

§ 180.352 Terbufos; tolerances for residues.

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(b) A time-limited tolerance to expire (date 2 years after date of publication of final rule based on this proposal) is established for combined residues of the insecticide/nematicide terbufos (S-[[1,1-dimethylthio] methyl] O,O-diethyl phosphorodithioate) and its cholinesterase-inhibiting metabolites in or on the following raw agricultural commodity:

Commodity	Parts per million
* * * *	*
Coffee beans, green ¹	0.05
* * * *	*

¹There are no U.S. registrations as of August 2, 1995 for the use of terbufos on the growing crop, coffee.

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BILLING CODE 6560-50-F

40 CFR Parts 180 and 185

[OPP-300393; FRL-4967-1]

RIN 2070-AC18

Mevinphos; Proposed Amendment and Revocation of Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes the revocation of all tolerances listed at 40 CFR 180.157 and 185.4200 for residues of the insecticide mevinphos (Phosdrin®) in or on all raw agricultural commodities and processed foods. EPA is initiating this action because all U.S. mevinphos registrations were canceled on July 1, 1994. Because existing stocks of mevinphos may be used through November 30, 1995, the proposed revocations will become effective May 31, 1996, in order to ensure that no mevinphos residue will occur on legally treated crops, whether they are raw agricultural commodities or processed foods.

DATES: Written comments, identified by the docket control number OPP-300393, must be received on or before October 2, 1995.

ADDRESSES: By mail, submit comments to: Public Response Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401

M St. SW., Washington, DC 20460. In person, deliver comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number "OPP-300393." No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit V. of this preamble.

Information submitted as a comment concerning this document 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 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 Virginia address given above from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Richard Dumas, Special Review and Reregistration Division (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: Special Review Branch, Third floor, Crystal Station 1, 2800 Crystal Drive, Arlington, VA 22202, Telephone number: (703) 308-8015, e-mail: dumas.richard@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Mevinphos (Phosdrin®) is a broad-spectrum organophosphate insecticide primarily used on specialty/minor use crops. It is used chiefly as an acaricide and was registered for use on 25 crops (principally leafy greens and cole crops) before cancellation. It has been produced in the U.S. by the sole technical registrant, Amvac Corporation of Los Angeles, California. Prior to its cancellation, approximately 200,000 to

500,000 pounds of active ingredient were used annually in the U.S.

II. Legal Background

The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes the establishment by regulation of maximum permissible levels of pesticides in or on foods. Such regulations are commonly referred to as "tolerances." Without such tolerances or exemptions from tolerances, a food containing pesticide residues is considered to be "adulterated" under section 402 of the FFDCA, and hence may not legally be moved in interstate commerce (21 U.S.C. 342). Commodities subject to this proposal must no longer contain mevinphos residues following the revocation of the tolerances. To establish a tolerance for pesticide residues in or on raw agricultural commodities under section 408 of FFDCA, EPA must find that the promulgation of the rule would "protect the public health" (21 U.S.C. 346a(b)). To establish food additive regulations (FARs) to cover pesticide residues in processed foods under section 409 of FFDCA, EPA must determine that the proposed use of the food additive will be safe (21 U.S.C. 348). For a pesticide to be sold and used in the production of a food crop or food animal, the pesticide must not only have appropriate tolerances or FARs under FFDCA, but must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 et seq.). FIFRA requires the registration of pesticides that are sold and distributed in the U.S.

This document proposes the revocation of all tolerances and FARs (hereafter tolerances will refer to both tolerances and FARs) established under sections 408 and 409 of the FFDCA, 21 U.S.C. 301 et seq., for residues of the pesticide mevinphos in or on all previously registered crops, as listed in 40 CFR 180.157 and 185.4200. In the absence of the appropriate clearances under FFDCA for residues of a pesticide on food or feed, any agricultural commodity or processed food domestically produced and/or imported into the United States found to contain mevinphos residues is adulterated under section 402 of FFDCA.

III. Regulatory Background

On June 30, 1994, when EPA was prepared to issue a Notice of Intent to Suspend all mevinphos registrations because of acute poisoning incidents involving agricultural workers, Amvac submitted a request for voluntary cancellation. EPA accepted this request and on July 1, 1994, issued a

Cancellation Order for all mevinphos registrations, effective immediately. The Agency subsequently published a Notice of Receipt of Request for Cancellation, Announcement of Cancellation Order, and FIFRA section 6(g) Notification for Mevinphos in the **Federal Register** of August 1, 1994 (59 FR 38973). The Cancellation Order was subsequently modified on January 13, 1995, to extend the distribution, sale, and use to November 30, 1995, from December 30, 1994, for sale and distribution and February 28, 1995, for use. Notice of this amendment was published on April 5, 1995 (60 FR 17357).

IV. Current Proposal

EPA is proposing to revoke all mevinphos tolerances. The proposed date of revocation is May 31, 1996. EPA believes that there is little likelihood, if any, that residues of mevinphos would be observed in legally treated commodities after May 31, 1996. Also, mevinphos is not persistent and the Agency does not believe that mevinphos residues will be found in processed foods. Therefore, setting action levels is not necessary.

The Agency believes that it is appropriate to initiate revocation of tolerances at this time because mevinphos is no longer registered in the U.S. In accordance with the voluntary cancellation requested by Amvac, the sole technical registrant for mevinphos, all use of mevinphos is scheduled to cease after November 30, 1995. EPA believes that it is appropriate to revoke tolerances covering residues of a pesticide for which there is no legal domestic use unless it can be shown by interested parties that there is a need for the tolerances, and that the tolerances are protective of the public health. Such tolerances may be needed, for example, if interested parties can show that the pesticide is used in foreign countries on crops that may be destined for the U.S.

It should be noted that in order for any tolerances to be retained, EPA must determine, under sections 408 and 409 of FFDCA, that the particular tolerance is protective of public health. For EPA to make this public safety finding, it must have adequate data to assess the risks that may result from exposure to mevinphos residues in or on food. EPA generally requires submission of such information (such as residue data) to support pesticide registrations under FIFRA and to maintain tolerances under FFDCA. With all domestic use of mevinphos ending November 30, 1995, EPA must have adequate data to demonstrate that imported foods treated with mevinphos are safe. Such data are

not available at this time and EPA does not anticipate the receipt of such data because the sole technical registrant for mevinphos has voluntarily canceled all of its U.S. mevinphos registrations.

Based upon available data, the Agency has completed a preliminary acute dietary risk assessment from exposure to mevinphos. The assessment indicates a concern, particularly for infants and children. EPA recognizes that the dietary risk concern may be diminished if interested parties submit adequate exposure and/or toxicity data that show that the preliminary assessment is not accurate. However, the data base currently available to EPA is inadequate and does not appear to provide a basis to conclude that the preliminary assessment is inaccurate.

This proposal serves as a notice to all parties interested in the disposition of mevinphos tolerances. If EPA does not receive comment by October 2, 1995, EPA will issue a final order revoking all mevinphos tolerances. Because EPA believes it is appropriate to preclude review of objections raising issues not provided in comments submitted in response to the proposal, EPA encourages all parties interested in the status of mevinphos tolerances to submit comments.

V. Public Docket

A record has been established for this rulemaking under docket number "OPP-300393" (including comments and data submitted electronically as described below). 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for the rulemaking as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the

official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

VI. Other Regulatory Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1994), the Agency must determine whether the regulatory action is "significant," and therefore, subject to all the requirements of the Order, such as Regulatory Impact Assessments and review by the Office of Management and Budget (OMB). In section 3(f), the Order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the national economy of \$100 million or more, or adversely and materially affecting a sector of the national economy, such as productivity, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs; or (4) raising novel legal or policy issues out of legal mandates, the President's priorities, or the principles set forth in the Order.

Pursuant to the terms of this Order, EPA has determined that this proposed rule is not "significant" and, therefore, is not subject to the requirements of the Order, such as OMB review or other actions. EPA does not expect any significant economic impacts to result from the revocation of mevinphos tolerances, because all U.S. mevinphos registrations have been canceled and no further use of mevinphos will be permitted after November 30, 1995.

B. Regulatory Flexibility Act

This proposed rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96-354; 94 Stat. 1164, 5 U.S.C. 601 *et seq.*), and it has been determined that it will not have any impact on small businesses, small governments, or small organizations.

This proposed rule is intended to prevent the sale of food commodities containing pesticide residues where the subject pesticide has been used in an unregistered or illegal manner, as well as to prevent food commodities containing any mevinphos residues from entering the U.S.

As stated above, because mevinphos is not registered in the U.S. and will not be used in the U.S. after November 30,

1995, EPA does not expect significant any economic impact at any level of business enterprise if mevinphos tolerances are revoked on May 31, 1996; especially since all use of mevinphos will have ended 6 months before this date. Accordingly, I certify that this regulatory action does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

C. Paperwork Reduction Act

This proposed regulatory action does not contain any information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. (Sec. 408(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346 a(m))).

List of Subjects in Parts 180 and 185

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

Dated: July 25, 1995.

Losi Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR parts 180 and 185 be amended to read as follows:

- 1. In Part 180:

PART 180—AMENDED

a. The authority citation for part 180 would continue to read as follows:
Authority: 21 U.S.C. 346a and 371.

§ 180.157 [Removed]

- b. Section 180.157 is removed.
- 2. In Part 185:

a. The authority citation for part 185 would continue to read as follows:
Authority: 21 U.S.C. 346a and 348.

§ 185.4200 [Removed]

- b. Section 185.4200 is removed.

[FR Doc. 95-18874 Filed 8-1-95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 412, 413, 424, 485, and 489

[BPD-825-CN]

RIN 0938-AG95

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1996 Rates; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule; correction.

SUMMARY: In the June 2, 1995, issue of the **Federal Register** (60 FR 29202), we published a proposed rule addressing revisions to the Medicare hospital inpatient prospective payment systems for operating costs and capital-related costs to implement necessary changes arising from our continuing experience with the system.

Additionally, in the addendum to that proposed rule, we described proposed changes in the amounts and factors necessary to determine prospective payment rates for Medicare hospital inpatient services for operating costs and capital-related costs. The changes would be applicable to discharges occurring on or after October 1, 1995. We also set proposed rate-of-increase limits as well as proposing policy changes for hospitals and hospital units excluded from the prospective payment systems. This document corrects errors made in the proposed rule.

FOR FURTHER INFORMATION CONTACT: Nancy Edwards (410) 966-4532.

SUPPLEMENTARY INFORMATION: In our June 2, 1995, proposed rule (60 FR 29202), we stated that we were including as Appendix C the report to Congress on our initial recommendation on the update factors for prospective payment hospitals and hospitals

excluded from the prospective payment system (60 FR 29258). The report consists of letters to the President of the Senate and the Speaker of the House of Representatives. Subsequently, we discovered that the incorrect report was inadvertently printed in the proposed rule.

In addition to publishing the proper report to Congress, we are making several other corrections to the June 2, 1995 proposed rule.

The proposed rule (FR Doc 95-13183) published June 2, 1995 (60 FR 29202) is corrected as follows:

- 1. On page 29250, beginning at the bottom of the second column, section VIII.B.9 of the preamble is deleted and replaced with the following: 9. PPS Payment Impact File

This file contains data used to estimate FY 1996 payments under Medicare's prospective payment systems for hospitals' operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, the PPS-IX and PPS-X Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment system published in the **Federal Register**. This file is available for release one month after publication of the proposed rule in the **Federal Register**, with an updated version available one month after publication of the final rule.

Media: Diskette

File Cost: \$145.00

Periods Available: FY 1996 PPS Update

§ 412.23 [Corrected]

- 2. On page 29251, second column, in § 412.23(e)(2)(i), at the end of the fifth line, add the word "or".

- 3. On page 29329, Table 6c—Invalid Diagnosis Codes is corrected and new Table 6d—Invalid Procedure Codes is added to read as follows:

TABLE 6C.—INVALID DIAGNOSIS CODES

Diagnosis code	Description	CC	MDC	DRG
005.8	Other bacterial food poisoning	N	6	182, 183, 184.
278.0	Obesity	N	10	296, 297, 298.
415.1	Pulmonary embolism and infarction	Y	4	78
			15	387, 389.
569.6	Colostomy and enterostomy malfunction	Y	6	188, 189, 190.
690	Erythematous squamous dermatosis	N	9	283, 284.
787.9	Other symptoms involving digestive system	N	6	182, 183, 184.
989.8	Toxic effect of other substances, chiefly nonmedicinal as to source	N	21	449, 450, 451.
997.0	Central nervous system complications	Y	1	34, 35
			15	387, 389.
997.9	Complications affecting other specified body systems, not elsewhere classified	Y	21	452, 453.
V12.5	Personal history of diseases of circulatory system	N	23	467.