

1921 Jefferson Davis Highway, Arlington, VA.

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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, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12866.

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA 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: October 26, 1995.

Peter Caulkins, Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is 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 § 180.408, paragraph (a) is amended by revising the introductory text and by amending the table therein by revising the entry for grasses, forage and by adding and alphabetically inserting a new entry for grass, hay, to read as follows:

§ 180.408 Metalaxyl; tolerances for residues.

(a) Tolerances are established for the combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methylester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on the following raw agricultural commodities:

Commodity	Parts per million
* * * *	*
Grass, forage	10.0
Grass, hay	25.0
* * * *	*

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[FR Doc. 95-30116 Filed 12-12-95; 8:45 am]
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40 CFR Part 180

[PP 8F3607/R2184; FRL-4985-3]

RIN 2070-AB78

Glufosinate Ammonium; Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes time-limited tolerances for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolite, 3-methylphosphinopropionic acid, in or on various raw agricultural commodities (RAC's). AgrEvo USA Co. submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) requesting the tolerances. The document also conforms the chemical expression for the herbicide to Chemical Abstract nomenclature.

EFFECTIVE DATE: This regulation becomes effective December 13, 1995. The tolerances will expire on July 13, 1999.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 8F3607/R2184], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance

Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted 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 copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 8F3607/R2184]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6224; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 26, 1995 (60 FR 38334), EPA issued a notice announcing that AgrEvo USA Co., Little Falls One, 2711 Centerville Rd., Wilmington, DE 19808, had submitted an amendment to PP 8F3607 (published at 53 FR 18897, May 25, 1988) proposing to amend 40 CFR 180.473 by adding tolerances for residues of glufosinate ammonium and its metabolite, 3-methylphosphinopropionic acid, in or on the following raw agricultural commodities: Tree nuts group at 0.10 ppm, almond hulls at 0.50 ppm, cattle fat at 0.05 ppm, cattle meat at 0.05 ppm, cattle meat byproducts (mbyp) at 0.10 ppm, eggs at 0.05 ppm,

goat fat at 0.05 ppm, goat meat at 0.05 ppm, goat mbyl at 0.10 ppm, hog fat at 0.05 ppm, hog meat at 0.05 ppm, hog mbyl at 0.10 ppm, horse fat at 0.05 ppm, horse meat at 0.05 ppm, horse mbyl at 0.10 ppm, milk at 0.02 ppm, poultry fat at 0.05 ppm, poultry meat at 0.05 ppm, poultry mbyl at 0.10 ppm, sheep fat at 0.05 ppm, sheep meat at 0.05 ppm, and sheep mbyl at 0.10 ppm. Almonds are not considered a poultry feed commodity under present EPA Guidelines, and AgrEvo USA Co. has requested that the proposed tolerances for secondary residues in eggs, poultry fat, meat, and meat byproducts be deleted from the tolerances requested. This document also amends 40 CFR 180.473 to change the chemical expression for the herbicide to that given above in conformity with Chemical Abstract nomenclature.

The chemical expression for glufosinate ammonium has been changed to follow that given by the Chemical Abstracts Index Name for this chemical. This action is taken in concert with the final rule for Premanufacture Notification; Revisions of Premanufacture Notification Regulations, published in the Federal Register of March 29, 1995 (60 FR 16298-16310). The proposed analytical method for determining residues is high-pressure liquid chromatography.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of these tolerances.

1. A battery of acute toxicity studies placing technical glufosinate-ammonium in Toxicity Categories II and III.

2. A 90-day feeding study in rats at dietary intakes of 0, 0.52, 4.1, 32, or 263 mg/kg/day with a no-observed-effect level (NOEL) of 4.1 mg/kg/day. The lowest-observed-effect level (LOEL) was established at 32 mg/kg/day based on increased absolute and relative kidney weights.

3. A 90-day feeding study in mice at dietary intakes of 0, 16.6, 67.1, or 278 mg/kg/day with a NOEL of 16.6 mg/kg/day and an LOEL of 67.1 mg/kg/day based on increased absolute and relative liver weights (both sexes) and an increase in serum potassium levels (males).

4. Three teratology studies in rats at doses from 0.5 to 250 mg/kg/day with no teratogenic effects occurring up to and including 250 mg/kg/day. A NOEL for developmental toxicity was 2.24 mg/

kg/day, based upon an increase in the incidence of dilated renal pelvis with hydronephrosis in the fetuses at 10 mg/kg/day. The maternal NOEL was also 2.24 mg/kg/day.

5. A teratology study in rabbits at doses of 0, 2, 6.3, or 20 mg/kg/day with no teratogenic effects occurring up to and including 20 mg/kg/day, and a maternal NOEL of 6.3 mg/kg/day and a developmental NOEL of 20 mg/kg/day, the highest dose tested.

6. A two-generation reproduction study in rats at dietary concentrations of 0, 40, 120, or 360 ppm with a NOEL for reproductive effects at 120 ppm (equivalent to 12 mg/kg/day) based upon reduced number of pups in the high-dose group. The NOEL for parental toxicity was also 120 ppm based upon increased kidney weights in the high-dose group.

7. A 12-month feeding study in dogs at doses of 0, 2, 5, or 8.5 mg/kg/day. The NOEL was 5.0 mg/kg/day based upon the death of one male and one female dog at 8.5 mg/kg/day with no other treatment-related toxicity.

8. A mouse carcinogenicity study at doses of 0, 2.8, 10.8, or 22.7 mg/kg/day in males and 0, 4.2, 16.2, or 64.0 mg/kg/day in females for 104 weeks with no carcinogenic effects observed under the conditions of the study up to and including 64 mg/kg/day and a systemic NOEL of 10.8 and 16.2 for males and females, respectively, based on the dose-related increase in mortality.

9. A chronic feeding/carcinogenicity study in rats at dietary doses of 0, 2.5, 8.8, or 31.5 mg/kg/day (males) and 0, 2.4, 8.2, or 28.7 mg/kg/day (females) with a NOEL of 2.1 mg/kg/day for systemic effects based on an increase in mortality rate in females at the two higher doses. There were no treatment-related carcinogenic effects at any dose level.

10. Acceptable studies on gene mutation (*Salmonella*, *E. coli*, and mouse lymphoma assays), structural chromosomal aberration (*in vivo* micronucleus assay in mice), and other genotoxic effects (unscheduled DNA synthesis assay with rat hepatocytes) yielded negative results.

11. Pharmacokinetic and metabolism studies in rats indicated that approximately 80 to 90 percent of the orally administered dose of glufosinate ammonium remained unabsorbed and was eliminated in the feces. Approximately 10 to 15 percent was eliminated in the urine. The major metabolic pathway is oxidative deamination yielding the metabolite, 3-methyl-phosphinico propionic acid.

The chronic analysis used a Reference Dose (RfD) of 0.02 mg/kg/ body weight

day, based on an NOEL of 2.1 mg/kg/day and an uncertainty factor of 100. The NOEL is based on a 2-year rat feeding study that demonstrated increased absolute and relative kidney weight in males as an endpoint effect.

Using tolerance-level residues and assumptions that 100 percent of every crop for which glufosinate-ammonium has a proposed use is treated, the total Theoretical Maximum Residue Contribution (TMRC) for the general population and the highest exposed subgroup in DRES are as follows (as percent of RfD): General population, 0.627 percent; nonnursing infants less than 1-year-old, 3.7 percent.

A data gap currently exists for a rat carcinogenicity study. All tolerances are time-limited because of this gap. The time limitation allows for development and review of the data.

The analysis for glufosinate-ammonium using tolerance level residues suggests that the proposed uses on apples, grapes, and tree nut group will not cause exposure to exceed the levels at which the Agency believes there is an appreciable risk. All DRES subgroups are below 100 of the RfD for chronic effects.

The pesticide is useful for the purposes for which these tolerances are sought. The nature of the residues is adequately understood for the purpose of establishing these tolerances.

Adequate analytical methodology (gas chromatography with flame photometric detection of phosphorus) is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication, the enforcement methodology is being made available in the interim to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5937.

Based on the information cited above, the Agency has determined that the establishment of the time-limited tolerances by amending 40 CFR 180.473 will protect the public health; therefore, the time-limited tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed

with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(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). 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 8F3607/R2184] (including any objections and hearing requests 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 Room 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.

Written objections and hearing requests, identified by the document control number [PP 8F3607/R2184], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at: opp-Docket@epamail.epa.gov.

A copy of electronic objections and hearing requests filed with the Hearing Clerk 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 any objections and hearing requests 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 objections and hearing requests 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 review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in 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 referred to 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 the rights and obligations of recipients thereof; 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 the 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: November 30, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is 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 § 180.473, by revising paragraph (a), to read as follows:

§ 180.473 Glufosinate ammonium; tolerances for residues.

(a)(1) Time-limited tolerances are established for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolite, 3-methylphosphinopropionic acid, in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration date
Almond hulls	0.50	July 13, 1999
Apples	0.05	Do.
Cattle, fat	0.05	Do.
Cattle, meat	0.05	Do.
Cattle, mbyp	0.10	Do.
Goats, fat	0.05	Do.
Goats, meat	0.05	Do.
Goats, mbyp	0.10	Do.
Grapes	0.05	Do.
Hogs, fat	0.05	Do.
Hogs, meat	0.05	Do.
Hogs, mbyp	0.10	Do.
Horses, fat	0.05	Do.
Horses, meat	0.05	Do.
Horses, mbyp	0.10	Do.
Milk	0.02	Do.
Sheep, fat	0.05	Do.
Sheep, meat	0.05	Do.
Sheep, mbyp	0.10	Do.
Tree nuts group	0.1	Do.

(2) Residues in these commodities not in excess of the established tolerances resulting from the uses described in paragraph (a)(1) of this section remaining after expiration of the time-limited tolerance will not be considered to be actionable if the herbicide is applied during the term of and in accordance with the provisions of paragraph (a)(1) of this section.

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