

Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 13, 1995.

Stephen L. Johnson,
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. 346a and 371.

2. In § 180.1(h) by amending the table therein by revising the entry for summer squash, to read as follows:

§ 180.1 Definitions and interpretations.

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(h) * * *

A	B
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Summer squash	Fruits of the gourd (Cucurbitaceae) family that are consumed when immature, 100% of the fruit is edible either cooked or raw, once picked it cannot be stored, has a soft rind which is easily penetrated, and if seeds were harvested they would not germinate; e.g., <i>Cucurbita pepo</i> (i.e., crookneck squash, straightneck squash, scallop squash, and vegetable marrow); <i>Lagenaria</i> , spp. (i.e., spaghetti squash, hyotan, cucuzza); <i>Luffa</i> spp. (i.e., hechima, Chinese okra); <i>Momordica</i> spp. (i.e., bitter melon, balsam pear, balsam apple, Chinese cucumber); <i>Sechium edule</i> (chayote); and other cultivars and/or hybrids of these.
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40 CFR Part 180

[PP 3E4249/P613; FRL-4949-2]

RIN 2070-AC18

Fenarimol; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a tolerance for the combined residues of the fungicide fenarimol in or on the imported raw agricultural commodity bananas at 0.5 part per million (ppm). Not more than 0.25 ppm shall be present in the pulp after the peel is removed. DowElanco petitioned for this regulation to establish a maximum permissible level for combined residues of the fungicide.

DATES: Comments, identified by the document control number [PP 3E4249/P613], must be received on or before May 26, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the comments to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be

claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6900; e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA is proposing to establish an import tolerance for the combined residues of the fungicide fenarimol, [*alpha*-(2-chlorophenyl)-*alpha*-(4-chlorophenyl)-5-pyrimidinemethanol] and its metabolites [*alpha*-(2-chlorophenyl)-*alpha*-(4-chlorophenyl)-1,4-dihydro-5-pyrimidinemethanol and 5-(2-chlorophenyl)-(4-chlorophenyl)methyl]-3,4-dihydro-4-pyrimidinol measured as the total of fenarimol and 5-[(2-chlorophenyl)-(4-chlorophenyl)methyl]pyrimidine (calculated as fenarimol)], in or on the

raw agricultural commodity bananas at 0.5 part per million (ppm). Not more than 0.25 ppm shall be present in the pulp after the peel is removed. The proposed regulation to establish a maximum permissible level of the fungicide pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, by amending 40 CFR 180.421 to include this commodity was requested in a pesticide petition, PP 3E4249, submitted by DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189. The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerance include the following:

1. A 1-year dog-feeding study using doses of 0, 1.25, 12.5, and 125 milligrams/kilogram (mg/kg) body weight (bwt)/day. The no-observed-effects level (NOEL) is 12.5 mg/kg bwt/day. The 125 mg/kg bwt/day dose level caused increased serum alkaline phosphatase, increased liver weights, increased *p*-nitroanisole *o*-demethylase activity, and mild hepatic bile stasis.

2. An initial 2-year chronic feeding/ oncogenicity study in rats using dietary concentrations of 0, 50, 130, and 350 ppm (equivalent to doses of 0, 2.5, 6.5, and 17.5 mg/kg bwt/day). In a **Federal Register** document published in the issue of March 5, 1986 (51 FR 7567), the Agency indicated fenarimol to be oncogenic. In that document, the Agency's initial conclusion that fenarimol was oncogenic was based on a finding in the 2-year rat study of a statistically significant increase in hepatic lesions (adenomas and

hyperplastic nodules) at the highest dose tested (17.5 mg/kg bwt/day), when data for male and female rats were combined.

Since that time, the compound has been reevaluated. The Agency now considers it more appropriate to separate data for males and females and also to separate hyperplastic nodules from tumors (adenomas and carcinomas). When a reevaluation of the hepatic lesions for males and females was performed separately with the elimination of hyperplastic nodules, the data did not demonstrate a statistically significant increased incidence in adenomas and/or carcinomas in either sex. Moreover, the mouse oncogenicity study did not demonstrate oncogenic potential at dose levels up to and including a dose level of 85.7 mg/kg bwt/day (the highest dose level tested).

Because of the appearance of a low incidence of fatty change of the liver (nonneoplastic pathological lesions) in the low-dose groups in this study, it was unclear if a NOEL for fatty change of the liver was established in this study.

3. Additional 2-year chronic feeding/ oncogenicity studies in rats using dietary concentrations of 0, 12.5, 25, and 50 ppm (equivalent to doses of 0, 0.63, 1.25, and 2.5 mg/kg bwt/day). The purpose of these additional studies was to assist in determining a NOEL for fatty liver changes. The first of these two studies was compromised, however, by an outbreak of chronic respiratory disease which reduced survival in all experimental groups, including controls. The study was then repeated with the same dose levels. In the second study, no fatty liver changes or oncogenic effects were observed at the doses tested under the conditions of the study. Using data from all three 2-year studies, a NOEL for fatty liver change of 6.5 mg/kg bwt/day was established.

4. A 2-year oncogenicity study in mice using dietary concentrations of 0, 50, 170, and 600 ppm (equivalent to 0, 7, 24.3, and 85.7 mg/kg bwt/day) that was negative for oncogenic effects at all doses tested under the conditions of the study. At 600 ppm, an increase in fatty change of the liver was demonstrated. The NOEL for this effect was 170 ppm (24.3 mg/kg bwt/day).

5. A rabbit teratology study that was negative for teratogenic effects at all doses tested (0, 5, 10, and 35 mg/kg).

6. A rat teratology study that demonstrated hydronephrosis at 35 mg/kg (doses tested were 0, 5, 13, and 35 mg/kg). A second study in rats (with a postpartum evaluation) again demonstrated hydronephrosis at 35 mg/kg, but also indicated that the dose level of 35 mg/kg was associated with a

maternal toxic effect (decreased body weight gain during treatment). The Agency considers the NOEL for hydronephrosis and for maternal toxicity to be 13 mg/kg.

7. A multigeneration reproduction study in rats that demonstrated decreased fertility in males and delayed parturition and dystocia in females at 5 mg/kg bwt/day. The NOEL for reproductive effects in this study was 2.5 mg/kg bwt/day.

8. Multigeneration reproduction studies in guinea pigs and mice that were negative for reproductive effects at doses up to 35 mg/kg bwt/day (highest dose tested) and 20 mg/kg bwt/day, respectively.

9. An aromatase inhibition study in rats that showed fenarimol to be a moderately weak inhibitor of aromatase activity.

The adverse reproductive effects observed in the rat multigeneration reproduction study are considered to be a species-specific effect caused by aromatase inhibition. This enzyme promotes normal sexual behavior in rats and mice, but not in guinea pigs, primates, or man. A NOEL of 35 mg/kg bwt/day for reproductive effects relevant to humans was established in the multigeneration reproduction study in guinea pigs.

10. A mouse lymphoma forward mutation assay, a DNA repair synthesis study in rat liver culture systems, gene mutation assays in *Salmonella typhimurium* (Ames test) and *Escherichia coli*, a dominant-lethal assay in Wistar rats, an assay for transformation activity in the C3H/10T 1/2 embryonic mouse fibroblast, and an *in vivo* assay for chromosome aberration in the Chinese hamster. Fenarimol did not demonstrate mutagenic activity in any of these studies. Furthermore, fenarimol did not induce altered foci or neoplastic nodules in an initiation and promotion study in rat liver tissue.

Based on the above findings, the Agency concluded that fenarimol was not oncogenic in long-term studies in rats and mice under the test conditions in which the highest dose tested for both species approached a maximum-tolerated dose as evidenced by increased fatty change in the liver.

The acceptable daily intake (ADI) based on the 2-year rat chronic feeding study (NOEL of 6.5 mg/kg bwt/day) with an uncertainty factor of 100 is calculated to be 0.065 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) from previously established tolerances and the tolerance established here is 0.000431 mg/kg/day for the general population and utilizes 0.66% of the ADI. The percentage of the

ADI for the most highly exposed subgroup, non-nursing infants (less than 1 year old), is 2.68%. The TMRC was calculated based on the assumption that fenarimol occurs at the maximum legal limit in all of the dietary commodities for which tolerances are proposed. Even with this probable large overestimate of exposure/risk, the TMRC is well below the ADI for the population as a whole and for each of the 22 subgroups considered. Thus, the dietary risk from exposure to fenarimol appears to be minimal.

The nature of the residues is adequately understood, and adequate analytical methodology is available for enforcement. Prior to their publication in the Pesticide Analytical Manual, Vol. II, the enforcement methodology is being made available in the interim to anyone who is interested in pesticide enforcement when requested from: Calvin Furlow, Public Information Branch, Field Operations Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 1128C, CM 2, 1921 Jefferson Davis Hwy, Arlington, VA 22202, (703)-305-5232.

The pesticide is considered useful for the purpose for which the tolerance is sought. Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerances are established as set forth below. By way of public reminder, this notice also reiterates the registrant's responsibility under section 6(a)(2) of FIFRA, to submit additional factual information regarding adverse effects on the environment and to human health by these pesticides.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 3E4249/P613]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from

8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

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 17, 1995.

Donald R. Stubbs,

Acting 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. 346a and 371.

2. In § 180.421(b) by revising the table therein, to read as follows:

§ 180.421 Fenarimol; tolerances for residues.

Commodity	Parts per million
Bananas ¹	0.5 (Not more than 0.25 ppm shall be present in the pulp after peel is removed)
Cherries	1.0.
Grapes	0.2.

¹There are no United States registrations for bananas as of April 26, 1995.

[FR Doc. 95-10252 Filed 4-21-95; 2:56 pm]

BILLING CODE 6560-50-F

40 CFR Part 300

[FRL-5196-8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of Intent to Delete the Jackson Township Landfill Superfund Site from the National Priorities List; Request for Comments.

SUMMARY: The United States Environmental Protection Agency (EPA), Region II, announces its intent to delete the Jackson Township Landfill Site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B of 40 CFR Part 300 which is the National Oil & Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the New Jersey Department of Environmental Protection (NJDEP) have determined that no further remedial action by the responsible party is appropriate under CERCLA. In addition, EPA and NJDEP have determined that remedial activities conducted to date at the site have been protective of public health, welfare, and the environment.

DATES: Comments concerning the deletion of the Jackson Township Landfill Site from the NPL may be submitted on or before May 26, 1995.

ADDRESSES: Comments should be submitted to: Joseph Gowers, Remedial Project Manager, U.S. Environmental Protection Agency, Region II, 290

Broadway, 19th Floor, New York, New York 10007-1866.

Comprehensive information on the Jackson Township Landfill Site is contained in the NJDEP public docket and is available for viewing, by appointment only, at: NJDEP-Bureau of Community Relations, 401 East State Street, CN 413, Trenton, NJ 08625, Phone: (609) 984-3081, 8.30 AM to 4.30 PM—Monday through Friday (excluding holidays), Contact: Donald Kakas.

Information on the Site is also available for viewing at the Jackson Township Landfill Site Administrative Record Repositories located at: Jackson Township Municipal Complex, RD#4, Box 1000, Jackson, NJ 08527, Monday-Friday: 9am-5pm, (908) 928-1200
Ocean County Library, 101 Washington Street, Toms River, NJ 08753, Monday-Friday: 9am-9pm, Saturday: 9am-5pm (908) 349-6200

SUPPLEMENTARY INFORMATION:

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- I. Introduction
- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis for Intended Site Deletion

I. Introduction

EPA Region II announces its intent to delete the Jackson Township Landfill Site from the NPL and requests public comment on this deletion. The NPL is Appendix B to the NCP, which EPA promulgated pursuant to Section 105 of CERCLA, as amended. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of those sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substances Superfund Response Trust Fund (the Fund). Pursuant to § 300.425(e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions, if conditions at the site warrant such action.

EPA will accept comments concerning the deletion of the Jackson Township Landfill Site from the NPL for 30 days after publication of this notice in the **Federal Register** until May 26, 1995.

Section II of this notice explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses how the Jackson Township Landfill Site meets the NPL deletion criteria.

II. NPL Deletion Criteria

The NCP establishes the criteria that the Agency uses to delete sites from the