

proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCFA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 4E4359/P604]. 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, Oct. 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: February 28, 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 § 180.205, paragraph (a) is amended in the table therein by adding and alphabetically inserting the raw agricultural commodities lentils, lentil forage, and lentil hay, to read as follows:

§ 180.205 Paraquat; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	*
Lentils	0.3
Lentil, forage	0.1
Lentil, hay	0.4
* * *	*

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40 CFR Part 180

[PP 0E3909, 2E4052, 2E4065, 2E4092, and 3E4162/P602; FRL-4936-1]

RIN 2070-AC18

Pesticide Tolerances for 2-[1-(Ethoxyimino)Butyl]-5-[2-(Ethylthio)Propyl]-3-Hydroxy-2-Cyclohexen-1-One

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish time limited tolerances for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (also referred to in this document as sethoxydim) and its metabolites in or on various raw agricultural commodities. The Interregional Research Project No. 4 (IR-4) requested the proposed regulation to establish maximum permissible levels for residues of the herbicide. These time-limited tolerances would expire on December 31, 1996.

DATES: Comments, identified by the document control number [PP 0E3909,

2E4052, 2E4065, 2E4092, and 3E4162/P602], must be received on or before April 14, 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 comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this notice 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: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8783.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petitions (PP) 0E3909, 2E4052, 2E4065, 2E4092, and 3E4162 to EPA on behalf of the named Agricultural Experiment Stations.

These petitions request that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.412 by establishing time-limited tolerances for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on certain raw agricultural commodities as follows:

1. *PP 0E3909.* Petition submitted on behalf of the Experimental Stations of Massachusetts, Washington, and

Wisconsin proposing a tolerance for cranberry at 2.0 parts per million (ppm).

2. *PP 2E4052*. Petition submitted on behalf of the Experimental Stations of South Dakota and Washington proposing tolerances for peppermint and spearmint at 30 ppm.

3. *PP 2E4065*. Petition submitted on behalf of the Experimental Station of Florida proposing a tolerance for endive at 2.0 ppm. The petitioner proposed that use of sethoxydim on endive be limited to Florida based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

4. *PP 2E4092*. Petition submitted on behalf of the Experimental Stations of California, Florida, Maryland, Michigan, New Jersey, North Carolina, and Tennessee proposing a tolerance for carrot at 1.0 ppm.

5. *PP 3E4162*. Petition submitted on behalf of the Experimental Stations of Arkansas, Arizona, Michigan, North Carolina, Oklahoma, and Washington proposing a tolerance for asparagus at 4.0 ppm.

The scientific data submitted in the petitions and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. Several acute toxicology studies place technical sethoxydim in acute toxicity category IV for primary eye and dermal irritation and acute toxicity category III for acute oral, dermal, and inhalation. The dermal sensitization - guinea pig study was waived because no sensitization was seen in guinea pigs dosed with the end-use product Poast (18 percent a.i.).

2. A 1-year feeding study with dogs fed diets containing 0, 8.86/9.41, 17.5/19.9, and 110/129 milligrams (mg)/kilogram (kg)/day (males/females) with a no-observed-effect-level (NOEL) of 8.86/9.41 mg/kg/day (males/females) based on equivocal anemia in male dogs at the 17.5-mg/kg/day dose level.

3. A 2-year chronic feeding/carcinogenicity study with mice fed diets containing 0, 40, 120, 360, and 1,080 ppm (equivalent to 0, 6, 18, 54, and 162 mg/kg/day) with a systemic NOEL of 120 ppm (18 mg/kg/day) based on non-neoplastic liver lesions in male mice at the 360-ppm (54 mg/kg/day) dose level. There were no carcinogenic effects observed under the conditions of the study. The maximum tolerated dose (MTD) was not achieved in female mice.

4. A 2-year chronic feeding/carcinogenic study with rats fed diets

containing 0, 2, 6, and 18 mg/kg/day with a systemic NOEL greater than or equal to 18 mg/kg/day (highest dose tested). There were no carcinogenic effects observed under the conditions of the study. This study was reviewed under current guidelines and was found to be unacceptable because the doses used were insufficient to induce a toxic response and an MTD was not achieved.

5. A second chronic feeding/carcinogenic study with rats fed diets containing 0, 360, and 1,080 ppm (equivalent to 18.2/23.0, and 55.9/71.8 mg/kg/day (males/females)). The dose levels were too low to elicit a toxic response in the test animals and failed to achieve an MTD or define a lowest effect level (LEL). Slight decreases in body weight in rats at the 1,080-ppm dose level, although not biologically significant, support a free-standing no-observed-adverse-effect-level (NOAEL) of 1,080 ppm (55.9/71.8 mg/kg/day (males/females)). There were no carcinogenic effects observed under the conditions of the study.

6. A developmental toxicity study in rats fed dosages of 0, 50, 180, 650, and 1,000 mg/kg/day with a maternal NOAEL of 180 mg/kg/day and a maternal LEL of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining); and a developmental NOAEL of 180 mg/kg/day, and a developmental LEL of 650 mg/kg/day (21 to 22 percent decrease in fetal weights, filamentous tail, and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternbrae and/or metatarsals, and pubes).

7. A developmental toxicity study in rabbits fed doses of 0, 80, 160, 320, and 400 mg/kg/day with a maternal NOEL of 320 mg/kg/day and a maternal LOEL of 400 mg/kg/day (37% reduction in body weight gain without significant differences in group mean body weights and decreased food consumption during dosing); and a developmental NOEL greater than 400 mg/kg/day (highest dose tested).

8. A two-generation reproduction study with rats fed diets containing 0, 150, 600, and 3,000 ppm (approximately 0, 7.5, 30, and 150 mg/kg/day) with no reproductive effects observed under the conditions of the study.

Although the dose levels were insufficient to elicit a toxic response, the Agency considers this study usable for regulatory purposes and has established a free-standing NOEL of 3,000 ppm (approximately 150 mg/kg/day).

9. Mutagenicity studies including: Ames assays were negative for gene mutation in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA 1537, with and without metabolic activity; a Chinese hamster bone marrow cytogenetic assay was negative for structural chromosomal aberrations at doses up to 5,000 mg/kg in Chinese hamster bone marrow cells in vivo; and recombinant assays and forward mutations tests in *Bacillus subtilis*, *Escherichia coli*, and *S. typhimurium* were all negative for genotoxic effects at concentrations of greater than or equal to 100 percent.

10. In a rat metabolism study, excretion was extremely rapid and tissue accumulation was negligible.

The reference dose (RfD) is calculated at 0.09 mg/kg of body weight/day, based on a NOEL of 8.86 mg/kg/day from the 1-year feeding study in dogs and an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) from existing tolerances for the overall U.S. population is estimated at 0.031961 mg/kg of body weight/day, or 36% of the RfD. The proposed tolerances for asparagus, carrot, cranberry, endive, peppermint, and spearmint will increase the TMRC by 0.000701 mg/kg of body weight/day and will utilize less than 1 percent of the RfD for the overall U.S. population. EPA estimates indicate that dietary exposure will not exceed the RfD for any population subgroup for which EPA has data.

These tolerances are proposed as time-limited tolerances since an acceptable carcinogenicity study is needed in one rodent species. A repeat chronic feeding/carcinogenicity study in rats is underway and is due to be submitted to EPA in November of 1995. The Agency will reassess sethoxydim tolerances based on the outcome of the rat chronic feeding/carcinogenicity study and, if appropriate, will establish permanent tolerances for asparagus, carrot, cranberry, endive, peppermint and spearmint. In the interim, the Agency concludes that there is little risk from establishment of the proposed tolerances since available studies in rats and mice indicate no carcinogenic effects, there are adequate data to establish a RfD, existing tolerances and the proposed tolerances do not exceed the RfD, and the proposed tolerances utilize less than 1 percent of the RfD.

The nature of the residue is adequately understood, and adequate analytical methods are available for enforcement purposes. Enforcement methods for sethoxydim are listed in the Pesticide Analytical Manual, Vol. II (PAM II). Enforcement methods have

also been submitted to the Food and Drug Administration for publication in PAM II. Because of the long lead time for publication of the analytical methods in PAM II, the analytical methods are being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5937.

There is no reasonable expectation that secondary residues will occur in milk, eggs or meat of livestock and poultry from the proposed uses of sethoxydim on asparagus, cranberries, endive, and mint; there are no livestock feed items associated with these commodities. Any secondary residues occurring in meat, fat, meat byproducts and milk of cattle, goats, hogs, horses and sheep from the proposed use on carrots will be covered by existing tolerances. There are no residues expected to occur in poultry meat, meat byproducts, fat or eggs since carrots are not considered a poultry feed item.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerances be established as set forth below.

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 OE3909, 2E4052, 2E4065, 2E4092, and 3E4162/P602]. All written comments filed in response to these petitions 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, Oct. 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: February 28, 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 § 180.412, by revising the section heading and the introductory text of paragraphs (a) and (b) to correct the spelling of the chemical name and by adding new paragraphs (c) and (d), to read as follows:

§ 180.412 2-[1-(Ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one; tolerances for residues.

(a) Tolerances are established for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following raw agricultural commodities:

* * * * *

(b) Tolerances with regional registration, as defined in § 180.1(n), are established for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following raw agricultural commodities:

* * * * *

(c) Time-limited tolerances to expire December 31, 1996, are established for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following raw agricultural commodities:

Commodity	Parts per million
Asparagus	4.0
Carrot	1.0
Cranberry	2.0
Peppermint	30.0
Spearmint	30.0

(d) Time-limited tolerances to expire December 31, 1996, are established with regional registration, as defined in § 180.1(n), for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following raw agricultural commodities:

Commodity	Parts per million
Endive	2.0

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