

PART 271—INTERPRETATIVE RELEASES RELATING TO THE INVESTMENT COMPANY ACT OF 1940 AND GENERAL RULES AND REGULATIONS THEREUNDER

3. Part 271 is amended by adding Release No. IC-24426 and the release date of April 28, 2000, to the list of interpretive releases.

Dated: April 28, 2000.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 00-11079 Filed 5-3-00; 8:45 am]

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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; 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. This final rule also removes 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: This regulation is effective May 4, 2000. Objections and requests for hearings, identified by docket control number OPP-300913A, must be received by EPA on or before July 3, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300913A in the subject line on the first page of your response.

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.

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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 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). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. 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.

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; 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. EPA received one comment from a private citizen of Australia alleging that the poor health of a dog was due to cyromazine and stating that long-term implications and studies

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 or 100 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?

3. Please refer to the following publications available through PubMed at <http://www.ncbi.nlm.nih.gov>: "Feeding cyromazine to Luhmann hens: residues in tissues and effects on some biochemical constituents." Cyromazine was fed to Luhmann 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 postnatal

- 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 available 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 at 0.5 ppm; corn, sweet, stover at 0.5 ppm; 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 and 409. 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 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 (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(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, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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.2. Mail your copies, identified by docket control number OPP-300913A, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format 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).

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, 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 FFDCFA 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.

Dated: April 27, 2000.

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:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproduct ...	0.05
Cucurbit vegetables	1.0
Eggs	0.25
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 (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
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 May 4, 2000.

(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 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:

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 paragraph (a)(1) of this section.

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

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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