

ADDRESSES: Written comments should be addressed to Montel Livingston, Environmental Protection Specialist (AT-082), Air Programs Section, at the EPA Regional Office listed below.

Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. U.S. Environmental Protection Agency, Region 10, Air Programs Section, 1200 6th Avenue, Seattle, WA 98101.

The Oregon Department of Environmental Quality, 811 S.W. Sixth Avenue, Portland, Oregon 97204-1390.

FOR FURTHER INFORMATION CONTACT: Christi Lee, Air Programs Branch (AT-082), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553-1814.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action which is located in the Rules Section of this Federal Register.

Dated: September 22, 1995.

Carol M. Browner,

U.S. EPA Administrator.

[FR Doc. 95-24040 Filed 9-28-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 180

[PP 5E4464/P629; FRL-4973-7]

RIN 2070-AC18

Linuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to increase the established tolerance for residues of the herbicide linuron in or on the raw agricultural commodity asparagus. The proposed regulation to increase the maximum permissible level for residues of linuron was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4) pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

DATES: Comments, identified by the document control number, [PP 5E4464/P629], must be received on or before October 30, 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. Comments and data may also be submitted to OPP 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 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 5E4464/P629]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the "SUPPLEMENTAL INFORMATION" section of this document.

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 should not be submitted through e-mail. Information marked as CBI 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 4:30 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; e-mail: jamerson.hoyt@epamail.epa.gov.

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, submitted a pesticide petition (PP 5E4464) to EPA on behalf of the IR-4 Agricultural Experiment Stations of California, Indiana, Michigan, and New Jersey. The petition requests that the Administrator, pursuant to section 408(e) of the FFDCA, 21 U.S.C. 346a(e), amend 40 CFR 180.184 by increasing the established tolerance for residues of the herbicide linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-

methylurea] in or on the raw agricultural commodity asparagus from 3.0 parts per million (ppm) to 7.0 ppm. IR-4 proposed the increased tolerance for asparagus in response to the reregistration eligibility review and decisions on the pesticide case linuron, which was completed by EPA on April 28, 1995. The Reregistration Eligibility Decision (RED) requires that the established tolerance for linuron on asparagus be increased to 7.0 ppm.

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

1. A 1-year feeding study in dogs, which were fed diets containing 10, 25, 125, or 625 ppm (equivalent to 0.29, 0.79, 4.17, or 18.6 milligrams (mg)/kilogram (kg)/day for males; 0.3, 0.77, 3.49, or 16.1 mg/kg/day for females), with a no-observed-effect level (NOEL) for systemic toxicity of 25 ppm. The lowest-observed-effect level (LOEL) was established at 125 ppm based on hematology changes.

2. A 2-year feeding/carcinogenicity study in Sprague-Dawley rats, which were fed diets containing 50, 125, or 625 ppm (equivalent to 2.5, 6.25, or 31.25 mg/kg/day), with systemic NOEL's of 50 ppm for females and 625 ppm for males. The LOEL for systemic toxicity for females was established at 125 ppm based on hematotoxicity (a decrease in the percent hemoglobin). There was no decrease in percent hemoglobin in male rats at any dosage level tested.

Testicular interstitial cell adenomas were observed at a significantly increased incidence in male rats fed diets containing 125 and 625 ppm.

3. A 2-year feeding study in albino rats, which were fed diets containing 25, 125, or 625 ppm (equivalent to 1.25, 6.25, or 31.25 mg/kg/day), with a systemic NOEL of 125 ppm. Growth retardation and findings indicative of red blood cell disintegration were observed at the LOEL of 625 ppm.

4. An 18-month feeding study was conducted in rats to study the effects of linuron on methemoglobin and sulfhemoglobin blood concentrations. The dietary levels tested were 25, 125, or 625 ppm (1.25, 6.25, or 31.25 mg/kg/day). Significant changes in blood pigment were observed in the mid- and high-dose female rats and the high-dose male rats. NOELs were established at 125 ppm for male rats and 25 ppm for female rats.

5. A 2-year feeding/carcinogenicity in CD-1 mice, which were fed diets containing 50, 150, or 1,500 ppm (12, 35, or 455 mg/kg/day), showed a statistically significant increase in the

incidence of hepatocellular adenomas at 1,500 ppm for female mice, and borderline statistical significance was attained for hepatocellular adenomas at 50 ppm for male mice.

6. A developmental toxicity study in rats at dietary levels of 50, 125, or 625 ppm (5.0, 12.1, or 49.8 mg/kg/day), administered on days 6 to 15 of gestation with NOELs for maternal systemic toxicity and developmental toxicity established at 125 ppm. The LOEL of 625 ppm for maternal systemic toxic effects was based upon decreased body weight and food consumption values. The developmental toxicity LOEL of 625 ppm was based on increases in post-implantation loss and increases in the litter and fetal incidence of resorptions.

7. A developmental toxicity study in rabbits given gavage dosages of 5, 25, or 100 mg/kg/day on days 7 through 19 of gestation with a NOEL for developmental toxicity of 25 mg/kg/day and a NOEL for maternal toxicity of 5 mg/kg/day. The LOEL for maternal systemic toxicity (reduced body weight) was established at 25 mg/kg/day. The LOEL for developmental toxicity was established at 100 mg/kg/day based on an increased number of abortions, decreased mean number of fetuses per litter, decreased fetal body weight, and increased incidence of fetuses with skeletal variations of the skull at that dosage level.

8. A two-generation reproductive toxicity study in rats, which were fed diets containing 12.5, 100, or 625 ppm (equivalent to 0.84, 6.8, or 44.75 mg/kg/day for males; 1.0, 8.3, or 54.1 mg/kg/day for females), with no evidence of adverse effects on fertility or reproductive performance under the conditions of the study. The NOEL for parental systemic toxicity was established at 12.5 ppm based upon decrements in parental body weight gain. In addition, the results of this study support the hypothesis that rats exposed to linuron could develop interstitial cell hyperplasia and subsequent adenomas (Leydig cell tumors) of the testicular tissue via a mechanism of sustained hypersecretion of luteinizing hormone induced by the antiandrogenic potential of linuron.

9. Linuron did not produce gene mutation in an Ames assay or in an *in vitro* assay using Chinese hamster ovary cells. Linuron did not induce bone marrow chromosome aberrations *in vivo* and in other tests for genotoxicity. Linuron did not induce unscheduled DNA synthesis in isolated rat hepatocytes.

10. Metabolism studies in rats show that linuron was extensively

metabolized by male and female rats when administered by gavage, and there is no indication of accumulation of linuron or its metabolites in tissues and organs.

Linuron was placed in Special Review for carcinogenicity in 1982. It was later classified as a group C carcinogen (possible human carcinogen) with quantified cancer risk on the basis of a dose-related increase in interstitial cell hyperplasia and adenomas in the 2-year rat feeding study and hepatocellular tumors that appeared in low-dose male and high-dose female mice in a 2-year feeding study. Subsequent review by the Office of Pesticide Programs, Health Effects Division, Peer Review Committee and the Science Advisory Panel resulted in the decision to regulate linuron as a possible human carcinogen without quantified cancer risk. This decision was based on the weight-of-evidence, which suggested that the carcinogenic potential of linuron in humans is weak.

Dietary risk assessments for linuron were conducted using the Reference Dose (RfD) to assess chronic exposure and risk and the Margin of Exposure (MOE) for acute toxicity. The RfD for linuron is established at 0.008 mg/kg of body weight/day, based on a NOEL of 0.77 mg/kg/day from the 1-year feeding study in dogs and an uncertainty factor of 100. The anticipated residue contribution (ARC) from published tolerances and the proposed 7-ppm tolerance for asparagus utilizes 2 percent of the RfD for the general population. The ARC for the subgroup most highly exposed, nonnursing infants (less than 1-year old), utilizes 6 percent of the RfD. EPA concludes that established tolerances and the proposed increased tolerance for asparagus pose a negligible dietary risk to humans. The MOE is a measure of how closely acute dietary exposure comes to the NOEL from the toxicity endpoint of concern. For linuron, the MOE was calculated as a ratio of the NOEL (25 mg/kg/day) from the rabbit developmental toxicity study to dietary exposure (0.03125 mg/kg/day), as estimated by the high-end exposure for the population subgroup at greatest risk (females of childbearing age). The MOE for this subgroup is estimated at 800 for high-end exposure. Acute dietary margins of exposure of less than 100 are generally of concern to EPA. A MOE of 800 poses minimal risk.

The nature of the residue in plants is adequately understood. An adequate analytical method has been published in Pesticide Analytical Manual, Vol. II (PAM Vol. II).

There is no reasonable expectation that secondary residues will occur in

milk, and eggs, or meat, fat and meat byproducts of livestock and poultry; there are no livestock feed items associated with asparagus.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that amending 40 CFR 180.184 to increase the tolerance for linuron from 3 ppm to 7 ppm would protect the public health. Therefore, it is proposed that the tolerance 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 notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

A record has been established for this rulemaking under docket number [PP 5E4464/P629] (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 this 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.

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: September 20, 1995.

Peter Caulkins,

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 § 180.184, paragraph (a) is amended in the table therein by revising the entry for asparagus, to read as follows:

§ 180.184 Linuron; tolerances for residues.

(a) * * *

Commodity	Parts per million
Asparagus	7.0
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[FR Doc. 95-24210 Filed 9-28-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP 1E3979/P632; FRL-4977-6]

RIN 2070-AC18

Clopyralid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a tolerance for residues of the herbicide clopyralid in or on the raw agricultural commodity asparagus. The proposed regulation to establish a maximum permissible level for residues of the herbicide was requested in a petition submitted under the Federal Food, Drug and Cosmetic Act (FFDCA) by the Interregional Research Project No. 4 (IR-4).

DATES: Comments, identified by the document control number [PP 1E3979/P632], must be received on or before October 30, 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. Comments and data may also be submitted to OPP by sending electronic mail (e-mail) to:

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"SUPPLEMENTARY INFORMATION" section of this document.

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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 petition (PP) 1E3979 to EPA on behalf of the Agricultural Experiment Stations of Arkansas, California, Maryland, Michigan, Minnesota, and Washington. The petition requests 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 180.431 by establishing a tolerance for residues of the herbicide clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) in or on the raw agricultural commodity asparagus at 1.0 part per million (ppm).

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:

1. A 1-year feeding study in dogs, which were fed diets containing 0, 100, 320, and 1,000 milligrams (mg)/kilogram (kg)/day, with a no-observed-effect-level (NOEL) of 100 mg/kg/day. The lowest-observed-effect level (LOEL) was established at 320 mg/kg/day based on increased liver weights and decreased erythrocyte counts and hemoglobin and hematocrit values.