for humans.

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 the following raw agricultural commodities: dry bean, except cowpea, cabbage, chinese; mustard greens, mango, potato, leafy vegetables (except Brassica) group, cucurbit vegetables group, tomato, onions, mushroom, lima beans and pepper. Cyromazine tolerances are established for milk and tissues of cattle, goat, hog, horse, and sheep as a result of feeding cyromazine treated feed items. Rotational crop tolerances are established for sweet corn, radishes, and cotton. Additionally, cyromazine is registered for use as a feed through treatment for poultry for the control of flies and maggots in poultry manure. As a result of the feed-through use, tolerances are established for residues of cyromazine in egg and poultry tissues. Risk assessments were conducted by EPA to assess dietary exposures from cyromazine in food as follows:

i. *Acute exposure.* Quantitative 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. For this assessment, an appropriate endpoint attributable to a single dose (exposure) of cyromazine was not observed in oral toxicity studies.

ii. *Chronic exposure.* In conducting this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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 assessment: An unrefined chronic exposure analysis (Tier 1) was conducted for cyromazine using the DEEM software. The assumptions of the chronic dietary exposure assessment are tolerance-level residues and one hundred percent crop-treated.

iii. *Cancer.* Cyromazine is classified as a Group E carcinogen (evidence of non-carcinogenicity for humans), and was shown not to be carcinogenic in mice or rats following long-term dietary administration. The available mutagenicity data suggest that cyromazine does not have genotoxic activity.

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. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and 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 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 III.E.

In soil, cyromazine is stable to hydrolysis and photolysis and is rather persistent in aerobic soil (half-life value of 150 days). The field studies confirmed this half-life value, where average half-lives varied from 75 days to more than 250 days. Soil adsorption coefficients are generally low. This would indicate that cyromazine has the potential to leach through soils, especially sand and silt loam soils.

The EECs for cyromazine reflect six applications of cyromazine at 0.125 lbs ai/A. For surface water, the annual average of 15.5 µg/L (or ppb) is based on use of the FIRST model. The groundwater EEC of 5.3 µg/L has been estimated by the SCI-GROW2 program. Both of these surface and groundwater values represent upper-bound conservative estimates for concentrations that might be found in

surface water and groundwater due to the use of cyromazine.

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).

Cyromazine is not registered for use on any sites that would result in residential exposure. There are no currently existing or proposed uses for cyromazine in residential or public sites and therefore no residential risk assessment was performed.

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.''

EPA does not have, at this time, available data to determine whether cyromazine has a common mechanism of toxicity with other substances. 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 cyromazine and any other substances and cyromazine does not appear to produce a toxic metabolite produced by other substances. EPA has determined, however, that there is no known mechanism of toxicity that would support grouping cyromazine by a common mechanism with atrazine, simazine, and cyanazine. For the purposes of this tolerance action, therefore, EPA has not assumed that cyromazine 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 the 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 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. *Prenatal and postnatal sensitivity*. There is no evidence of susceptibility and no residual uncertainties for pre- and post-natal toxicity resulting from exposure to cyromazine.

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 because:

- There is no evidence of increased susceptibility (quantitative or qualitative) to rats or rabbits following in utero exposure or post-natal exposure to rats. In the prenatal developmental toxicity study in rats, the NOAEL for developmental toxicity was higher than the maternal NOAEL. In the developmental toxicity study in rabbits, no evidence of developmental toxicity was noted. For developmental toxicity, the NOAEL was > 60 mg/kg/day highest dose tested (HDT). In the two-generation reproduction study in rats no reproductive effects were observed. In this study, the reproductive NOAEL is ≥ 150 mg/kg/day (HDT). No neurotoxic effects were observed in the available data, and there is no requirement for a developmental neurotoxicity study. Further, exposure assessments have been conducted in a manner unlikely to underestimate exposure.
- The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- The dietary food exposure assessment is based on current and proposed registrations and is completely unrefined (i.e. tolerance level residues and 100% crop treated). The dietary exposure analysis will not underestimate exposure/risk.
- No residual uncertainties were identified in the exposure database.
- There are no residential uses for cyromazine.

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 (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + 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*. An appropriate endpoint attributable to a single dose (exposure) of cyromazine was not observed in oral toxicity studies. Thus, an acute dietary endpoint was not chosen, and cyromazine is not expected to pose an acute risk.

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 8.3% of the cPAD for the U.S. population, 5.0% of the cPAD for all infants (< 1 year old), 13% of the cPAD for children 1–2 years old, and 7.5% of the cPAD for females 13–49 years old. 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)	Ground Water EEC (ppb)	Surface Water EEC (ppb)	Chronic DWLOC (ppb)
General U.S. Population	0.075	8.3	5.3	15.5	2.4×10^3
All Infants (< 1 year old)	0.075	5.0	5.3	15.5	7.1×10^2
Children 1–2 years old	0.075	13	5.3	15.5	6.5×10^2
Females 13–49 years old	0.075	7.5	5.3	15.5	2.1×10^3

3. *Aggregate cancer risk for U.S. population*. Cyromazine is not expected to pose a cancer risk to humans.

4. *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

Methods AG–408 (HPLC,/UV) and AG–417A (GLC/NPD) are the tolerance enforcement methods for cyromazine as published in the Pesticide Analytical Manual (PAM), Vol. II. These methods combined and with minor modifications comprise Method AG–621. The residue data submitted in support of these petitions were generated using Methods AG–408 and AG–621. Method AG–621 has been adequately validated for use for the determination of residues of cyromazine in/on bulb vegetables, leafy Brassica vegetables, and turnip greens. Method AG–408 is adequate for enforcement of the proposed tolerance for residues of cyromazine.

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

Codex, Canadian or Mexican Maximum Residue Limits (MRLs) are not established for cyromazine in/on leafy Brassica vegetables, bulb vegetables, and turnip greens. Therefore, no compatability problems exist for the tolerances established by this rule.

V. Conclusion

Therefore, the tolerances are established for residues of cyromazine, (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) in or on leek; onion, green; onion, potato; onion, tree; onion, welsh; and shallot, fresh leaves at 3.0 ppm, garlic, bulb; garlic, great-headed, bulb; onion, dry bulb; rakkyo, bulb; and shallot, bulb at 0.2 ppm, vegetable, brassica, leafy, group 5, except broccoli at 10.0 ppm, broccoli at 1.0 ppm, turnip, greens; cabbage, abyssinian; cabbage, seakale; and hanover salad, leaves at 10.0 ppm, and kidney of cattle, goat, hog, horse, and sheep at 0.2 ppm, and meat byproducts, except kidney, of cattle, goat, hog, horse, and sheep at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, 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 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–2003–0269 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 24, 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*, 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–2003–0269, 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. Statutory and Executive Order Reviews

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. 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: September 10, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 as follows:

■ a. By revising the commodities cattle, goat, hog, horse, and sheep meat byproducts in the table in paragraph (a).

■ b. By revising the commodities onion, dry bulb and onion, green in the table in paragraph (a).

■ c. By alphabetically adding commodities in the table in paragraph (a).

■ d. By removing and reserving paragraph (c).

§ 180.414 Cyromazine; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Broccoli	1.0
Cabbage, abyssinian	10.0
Cabbage, seakale	10.0
* * *	* *
Cattle, kidney	0.2
Cattle, meat byproducts, except kidney	0.05
* * *	* *
Garlic, bulb	0.2
Garlic, great-headed, bulb	0.2
* * *	* *
Goat, kidney	0.2
* * *	* *
Goat, meat byproducts, except kidney	0.05
Hanover salad, leaves	10.0
* * *	* *
Hog, kidney	0.2
* * *	* *
Hog, meat byproducts, except kidney	0.05
* * *	* *
Horse, kidney	0.2
* * *	* *
Horse, meat byproducts, except kidney	0.05
* * *	* *
Leek	3.0
* * *	* *
Onion, dry bulb	0.2
Onion, green	3.0
Onion, potato	3.0
Onion, tree	3.0
Onion, welsh	3.0
* * *	* *
Rakkyo, bulb	0.2
Shallot, bulb	0.2
Shallot, fresh leaves	3.0
* * *	* *
Sheep, kidney	0.2
* * *	* *
Sheep, meat byproducts, except kidney	0.05
* * *	* *
Turnip, greens	10.0
Vegetable, brassica, leafy, group 5, except broccoli	10.0
* * *	* *

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

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[FR Doc. 03–24012 Filed 9–23–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0270; FRL–7324–5]

Sulfentrazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of the herbicide sulfentrazone and its metabolites in or on asparagus; bean, lima, succulent; cabbage; corn, field, forage; corn, field, grain; corn, field, stover; horseradish, roots; pea and bean, dried shelled, except soybean, subgroup 6C; peanut; peanut, meal; peppermint, tops; potato; spearmint, tops; sugarcane, cane; sugarcane, molasses; and sunflower, seed. EPA is also deleting certain sulfentrazone tolerances that are no longer needed as result of this action. The Interregional Research Project Number 4 and FMC Corporation requested these tolerances 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 September 24, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0270, must be received on or before November 24, 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: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703)308–9368; e-mail address: *jamerson.hoyt@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:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)