ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180
[OPP–300913A; FRL–6556–3]
RIN 2070–AB78

Cyromazine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule establishes permanent 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; onions, 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; radishes, root at 0.5 ppm; radishes, tops at 0.5 ppm; lime 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. This final rule also removes melamine, a metabolite of cyromazine from the tolerance expression since it is no longer considered a residue of concern.

DATES: This regulation is effective May 25, 2000. Objections and requests for hearings, identified by docket control number OPP–300913A, must be received by EPA on or before May 24, 2000.

For further information contact: By mail: Linda DeLuise, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5428; e-mail address: deluise.linda@epa.gov.

II. Background and Statutory Findings

In the Federal Register of September 15, 1999 (64 FR 50043) (FRL–6098–7), EPA issued a proposed rule which announced that Novartis Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419 and the Interregional Research Project (IR–4) had submitted pesticide petitions (PP) 5E4450, 5F4574, 6F4613, 5F4546, 6F3332, and 7E4905 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) proposing that 40 CFR part 180 be amended by establishing a tolerance for cyromazine in or on mango at 0.3 parts per million (ppm); onion, green at 2.0 ppm; onions, 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; radishes, root at 0.5 ppm; radishes, tops at 0.5 ppm; lime 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, and sheep) at 0.05 ppm. EPA received one comment from a private citizen of Australia alleging that the health of a dog was due to cyromazine and stating that long-term implications and studies

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

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select 'Laws and Regulations' and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/.

2. In person. The Agency has established an official record for this action under docket control number OPP–300913A. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

This regulation is effective May 25, 2000.
had not been addressed in this petition. In particular the citizen stated:

1. On 14 September 1999, an Adverse Reaction Experience Report was submitted to the National Registration Authority in Australia on the use and subsequent ill-health of a dog after long-term ingestion of cyromazine available in Australia as an oral flea control. Period was some 4-5 years at 300 mg/day for 27 kg dog. The dog’s kidneys and liver were enlarged and her immune system dysfunctional. The cyromazine was immediately stopped at a veterinarian’s request and the dog’s organs continually become less inflamed. The flea control tablet was withdrawn from the market some 2 or 3 years ago, due to fatalities in a number of animals due to liver failure. The product was subsequently re-released with warning that only dogs which had shown no reaction to the “Decaflea” could use it.

2. If a factor of 10% of 0.1 ppm is used from animal reaction to allowable human exposure, how does very short-term fatal liver dysfunction in dogs equate to long-term ingestion by humans, especially infants and children. How does this equate to humans who already have liver and kidney disease/dysfunction?


Cyromazine was fed to Luemann hens at 0.15 ppm level supplemented the basal diet for 3 weeks. The build up of cyromazine residues in liver and muscles of hens up to 7th day. During the 3 weeks of feeding on the treated diet, the accumulated residues reduced the blood glucose and hepatic protein significantly up to 2 weeks. Also such residues had adverse effects on the activities of alkaline phosphates and transaminase and extend on red blood cells, white blood cells, hemoglobin content and packed cell volume compared with the untreated hens.

“Effects of CGA-72662 (Larvadex) in turkeys during rearing and reproduction” . . . The kidneys were characterized as enlarged, nodular and cystic, containing urate deposits and areas of necrosis. I suggest that although short-term studies have been carried out on cyromazine, the long-term implications have not been addressed in this petition.

Allowing increased levels of cyromazine in foods loved by children, e.g., milk, mangoes and sweet corn without long-term studies of the effects of this toxin is tantamount to negligence.

EPA responses to these comments follows:

The cyromazine data base contains all required studies, this includes (sometimes with several studies for each study category):

- Acute oral toxicity in the rat
- Acute dermal toxicity in the rabbit
- Acute inhalation toxicity in the rat
- Primary eye irritation in the rabbit
- Primary dermal irritation in the rabbit
- Dermal sensitization in the guinea pig

Subchronic oral toxicity in the rat (13 weeks)
Subchronic oral toxicity in the dog (13 weeks)
Subchronic dermal toxicity in the rabbit (21 days)
Chronic oral toxicity in the rat (2 year)
Chronic oral toxicity in the dog (6 month)
Developmental toxicity in the rat
Developmental toxicity in the rabbit
Developmental toxicity in the rabbit with females pregant
Multigeneration reproduction study in the rat
Carcinogenicity study in the rat (2 year)
Carcinogenicity study in the mouse (2 year)
Mutagenicity battery
General metabolism in the rat
General metabolism in sheep
General metabolism in the chicken
General metabolism in the goat
General metabolism in the cow
Dermal absorption in the rat

All the required acute, short-term and long-term studies have been conducted. The Agency has assessed the long-term human health effects from exposure to cyromazine. The dog studies only indicate effects on the hematological parameters (hematocrit and hemoglobin levels); there was an increase in liver weight in the 13–week study, but this was not seen in any other species. There was no indication of effects in the dog on the liver (other than weight, a normal physiological response to metabolism of the compound, no supportive histopathology was noted), kidneys, or on the immune system. The Agency notes that “Decaflea” product administered to the dog also contained 200 milligrams/tablet of diethylcarbamazine citrate, an ethyl carbamate and heartworm animal drug.

If the health effects seen in the dog were treatment-related, the presence of this compound should also have been investigated as a possible cause.

In regards to the two open literature studies cited, the Agency notes that the first open literature study is an Egyptian study in chickens looking at liver function. The results indicate that the liver was functioning normally to detoxify the administered compound. The second study was in turkeys intended to assess the effects on reproduction. This study utilized extremely high doses (up to 2 grams per kilogram diet). These are doses that exceeded even our limit doses. Since the turkey is one of the treated species for fly control, this study was not an evaluation of the reproductive effects, but rather a true toxicity study (producing adverse effects) as opposed to hazard studies used by EPA to evaluate potential hazards to humans.

The investigators had to reduce one dose due to palatability problems (the turkeys would not eat the treated diet). The kidney effects were due to an overburdening of the organ from the extremely high doses. The Agency conducted open literature searches to determine if there was any report of adverse effects not reported previously and no additional information was found.

As stated previously and as indicated in the September 15, 1999 Federal Register proposal for cyromazine, the Agency has sufficient data to assess the short- and long-term hazards of cyromazine with special consideration to the sensitivity of infants and children from exposure to cyromazine as required by the FQPA.

The petitions requested that 40 CFR 180.414 be amended by establishing a tolerance for residues of the insecticide cyromazine, in or on mango at 0.3 parts per million (ppm); onion, green at 2.0 ppm; onions, 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; corn, sweet, foot; radishes, root at 0.5 ppm; radishes, 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. Based on the risk assessments discussed in the proposed rule and the findings made therein, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population and to infants and children from aggregate exposure to residues of cyromazine. Therefore, tolerances are established as set forth below.

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408.

However, the period for filing objections is now 60 days, rather than 30 days.
A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300913A 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 July 3, 2000.

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

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(f) 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.”

IV. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to
include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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


James Jones,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.414 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:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Cattle, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Cattle, meat byproduct</td>
<td>0.05</td>
</tr>
<tr>
<td>Cucurbit vegetables</td>
<td>1.0</td>
</tr>
<tr>
<td>Eggs</td>
<td>0.25</td>
</tr>
<tr>
<td>Goats, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, meat byproduct</td>
<td>0.05</td>
</tr>
<tr>
<td>Hogs, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Hogs, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Hogs, meat byproduct</td>
<td>0.05</td>
</tr>
<tr>
<td>Horses, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Horses, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Horses, meat byproduct</td>
<td>0.05</td>
</tr>
<tr>
<td>Leafy vegetables (except Brassica)</td>
<td>7.0</td>
</tr>
<tr>
<td>Lima beans</td>
<td>1.0</td>
</tr>
<tr>
<td>Mango</td>
<td>0.3</td>
</tr>
<tr>
<td>Milk</td>
<td>0.05</td>
</tr>
<tr>
<td>Mushrooms</td>
<td>1.0</td>
</tr>
<tr>
<td>Onion, dry bulb</td>
<td>2.0</td>
</tr>
<tr>
<td>Onion, green</td>
<td>0.1</td>
</tr>
<tr>
<td>Peppers</td>
<td>1.0</td>
</tr>
<tr>
<td>Potato</td>
<td>0.8</td>
</tr>
<tr>
<td>Poultry, fat (from chicken layer hens and chicken breeder hens only)</td>
<td>0.05</td>
</tr>
<tr>
<td>Poultry, meat (from chicken layer hens and chicken breeder hens only)</td>
<td>0.05</td>
</tr>
<tr>
<td>Poultry, meat byproduct (from chicken layer hens and chicken breeder hens only)</td>
<td>0.05</td>
</tr>
<tr>
<td>Sheep, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Sheep, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Sheep, meat byproduct</td>
<td>0.05</td>
</tr>
<tr>
<td>Tomato</td>
<td>0.5</td>
</tr>
</tbody>
</table>

There are no U.S. registrations on mango as of May 4, 2000.

(ii) It is used as a feed additive only in 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. [Reserved]

(c) Tolerances with regional registrations. 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:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabbage, Chinese</td>
<td>3.0</td>
</tr>
<tr>
<td>Mustard, Chinese</td>
<td>3.0</td>
</tr>
<tr>
<td>Corn, sweet (kernels plus cob with husks removed)</td>
<td>0.1 ppm</td>
</tr>
<tr>
<td>Cotton, undelinted seed</td>
<td>0.1 ppm</td>
</tr>
<tr>
<td>Corn, sweet, forage</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>Corn, sweet, stover</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>Radish, root</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>Radish, tops (leaves)</td>
<td>0.5 ppm</td>
</tr>
</tbody>
</table>

[FR Doc. 00–11146 Filed 5–3–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300995; FRL–6554–9]

RIN 2070–AB78

Azoxystrobin: Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation increases the tolerances for residues of azoxystrobin (methyl) (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl(Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or