• Electric generation data from electric generators that do not burn fuel from May through September for the years 1995 through 1998.

• Nameplate capacity data for electric generators that do not burn fuel.

• Heat rate data for EGUs.

• Heat input data for May through September for the years 1997 and 1998 for EGUs.

• Heat input data for May through September for the year 1995 for non-EGUs. In addition, if you find that the heat input for your non-EGU during May through September for the year 1995 is not representative of your unit's operation over the last several years, then you may comment and provide us heat input data for May through September for the years 1996, 1997, and/or 1998.

See the section entitled ''What supporting documentation do I need to provide with my comments?'' in the August 9, 1999 notice of data availability for further details on information you should provide with your comments.

If you have already submitted comments on the August 9, 1999 notice of data availability, you may submit supplementary comments.

5. What Things Is EPA Not Requesting Comment On?

EPA is requesting comment only on the data in the data files referenced here and in the August 9, 1999 notice of data availability. We are not requesting comment on any other issue or data.

6. Where Are the Data Files?

The data files are available on the Regional Transport of Ozone webpage at http://www.epa.gov/ttn/rto/. You will find links to the data under the ''Related Documents and Data'' subheadings under the ''Transport FIPs'' and ''Section 126 Petitions'' headings on the Regional Transport of Ozone webpage. Look for a WinZip file labeled ''a WinZip file containing heat input and electric generation data that EPA or States could use for determining NOx allowance allocations. EPA requests comment on these data.'' In addition to the data files, the WinZip file also contains a text file describing the fields in the data files, ''readme.txt,'' and a text file describing EPA's method for preparing the electric generation data, ''outmethd.txt''. In addition, these data are in Docket Nos. A–97–43 (Section 126 rulemaking) and A–98–12 (Section 110 FIP rulemaking).

Dated: September 9, 1999.

Paul Stolpman,

Director, Office of Atmospheric Programs.

[FR Doc. 99–24038 Filed 9–14–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300913; FRL–6098–7]

RIN 2070–AB78

Cyromazine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish tolerances for residues of cyromazine (CAS No. 66215–27–8) in or on mango at 0.3 parts per million (ppm); onion, green at 2.0 ppm; onion, dry bulb at 0.1 ppm; potato at 0.8 ppm; corn, sweet, (kernels plus cob with husks removed) at 0.5 ppm; corn, sweet, forage at 0.5 ppm; corn, sweet, stover at 0.5 ppm; radish, roots at 0.5 ppm; radish, tops at 0.5 ppm; lima beans at 1.0 ppm; cotton, undelinted seed at 0.1 ppm; milk at 0.05 ppm; and meat, fat and meat byproducts (of cattle, goats, hogs, horses and sheep) at 0.05 ppm. EPA also proposes to remove melamine, a metabolite of cyromazine from the tolerance expression since it is no longer considered a residue of concern. The Interregional Research Project (IR-4) and Novartis Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: Comments, identified by the docket control number ''OPP–300913,'' must be received by EPA on or before November 15, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300913], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 100, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300913]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Linda DeLuise, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 202, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–5428; e-mail: deluise.linda@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 11, 1997 (62 FR 37246) (FRL–5723–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP) for tolerances by Novartis Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419. The notice included summaries of the petitions prepared by Novartis Crop Protection, Inc., 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 tolerances for residues of the insecticide cyromazine and its metabolite melamine, in or on various food commodities as follows:

1. Novartis Corporation PP5E4450 proposes the establishment of a tolerance for mangoes at 0.3 ppm.

2. Norvartis Corporation PP5F4576 proposes the establishment of a tolerance for onion, green at 3.0 ppm and onion, dry bulb at 0.3 ppm.

3. Novartis Corporation PP6F4613 proposes the establishment of a tolerance for potato at 1.5 ppm.

4. Novartis Corporation PP5F4546 proposes establishment of a tolerance for cotton, undelinted seed at 0.2 ppm.

5. Novartis Corporation PP6F3332 proposes establishment of tolerances for sweet corn, (kernels plus cob with husks removed), forage and stover at 0.5 ppm; radish roots, and tops at 0.5 ppm; and milk at 0.04 ppm for cyromazine and 0.02 ppm melamine.

6. Novartis Corporation PP6F3332 proposes establishment of a tolerance for meat, fat and meat byproducts (of cattle, goats, hogs, horses and sheep) at 0.05 ppm.

7. IR-4 PP7E4905 proposes the establishment of a tolerance for lima beans at 3.0 ppm.

The tolerance requests for cotton, corn and radish are for indirect or inadvertent residues when these commodities are planted as rotational crops. The tolerance request for mangoes is for a tolerance to enable the importation of mangoes treated in Mexico with cyromazine. There are no U.S. registrations for use of cyromazine on mangoes as of the date of this publication.

There currently exists separate tolerances in 40 CFR 180.414(a) for cyromazine on celery at 10.0 ppm and lettuce, head at 5.0 ppm. Since the crop group leafy vegetables (except Brassica) includes celery and lettuce, (head) these individual tolerances under 40 CFR 180.414(a) are being removed.

EPA has concluded that only residues of the parent compound cyromazine need to be regulated and used for risk assessment and is proposing that melamine, a metabolite of cyromazine, be removed from the tolerance expression as a residue of toxicological concern.

Melamine was initially included in the tolerance expression for cyromazine because of limited evidence of its carcinogenic potential in laboratory animals. At that time EPA agreed with FDA's Cancer Assessment Committee that melamine was not a carcinogen, *per se*, but was indirectly responsible for the induction of urinary bladder neoplasia through production of stones in the bladder. A detailed discussion of the initial risk of melamine can be found in the **Federal Register** of April 27, 1984 (49 FR 18120). Since then EPA has reassessed the weight-of-the evidence for both cyromazine and melamine with particular reference to their carcinogenic potential. Cyromazine is classified as a group ''E'' carcinogen (no evidence of carcinogenicity) with an chronic RfD of 0.0075 milligram/kilogram/day (mg/kg/day) with an uncertainty factor (UF) of 100 using a no observed adverse effect level (NOAEL) of 0.75 mg/kg/day and a lowest observed adverse effect level (LOAEL) of 7.5 mg/kg/day.

Melamine is a chemical intermediate in the manufacture of amino resins and plastics as well as a contaminate and/or a metabolite of several pesticides including cyromazine. Melamine produced bladder tumors only in the male rat urinary bladder at very high doses i.e., at a threshold effect > 10,000 ppm in the diet. These tumors were due to the accumulation of stones (hard crystalline solids) which caused irritation and secondarily resulted in the formation of tumors; therefore melamine is not considered to be a direct carcinogen by the Agency.

In addition, only about 10% of cyromazine is converted to melamine *in vivo*. Anticipated human dietary and occupational exposure to the parent compound cyromazine from its current pesticide usage is estimated to result in melamine concentrations far below the NOAEL in rats (500 mg/kg/day) that led to formation of stones in rats. Thus, EPA does not have any toxicological concerns for the minimal amount of melamine residues that could result from the use of the pesticide cyromazine. Also, melamine has been removed from the World Health Organization as a residue of concern for cyromazine, and Codex limits are established for the parent cyromazine only.

EPA determined that the requested tolerances for potatoes at 0.8 ppm, green onions at 2.0 ppm, onion, dry bulb at 0.1 ppm, cotton, undelinted seed at 0.1 ppm, and lima beans at 1.0 ppm are too high based upon the magnitude of the residue studies and removal of the metabolite melamine from consideration. Therefore, EPA is proposing that the tolerance be set at 0.8 ppm, 2.0 ppm, 0.1 ppm, 0.1 ppm, and 1.0 ppm respectively. As a result of the animal feed items, processed potato waste, potato culls and sweet corn forage and stover being added to the animal diet at this time, EPA concluded that the requested milk tolerance of 0.04 ppm was too low and is proposing it be increased to 0.05 ppm. Likewise, as a result of the animal feed items, EPA is proposing establishment of tolerances in meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep at 0.05 ppm.

EPA has reassessed the established cyromazine tolerances in order to determine the tolerance levels without melamine residues. As a result, EPA is proposing the tolerances be adjusted as follows: cucurbit vegetables from 2.0 to 1.0 ppm; leafy vegetables (except Brassica) from 10.0 to 7.0 ppm; mushrooms from 10.0 to 1.0 ppm; pepper from 4.0 to 1.0 ppm and tomato from 1.0 to 0.5 ppm. The tolerances for Chinese cabbage and Chinese mustard should remain at 3.0 ppm since the available field trial data do not support a lowering of the established tolerances. Since melamine is being removed from the tolerance expression EPA is proposing to remove 40 CFR 180.414(a)(2) because it is for melamine only on chicken byproducts.

Cyromazine is an insect growth regulator currently proposed for control of leafminers on lima beans, Colorado potato beetle and leafminers on potatoes and seed treatment for control of onion maggots on onions.

EPA is issuing this action as a proposal (rather than a final) because after review of the initial petitions and Notices of Filing the Agency has determined that:

1. The metabolite melamine should be removed from the tolerance expression.

2. The proposed tolerance in milk needs to be raised.

3. Additional tolerances on animal commodities (meat, fat and milk byproducts of cattle, goats, hogs, horses and sheep) are needed.

4. A notice of filing was not initially published after receipt of the petition for lima beans.

Interested persons are invited to submit comments on the proposed regulation. Comments must bear a notation indicating the docket control number ''OPP–300913.''

I. Background and Statutory Findings

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

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the

hazards of cyromazine and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of cyromazine in or on mangoes at 0.3 ppm; onion, green at 2.0 ppm; onion, dry bulb at 0.1 ppm; potato at 0.8 ppm; corn, sweet (kernels plus cob with husks removed) at 0.5 ppm; corn, sweet, forage at 0.5 ppm; corn, sweet, stover at 0.05 ppm; radish, root at 0.5 ppm; radish, tops at 0.05 ppm; lima beans at 1.0 ppm; cotton, undelinated seed at 0.1 ppm; milk at 0.05 ppm; and meat, fat and meat byproducts (of beef, goat, hogs, horses and sheep) at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by technical cyromazine are discussed in this unit.

A rat acute oral toxicity study with a LD_{50} of approximately 3,387 milligrams/kilogram (mg/kg). Toxicity Category III (Moderately Toxic).

A rat acute dermal toxicity study with an LD_{50} greater than 3,100 mg/kg. Toxicity Category III (Moderately Toxic).

A rat acute inhalation study with an LC_{50} greater than 2.9 mg/kg. Toxicity Category IV (Slightly Toxic).

A primary eye irritation study in the rabbit that showed no eye irritation.

A primary dermal irritation study in the rabbit that showed mild irritation. Toxicity Category IV.

A dermal sensitization study in the guinea pig that showed no sensitization.

In a 6-month feeding study in dogs the NOAEL was 30 ppm (0.75 mg/kg). The LOAEL was 300.0 ppm (7.5 mg/kg) based upon decreased hematocrit and decreased hemoglobin. Groups of male and female beagle dogs (4/sex/dose) were fed diets containing cyromazine at 0, 30, 300, or 3,000 ppm (0, 0.75, 7.5, or 75 mg/kg/day, respectively) for 6-months. No treatment related effects were observed in survival, clinical signs or body weight parameters. Pronounced effects on hematologic parameters, were manifested as decreases in hematocrit and hemoglobin levels at 300 and 3,000 ppm.

In a 24-month feeding study in rats the NOAEL for the study was 30 ppm (1.5 mg/kg/day). The LOAEL was 300.0 ppm (15.0 mg/kg) based on decreased body weight.

In a 24-month mouse chronic feeding carcinogenicity study the NOAEL was 50 ppm (7.5 mg/kg/day). The LOAEL was 1,000.0 ppm (150.0 mg/kg) based upon decreased body weight. There was no evidence of carcinogenicity at 3,000.0 ppm (450.0 mg/kg).

In a 24-month rat chronic feeding carcinogenicity study the NOAEL was greater than 3,000.0 ppm (150.0 mg/kg), highest dose tested. There was no evidence of carcinogenicity at 3,000 ppm.

In a rat developmental toxicity study the maternal NOAEL was 100 mg/kg/day. The maternal LOAEL was 300.0 mg/kg based on decreased body weight gain and clinical observations. The developmental NOAEL was 300.0 ppm. The developmental LOAEL was 600.0 mg/kg based upon an increase of minor skeletal variations.

In a rabbit developmental toxicity study the maternal NOAEL was 10.0 mg/kg. The maternal LOAEL was 30.0 mg/kg based upon decreased body weight gain and food consumption. The developmental NOAEL/LOAEL was greater than or equal to 60.0 mg/kg.

In a multi-generation study in rats the systemic NOAEL was 30.0 ppm (1.5 mg/kg). The systemic LOAEL was 1,000.0 ppm (50.0 mg/kg) based upon decreased body weights associated with decreased food consumption. The developmental/offspring systemic NOAEL was 1,000.0 ppm. The developmental/offspring systemic LOAEL was 3,000.0 ppm (150.0 mg/kg) based upon decreased body weight at birth thru weaning. There were no effects on reproductive parameters at the highest dose tested (3,000 ppm).

Studies on gene mutation and other genotoxic effects showed no evidence of point mutation in an Ames test; no indication of mutagenic effects in a dominant lethal test; and no evidence of mutagenic effects in a nucleus anomaly test in Chinese hamsters.

In a dermal absorption study, rats received dermal application of $_{14}C$ cyromazine (75W, formulation) in an aqueous solution at 0.10, 1.0 or 10 mg/rat. Absorption was measured at 10 and 24 hours post treatment. Cyromazine was rapidly absorbed into the skin (no peak discernible) in an inverse dose-related manner. The absorption into the skin was followed by a slower release into the body. There was no evidence that the compound was sequestered in the skin permanently. The main route of excretion was via the urine. At 10 hours post treatment, the absorption was 7.57, 5.06 and 1.84% for the low, mid and high doses, respectively. At 24 hours post exposure, the absorption was 6.87, 2.78 and 2.63% for the low, mid and high doses, respectively. For the 24–hour animals with 48–hour depletion period, the absorption was 16.07, 12.45 and 9.10% for the low, mid and high doses, respectively.

B. Toxicological Endpoints

1. *Acute toxicity.* (1-day) There was no toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats or rabbits. Therefore, a dose and an endpoint was not selected for this acute dietary risk assessment.

2. *Short- and intermediate-term toxicity.* The Agency selected short- and intermediate-term dermal and inhalation endpoints from the 6-month oral toxicity study in dogs, in which pronounced effects on hematological parameters were manifested as decreases in hematocrit and hemoglin levels at 7.5 (LOAEL) and 75 mg/kg/day. The hematological effects began during the first week of the study and continued throughout the study. The NOAEL is 0.75 mg/kg/day. A margin of exposure (MOE) of 100 or greater is adequate. For dermal inhalation exposure adsorption rates of 8% for dermal and 100% for inhalation are appropriate.

3. *Chronic toxicity.* The Agency selected a chronic RfD for cyromazine of 0.0075 mg/kg/day (NOAEL = 0.75 mg/kg/day; UF = 100). This RfD is based on a 6-month oral toxicity in dogs, in which pronounced effects on hematological parameters were manifested as decreases in hematocrit and hemoglobin levels at 7.5 (LOAEL) and 75 mg/kg/day.

4. *Carcinogenicity.* Cyromazine has been classified a Group E (evidence of non-carcinogenicity for humans) chemical by the Cancer Peer Review Committee.

C. Exposures and Risks

1. *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 at levels ranging from 1.0 ppm in tomatoes to 10 ppm in leafy vegetables and including poultry feed. In addition, EPA proposes to establish tolerances for mangoes at 0.3 ppm; onion, green at 2.0 ppm; onion, dry bulb at 0.1 ppm; potato at 0.8 ppm; cotton, undelinted seed at 0.1 ppm; corn, sweet, (kernels plus cob with husks removed) at 0.5 ppm; corn, sweet, forage at 0.5 ppm; corn, sweet, stover at 0.5 ppm; radish, root at 0.5 ppm; radish,

tops at 0.5 ppm; lima beans at 1.0 ppm; milk at 0.05 ppm and meat, fat and meat byproducts (of cattle, goat, hogs, horses and sheep) at 0.05 ppm. Risk assessments were conducted by EPA to assess dietary exposures from cyromazine as follows:

The Agency used Dietary Exposure Evaluation Model (DEEM™) software for conducting a Tier 3 chronic (non-cancer) dietary (food only) exposure analysis. The following assumptions were used in the assessment: (i) Percent crop-treated (PCT) estimates were utilized for cucurbit vegetables, leafy vegetables (except Brassica), onions, peppers and tomatoes; (ii) all other crops 100% crop-treated was assumed; (iii) anticipated residue estimates were used for milk, meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep; and (iv) all other commodities tolerance level residues were assumed. This assessment is considered to be somewhat refined. The chronic DEEM™ analysis indicates that the most highly exposed population subgroup is children (1 to 6 years old), which occupies 34% of the chronic RfD or chronic population adjusted dose (PAD)

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual PCT for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency believes that the three conditions, discussed in section 408(b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. With respect to PCT, estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the crop treated, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. As to 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 ensure's 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.

a. *Acute exposure and risk.* A food-use pesticide is presumed to pose an acute risk if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. There were no toxicological effects attributed to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

b. *Chronic exposure and risk.* The chronic and/or chronic PAD RfD used for the chronic dietary analysis is 0.0075 milligram/kilogram/body weight/day (mg/kg/bwt/day). The following assumptions were used in the dietary risk assessment: (i) PCT estimates were utilized for cucurbit vegetables, leafy vegetables (except Brassica), onions, peppers and tomatoes. All other crops 100% crop-treated was assumed; (ii) anticipated residue estimates were used for milk, meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep; and (iii) all other commodities tolerance level residues were assumed. The proposed and established cyromazine tolerances result in an exposure estimate that is equivalent to the following percents of the RfD: U.S. population (17% of RfD), non-nursing infants, (1 year old) (13% of RfD), children (1–6 years old) (34%), and children (7–12 years old) 26%. EPA is generally concerned with chronic exposures that exceed 100% of the RfD or PAD.

This chronic analysis for cyromazine is an over-estimate of dietary exposure from food due to the use of tolerance level residues for some commodities and the assumption that 100% of the crop would be treated for some of the commodities in this dietary exposure analysis. Thus in making a safety determination for these tolerances, EPA is taking into account this conservative exposure assessment.

2. *From drinking water.* The Agency has calculated drinking water levels of comparison (DWLOCs) for chronic (non-cancer exposure) to cyromazine in surface and ground water.

i. *Acute exposure and risk.* Because no acute dietary endpoint was determined, EPA does not expect exposure to cyromazine through drinking water to pose an acute risk.

ii. *Chronic exposure and risk.* EPA has calculated DWLOCs for chronic (non-cancer) exposure to cyromazine in surface and ground water. A human health DWLOC is the concentration of a pesticide in drinking water which would result in an acceptable aggregate risk after having factored in all food exposures and other non-occupational exposures for which EPA has reliable data. The DWLOCs are 220, 190, 50, and 210 parts per billion (ppb) for the U.S. population, females 13+, children, and others respectively. To calculate the DWLOCs for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure from DEEM™ was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to cyromazine in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures. Although cyromazine may be commercially applied to landscape ornamentals and around residences, EPA believes these uses will not result in any exposure through the oral route; therefore, aggregate exposure is limited only to food plus water.

Estimated maximum concentrations of cyromazine in surface and ground

water are 28.9 and 1.6 ppb, respectively. The modeling conducted was based on the environmental profile and the maximum seasonal application rate proposed for cyromazine (6 applications at 0.125 lbs/A). The estimated average concentrations of cyromazine in surface and ground water are less than the Agency's levels of comparison for cyromazine in drinking water as a contribution to chronic aggregate exposure. Thus, the Agency concludes that there is reasonable certainity of no harm from chronic exposure from drinking water.

The Agency bases this determination on a comparison of estimated concentrations of cyromazine in surface waters and ground waters to back-calculated ''levels of comparison'' for cyromazine in drinking water. These levels of comparison in drinking water were determined after the Agency has considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in this action. The estimates of cyromazine in surface and ground waters are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because the Agency 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 (including crop or residential) are added in the future, the Agency will reassess the potential impacts of cyromazine on drinking water as a part of the aggregate risk assessment process.

3. *From non-dietary exposure.* Cyromazine is currently registered for commercial outdoor use on landscape ornamentals and commercial interiorscapes. There are no lawn or indoor residential uses. Although cyromazine could be commercially applied to ornamentals around residences based upon the large MOE's calculated for occupational use (i.e. > 1,900) and minimal contact anticipated with the active ingredient after application, significant residential exposure is not expected.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Cyromazine is a member of the triazine class of pesticides. Other members of this class include atrazine, simizine, cyanazine, prometin, propazine, metribuzin, prometryn, and ametryn.

EPA does not have, at this time, available data to determine whether cyromazine has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyromazine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyromazine has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* There were no toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats or rabbits.

2. *Chronic risk (food + water).* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to cyromazine from food will utilize 17% of the chronic RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is 34% for children (1–6 years old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Based on the chronic dietary (food only) exposures and using default body weights and water consumption figures, chronic DWLOCs for drinking water were calculated. For chronic exposure, based on an adult body weight of 70 kg and 2L consumption of water per day, EPA's level of comparison from chronic dietary exposure in drinking water is 220 µg/L. For children (10 kg and consuming 1 liter water/day) the level of comparison for drinking water is 50 µg/L. The estimated chronic drinking water exposure for cyromazine is 28.9 µg/L. Thus the potential residues in drinking water are not greater the EPA's level of comparison. Therefore, the combined exposure of chronic dietary food and drinking water exposure to cyromazine would be no greater than 100% of the RfD for children or the general U.S. population. Due to the nature of the non- dietary use, EPA believes that the commercial use of cyromazine on landscape ornamentals will not result in any significant residential exposure. Therefore the chronic risk is the sum of food and water. The Agency concludes that there is reasonable certainty that no harm will result from aggregate exposure to cyromazine residues.

3. *Short- and intermediate-term risk.* These aggregate risk assessments take into account chronic dietary exposure from food and water (considered to be a background exposure level) plus (acute, intermediate, or chronic, as applicable) indoor and outdoor residential exposure. The Agency selected a dose and toxicological endpoint for assessments of short- and intermediate-term dermal and inhalation risk. However, since there are no significant residential uses for cyromazine (either established or pending) at this time, these risk assessments are not currently required.

4. *Aggregate cancer risk for U.S. population.* The Cancer Peer Review Committee determined that there is no evidence of carcinogenicity in studies in either the mouse or rat. Based upon this determination it can be concluded that cyromazine does not pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyromazine residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of cyromazine, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base 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. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or

children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the rabbit developmental study, the maternal (systemic) NOAEL was 10 mg/kg/day, the highest dose tested. In the rat developmental study, the developmental NOAEL was identified at 300 mg/kg/day, while the maternal NOAEL was 100 mg/kg/day. Although there were developmental findings at 600 mg/kg/day in rat fetuses, these findings were not severe effects and only occurred in the presence of maternal toxicity.

iii. *Reproductive toxicity study.* In the multi-generation study in rats the systemic NOAEL was 30.0 ppm (1.5 mg/kg). The systemic LOAEL was 1,000.0 ppm (50.0 mg/kg) based upon decreased body weights associated with deceased food consumption. The developmental/offspring systemic NOAEL was 1,000.0 ppm. The developmental/offspring systemic LOAEL was 3,000.0 ppm (150.0 mg/kg) based upon decreased body weight at birth thru weaning. There were no effect on reproductive parameters at the highest dose tested (3,000 ppm).

iv. *Prenatal and postnatal sensitivity.* The results of the rat and rabbit developmental studies did not demonstrate any potential for additional prenatal sensitivity. In the rat reproduction study, the parental and reproductive/developmental NOAELs were established at 1.5 and 50 mg/kg/day respectively which suggests that there is no special postnatal sensitivity to cyromazine.

v. *Conclusion.* Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, the Agency concludes that an additional safety factor of 10 is not necessary to be protective of infants and children.

2. *Acute risk.* There were no toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats or rabbits.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to cyromazine from food will utilize a maximum 34% of the RfD for children 1–6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. As noted above potential exposure from drinking water is at a level below EPA's level of comparisons. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyromazine residues.

4. *Short- and intermediate-term risk.* These aggregate risk assessments take into account chronic dietary exposure from food and water (considered to be a background exposure level) plus (acute, intermediate, or chronic, as applicable) indoor and outdoor residential exposure. The Agency selected a dose and toxicological endpoint for assessments of short- and intermediate-term dermal and inhalation risk. However, since there are no significant residential uses for cyromazine (either established or pending) at this time, these risk assessments are not currently required.

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

III. Other Considerations

A. Metabolism in Plants and Animals

EPA has reviewed the results of plant metabolism studies (celery, lettuce and tomato) and livestock metabolism studies (goat and hen). The metabolism of cyromazine in plants and animals is adequately understood for the purposes of these tolerances. The major residues in plants, milk, meat and meat byproducts (except liver and kidney) are cyromazine and melamine. The major residues in liver and kidney are cyromazine, melamine and 1-methylcyromazine. EPA concluded (see background) that the metabolite melamine was no longer a residue of concern and the metabolite 1-methhylcyromazine was only found in ruminants. Provided the dietary burden to animals remains low only the parent compound cyromazine needs to be included in the tolerance expression and used for dietary risk assessment.

B. Analytical Enforcement Methodology

Methods AG–408 and AG–417A are the tolerance enforcement methods as published in PAM, Vol II. These methods combined, and with minor modifications is Method AG–621. The residue data on the treated crops was analyzed by these methods. The limit of quantitation is 0.05 ppm for cyromazine and 0.05 ppm for melamine expressed as cyromazine equivalents. These extraction and cleanup procedures are similar to the Methods AG–408 and AG–417, but AG–621 uses a gas chromatography for analysis, while the other methods use high pressure liquid chromatography for determination of cyromazine and melamine levels in the crop matrix.

Methods AG–408 and AG–417 as listed in FDA's Pesticide Analytical Manual (PAM), Vol-II are adequate to enforce the proposed tolerance. AG–621 is acceptable to support the crop field trial residue data for cyromazine on RAC's.

The PAM II enforcement method for the determination of cyromazine residues limit of quantitation (LOQ) is 0.05 ppm in meat, fat, and meat byproducts.

C. Magnitude of Residues

Adequate residue data were provided to support permament tolerances of mangoes at 0.3 ppm; onion, green at 2.0 ppm; onion, dry blub at 0.1 ppm; potato at 0.8 ppm; corn, sweet (kernels plus cob with husks removed) at 0.5 ppm; corn, sweet, forage at 0.5 ppm; corn, sweet, stover at 0.5 ppm; radish, root at 0.5 ppm; radish, tops at 0.5 ppm; lima beans at 1.0 ppm; milk at 0.05 ppm; meat, fat and meat byproducts (of beef, goat, hogs, horses and sheep) at 0.05 ppm and in cotton, undelinted seed at 0.1 ppm. There were no data available for cotton gin products (commonly called cotton gin trash). The petitioner has committed to conduct the additional residue trials and obtain data for cotton gin byproducts. Although residue data for lima beans were conducted per the EPA guidance that was in effect at the time of the field trials, EPA now requires residue data for the succulent beans without the pods. EPA will issue a conditional registration for these uses while the petitioner generates the additional data.

Processing data provided for potatoes did not show any concentration of residues for potato chips above the tolerance level. For potato granules the concentration factor is below 1.5x value that is generally used for setting tolerances for processed commodities. Thus no tolerances are required for processed potato commodities.

The only significant animal feed items from either published or proposed tolerances are potato culls, processed potato waste and sweet corn forage and stover. Since none of these items are fed to poultry the established poultry tolerances are adequate.

A ruminant feeding study was submitted. Based upon the results of this study the data support permanent tolerances in milk at 0.05 ppm and meat, fat and meat byproducts (of cattle, goat, hogs, horses and sheep) at 0.05

ppm resulting from the feeding of animal commodities indicated above.

D. International Residue Limits

With deletion of the metabolite melamine there are no longer any compatibility problems between Codex limits, Mexican limits and proposed U.S. tolerances. There are currently no Codex, Canadian or Mexican limits for residues of cyromazine on potatoes and lima beans. There is a Codex limit of 0.01 ppm in milk which is less than the proposed tolerance of 0.05 ppm. Although residues in milk would most likely be below 0.05 ppm, this level is the limit of quatitation (LOQ) used for enforcement purposes for determination of cyromazine residues.

E. Rotational Crop Restrictions

Rotational crop tolerances are being requested for cotton, undelinated seed, sweet corn (kernels plus cob with husks removed), sweet corn forage and stover as well as radish, roots and tops (leaves). When these crops are planted as rotational crops, cyromazine is persistent in soils and residues can be present in crops that are rotated to treated crops. For those crops with no tolerances established, a 1 year plant back interval is specified on the label.

IV. Conclusion

Tolerances are being proposed for residues of cyromazine in mangos at 0.3 ppm; onion, green at 2.0 ppm; onion, dry bulb at 0.1 ppm; potato at 0.8 ppm; corn, sweet, (kernels plus cob with husks removed) at 0.5 ppm; corn, sweet, forage at 0.5 ppm; corn, sweet, stover at 0.5 ppm; radish, root at 0.5 ppm; radish, tops at 0.5 ppm; lima beans at 1.0 ppm; cotton, undelinted seed at 0.1 ppm; milk at 0.05 ppm; and meat, fat and meat byproducts (of cattle, goat, hogs, horses and sheep) at 0.05 ppm. Conditional Registration for use of cyromazine on succulent lima beans and cotton are being proposed to allow for development and review of additional residue field studies. The analysis for cyromazine using tolerance level residues shows that the proposed uses will not cause exposure to exceed levels at which EPA believes there is an appreciable risk. All population subgroups examined by EPA are exposed to cyromazine residues at levels below 100% of the RfD for chronic effects. Based on the information and data considered, EPA concludes that the proposed tolerances will be safe. Therefore, these tolerances are being proposed as set forth below.

V. Public Comment Procedures

EPA invites interested persons to submit written comments, information, or data in response to this proposed rule. After consideration of comments, EPA will issue a final rule. Such rule will be subject to objections. Failure to file an objection within the appointed period will constitute waiver of the right to raise in future proceedings issues resolved in the final.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300913] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of comments received electronically into printed, paper form as they are received and will place the paper copies in the official record. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This action proposes to establish tolerance under FFDCA section 408(e). 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). In addition this proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 40 CFR Part 180

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

Dated: August 26, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180 [AMENDED]

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

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

2. Section 180.414, is revised to read as follows:

§ 180.414 Cyromazine; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6 triamine) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproduct	0.05
Cucurbit vegetables	1.0
Eggs	0.25

Commodity	Parts per million
Goats, fat	0.05
Goats, meat	0.05
Goats, meat byproduct	0.05
Hogs, fat	0.05
Hogs, meat	0.05
Hogs, meat byproduct	0.05
Horses, fat	0.05
Horses, meat	0.05
Horses, meat byproduct	0.05
Leafy vegetables (except Brassica)	7.0
Lima beans	1.0
Mango[1]	0.3
Milk	0.05
Mushrooms	1.0
Onion, dry bulb	2.0
Onion, green	0.1
Peppers	1.0
Potato	0.8
Poultry, fat (from chicken layer hens and chicken breeder hens only)	0.05
Poultry, meat byproduct (from chicken layer hens and chicken breeder hens only)	0.05
Poultry, meat (from chicken layer hens and chicken breeder hens only)	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproduct	0.05
Tomato	0.5

1There are no U.S. registrations on mango as of (inset date of publication).

(2) The additive cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) may be safely used in accordance with the following prescribed conditions:

(i) It is used as a feed additive only in the feed for chicken layer hens and chicken breeder hens at the rate of not more than 0.01 pound of cyromazine per ton of poultry feed.

(ii) It is used for control of flies in manure of treated chicken layer hens and chicken breeder hens.

(iii) Feeding of cyromazine-treated feed must stop at least 3 days (72 hours) before slaughter. If the feed is formulated by any person other than the end user, the formulator must inform the end user, in writing, of the 3-day (72 hours) preslaughter interval.

(iv) To ensure safe use of the additive, the labeling of the pesticide formulation containing the feed additive shall conform to the labeling which is registered by the U.S. Environmental Protection Agency, and the additive shall be used in accordance with this registered labeling.

(v) Residues of cyromazine are not to exceed 5.0 parts per million (ppm) in poultry feed.

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the insecticide cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its metabolite, melamine (1,3,5-triazine-2,4,6-triamine), in connection with use of the pestiicde under section 18 emergency exemption granted by EPA. The tolerances are specified in the following table. These tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Turkey, fat	0.05	4/1/00
Turkey, meat	0.05	4/1/00
Turkey, meat byproduct	0.05	4/1/00

(c) *Tolerances with regional registrations.* As defined in 180.1(n), are established for the residues of cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cabbage, Chinese	3.0
Mustard, Chinese	3.0

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of cyromazine (*N*-cyclopropyl- 1,3,5-triazine-2,4,6-triamine), in or on the raw agricultural commodities when present therein as a result of the application of cyromazine to growing crops listed in paragraphs (a)(1) of this section.

Commodity	Parts per million
Cotton, undelinted seed	0.1
Corn, sweet, (kernels plus cob with husks removed)	0.5
Corn, sweet, forage	0.5
Corn, sweet, stover	0.5
Radish, root	0.5
Radish, tops (leaves)	0.5

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6437–8]

Tennessee: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to grant final authorization to the hazardous waste program revisions submitted by Tennessee. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is authorizing the State's program revisions as an immediate final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. The Agency has explained the reasons for this authorization in the preamble to the immediate final rule. If EPA does not receive adverse written comments, the immediate final rule will become effective and the Agency will not take further action on this proposal. If EPA receives adverse written comments, EPA will withdraw the immediate final rule and it will not take effect. EPA will then address public comments in a later final rule based on this proposal. EPA may not provide further opportunity for comment. Any parties interested in commenting on this action must do so at this time.

DATES: Written comments must be received on or before October 15, 1999.

ADDRESSES: Mail written comments to Narindar Kumar, Chief, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104; (404) 562–8440. You can examine copies of the materials submitted by Tennessee during normal business hours at the following locations: EPA Region 4, Library, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104, Phone number: (404) 562–8190; or Tennessee Department of Environment and Conservation, Division of Solid Waste Management, 5th Floor, L & C Tower, 401 Church Street, Nashville, Tennessee 37243–1535, Phone number: (615) 532–0850.

FOR FURTHER INFORMATION CONTACT: Narindar Kumar, Chief, RCRA Programs