

costs, and that is not required by statute, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless EPA consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. As discussed above, the final rule that removes the obligation that States, Territories, and authorized Tribes submit a section 303(d) list is deregulatory because it eliminates a current requirement. Thus, the requirements of section 6 of the Executive Order do not apply to this final rule.

#### *F. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments*

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's final rule does not significantly or uniquely affect the communities of Indian tribal governments nor does it impose substantial direct compliance costs on

them. Currently, there are no tribes authorized to establish TMDLs or lists of impaired waterbodies. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to today's final rule.

#### *G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This final rule is not subject to Executive Order 13045 because it is not "economically significant" and further, it does not establish an environmental standard intended to mitigate health or safety risks.

#### *H. National Technology Transfer and Advancement Act*

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d)(15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule does not involve any technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

#### *I. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective March 31, 2000, for reasons discussed previously in this preamble.

#### **List of Subjects in 40 CFR Part 130**

Environmental protection, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 27, 2000.

**Carol M. Browner,**  
Administrator.

For the reasons set out in the preamble, EPA is amending title 40, chapter I of the Code of Federal Regulations as follows:

#### **PART 130—[AMENDED]**

1. The authority citation for part 130 continues to read as follows:

**Authority:** 33 U.S.C. 1251 *et seq.*

2. Amend Section 130.7 by adding a new sentence after the third sentence in paragraph (d)(1) as follows:

#### **§ 130.7 Total maximum daily loads (TMDL) and individual water quality-based effluent limitations.**

\* \* \* \* \*

(d) \* \* \* (1) \* \* \* For the year 2000 submission, a State must submit a list required under paragraph (b) of this section only if a court order or consent decree, or commitment in a settlement agreement dated prior to January 1, 2000, expressly requires EPA to take action related to that State's year 2000 list. \* \* \*

\* \* \* \* \*

[FR Doc. 00-7986 Filed 3-30-00; 8:45 am]

**BILLING CODE 6560-50-P**

#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Part 180**

**[OPP-300986; FRL-6498-1]**

#### **2070-AB78**

#### **Glufosinate Ammonium; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-mono ammonium salt) and metabolites (3-methylphosphinico-propionic acid and 2-acetamido-4-methylphosphinico-butanoic acid), expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid equivalents in or on transgenic canola meal and seed and transgenic sugar beet molasses, roots and tops. AgrEvo USA Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. Revoked/expired tolerances under § 180.473 (b) are deleted from the regulation.

**DATES:** This regulation is effective March 31, 2000. Objections and requests for hearings, identified by docket control number OPP-300986, must be received by EPA on or before May 30, 2000.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6224 and e-mail address: miller.joanne@epa.gov.

**SUPPLEMENTARY INFORMATION:****I. General Information***A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person

**listed under FOR FURTHER INFORMATION CONTACT.***B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300986. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

**II. Background and Statutory Findings**

In the **Federal Register** of October 8, 1997, (62 FR 52544) (FRL- 5746-9) and July 14, 1999 (64 FR 37973) (FRL-6085-5), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d) as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP) for tolerance by AgrEvo USA Company, Little Falls Centre One, 2711 Centerville Road, Wilmington, DE 19808. These notices included a summary of the petition prepared by AgrEvo USA Company, the registrant. There were no comments received in response to the notices of filing.

These petitions requested that 40 CFR 180.473 be amended by establishing

permanent tolerances for combined residues of the herbicide glufosinate ammonium and its metabolites expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid in or on almond hulls at 0.50 part per million (ppm), apples at 0.05 ppm, bananas at 0.3 ppm (not more than 0.2 ppm shall be present in the pulp after peel is removed), cattle, fat and meat at 0.05 ppm; cattle, meat-by-products at 0.10 ppm; eggs at 0.05 ppm, goats, fat and meat at 0.05 ppm; goats, meat-by-products at 0.10 ppm; grapes at 0.05 ppm; hogs, fat and meat at 0.05 ppm; hogs, meat-by-product at 0.10 ppm; horses, fat and meat at 0.05 ppm; horses, meat-by-products at 0.10 ppm; milk at 0.02 ppm, potatoes at 0.8 ppm, potato chips at 1.6 ppm, potato granules/flakes at 2.0 ppm; poultry, fat and meat at 0.05 ppm; poultry, meat-by-products at 0.10 ppm; sheep, fat and meat at 0.05 ppm; sheep, meat-by-products at 0.10 ppm; transgenic aspirated grain fractions at 25.0 ppm; transgenic corn, field, forage at 4.0 ppm; transgenic corn, field, grain at 0.2 ppm; transgenic corn, field stover at 6.0 ppm; transgenic soybeans hulls at 5.0 ppm; transgenic soybeans at 2.0 ppm and tree nut group at 0.1 ppm.

This list included transgenic beet, sugar, tops (leaves) at 1.5 ppm; transgenic beet, sugar, root at 0.9 ppm; transgenic beet, sugar, molasses at 5.0 ppm; transgenic canola meal at 1.1 ppm and transgenic canola seed at 0.4 ppm. Tolerances were established for the former list of commodities on November 4, 1999 (64 FR 60112-60121). As EPA was not able to validate the analytical method submitted in support of tolerances for the commodities derived from transgenic canola and transgenic sugar beets, tolerances were not established at that time. AgrEvo USA Company revised the analytical method for determining residues in these commodities and the EPA has been able to validate the revised method and found it adequate for determining residues in these commodities. The level of the residues were also found appropriate.

The tolerances for canola and sugar beet commodities are listed under § 180.473(b) as commodities derived from transgenic canola and transgenic sugar beets and with commodities derived from transgenic corn and transgenic soybeans because the registered use-sites are for tolerant (transgenic) canola and tolerant (transgenic) sugar beets; and the metabolite residue 2-acetamido-4-methylphosphinico-butanoic acid is common to these tolerant (transgenic) crop plants cultured with the used of

glufosinate ammonium as a post-emergent herbicide.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue." \* \* \*

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

### III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for permanent tolerances for combined residues of glufosinate ammonium and its metabolite(s) in or on transgenic canola meal at 1.1 ppm, transgenic canola seed at 0.4 ppm transgenic beet, sugar, tops (leaves) at 1.5 ppm; transgenic beet, sugar, root at 0.9 ppm; transgenic beet, sugar, molasses at 5.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable

subgroups of consumers, including infants and children. The nature of the toxic effects caused by glufosinate ammonium are discussed in this unit.

1. Glufosinate ammonium (also referred to as DL-glufosinate ammonium or HOE 039866) is toxicity category III for acute oral, dermal, and eye irritation toxicities. It is toxicity category III for inhalation toxicity. It is not a dermal irritant (toxicity category IV) nor is it a dermal sensitizer.

2. In a sub-chronic oral toxicity study, glufosinate-ammonium (95.3% a.i.) was administered to 10 NMRI mice/sex/dose in the diet at levels of 0, 80, 320 or 1,280 ppm (equivalent to 0, 12, 48 or 192 mg/kg/day) for 13 weeks. Significant ( $p < 0.05$ ) increases were observed in serum aspartate aminotransferase and in alkaline phosphatase in high-dose (192 mg/kg/day) males. Also observed were increases in absolute and relative liver weights in mid- (48 mg/kg/day) and high-dose males. The no-observed-adverse effect level (NOAEL) is 12 mg/kg/day, the lowest-observe-adverse effect level (LOAEL) is 48 mg/kg/day based on the changes in clinical biochemistry and liver weights.

3. In a 21-day repeated dose dermal toxicity study, groups of 6 male and 6 female Wistar rats were treated with HOE 039866 (95.3%) in deionized water by dermal occlusion at doses of 0, 100, 300 or 1,000 mg/kg/day, 6 hours/day, 5 days/week for 21 applications in 30 days. An additional five males and five females/dose group were dose and observed for 44 days in a "recovery study". Two of 6 LDT males at 300 mg/kg/day, and 4 of 11 males and 2 of 11 females at 1,000 mg/kg/day displayed aggressive behavior, piloerection and a high startle response. There were no effects of toxicological importance on body weights, food consumption, hematology, clinical chemistry, urinalysis, organ weights, or gross or microscopic pathology. Based on clinical observations, the LOAEL is 300 mg/kg/day and the NOAEL is 100 mg/kg/day.

4. In an oncogenicity study, HOE 039866 (glufosinate ammonium) was administered to 50 NMRI mice/sex/dose in the diet at dose levels of 0, 80, 160 (males only) or 320 (females only) ppm for 104 weeks. Dose levels corresponded to 0, 2.83, 10.82, 22.60 mg/kg/day in males and 0, 4.23, 16.19, 66.96 mg/kg/day in females. The NOAEL for systemic toxicity is 80 ppm (10.82/16.19 mg/kg/day in M/F), and the LOAEL is 160/320 ppm (22.60 / 63.96 mg/kg/day in M/F), based on increased mortality in males, increased glucose levels in males and females, and consistent changes in glutathione levels in males. No increase

in tumor incidence was found in any treatment group.

5. In a chronic feeding study, HOE 039866 technical was fed to male and female beagle dogs for 12 months in the diet at levels of 2.0, 5.0 or 8.5 mg/kg/day. There were no overt signs of toxicity or dose-related effects on body weight, food consumption, ophthalmology, hematology, clinical chemistry, urinalyses or organ weights. Two dogs receiving 8.5 mg/kg/day died during the study as a result of heart and circulatory system failure from rapid diet consumption and necrotizing aspiration pneumonia. Electrocardiogram results of dosed males and females indicated a dose-related decrease in heart rate at 6 months; heart rates of dosed animals at 12 months were considered to be normal. The NOAEL is 5.0 mg/kg/day, the LOAEL is 8.5 mg/kg/day based on mortality.

6. In a rat oncogenicity study, glufosinate-ammonium (95.2-96.0% a.i.) was administered to Wistar rats (60/sex/group) for up to 24 months at 0, 1,000, 5,000, or 10,000 ppm (equivalent to 0, 45.4, 228.9, or 466.3 mg/kg/day in males and 0, 57.1, 281.5, or 579.3 mg/kg/day in females). The LOAEL for chronic toxicity is 5,000 ppm (equivalent to 228.9 mg/kg/day for male rats and 281.5 mg/kg/day for females), based on increased incidences of retinal atrophy. The chronic NOAEL is 1,000 ppm. Under the conditions of this study, there was no evidence of carcinogenic potential. Dosing was considered adequate based on increased incidences of retinal atrophy.

7. In a combined chronic toxicity/oncogenicity study, glufosinate ammonium was administered to 50 Wistar rats/sex/dose in the diet for 24 months at dose levels of 0, 40, 140, or 500 ppm (mean compound intake in males was 0, 1.9, 6.8, and 24.4 mg/kg/day and for females was 0, 2.4, 8.2 and 28.7 mg/kg/day, respectively). The LOAEL is 2.4 mg/kg/day (LDT) based on the increase in kidney glutamine synthetase activity and increased kidney weights in females. A NOAEL was not established. There was no clear demonstration of increased tumor incidence following exposure to glufosinate ammonium. Dosing was considered adequate based on the increase in kidney glutamine synthetase activity and increased kidney weights in females.

8. In a developmental toxicity study, groups of 20 pregnant female Wistar rats were administered HOE 039866 (glufosinate ammonium, 96.9 a.i.) by gavage at doses of 0, 0.5, 2.24, 10, 50 and 250 mg/kg/day from days 7 to 16 of

pregnancy. The no-observed-adverse effect level (NOAEL) for maternal toxicity is 10 mg/kg/day; the LOAEL is 50 mg/kg/day based on vaginal bleeding and hyperactivity in dams. In the fetus, the NOAEL is 50 mg/kg/day, based on dilated renal pelvis at the LOAEL of 250 mg/kg/day.

9. In a developmental toxicity study, groups of 15 pregnant female Himalayan rabbits were administered HOE 039866 by gavage at doses of 0, 2.0, 6.3 or 20.0 mg/kg/day from days 7 to 19 of pregnancy. The NOAEL for both maternal toxicity and developmental toxicity was 2.0 mg/kg/day. The LOAEL is 6.3 mg/kg/day based on reduced food consumption, body weight and weight gains and increased kidney weights in dams, and incomplete ossification in fetuses with fetal death at 20 mg/kg/day.

10. In a multigeneration reproduction study, glufosinate ammonium was administered to groups of 30 male and 30 female Wistar/Han rats in the diet at concentrations of 0, 40, 120 or 360 ppm (approximately 2.0, 6.0, 18.0 mg/kg). The LOAEL for systemic toxicity is 120 ppm (6 mg/kg/day) based on increased kidney weights in both sexes and generations. The systemic toxicity NOAEL is 40 ppm (2 mg/kg/day). The LOAEL for reproductive/developmental toxicity is 360 ppm (18 mg/kg/day) based on decreased number of viable pups in all generations. The NOAEL is 120 ppm.

11. There is no concern for mutagenic activity in several studies, including: *Salmonella spp.*, *E. coli*, *in vitro* mammalian cell gene mutation assays, mammalian cell chromosome aberration assays, *in vivo* mouse bone marrow micronucleus assays, and unscheduled DNA synthesis assays.

12. A rat metabolism study with dermal application showed that about 50% of the given radioactivity is absorbed 48 hours after a single dose application. In other metabolism studies, it was shown that over 80% of administered radioactivity is excreted within 24 to 48 hours as the parent compound in the feces and kidneys. Highest tissue levels were found in liver, kidney and gonads.

A consistent pattern of neurotoxicity was seen in several studies, including the subchronic, developmental and chronic studies in rats, mice and dogs. In addition to the clinical signs such as hyperactivity, aggressive behavior, piloerection, high startle response, retinal atrophy was observed. Changes in glutamine synthetase levels were observed in liver, kidney and brain in rats. These occurrences raise concern for the mechanism of neurotoxicity in these studies, an area where there are data

gaps. It is expected that the requested neurotoxicity studies will provide the information needed for further characterization of these effects.

Additional testing was conducted with the major metabolites, HOE 061517 and HOE 099730, as well as the L-isomer, identified as HOE 058192. These compounds, tested in subchronic rat, mouse and dog studies, and in developmental toxicity studies in rat and rabbit showed a similar profile of toxicity as the parent compound (HOE 039866).

#### B. Toxicological Endpoints

1. *Acute toxicity.* An acute RfD was not established for the general population. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicity studies. However, an acute RfD of 0.063 mg/kg/day was established for the females 13+ subgroup, based on a developmental NOAEL of 6.3 mg/kg/day in the rabbit and a 100x uncertainty factor (10x inter-10x intra-species extrapolation). The developmental LOAEL (20 mg/kg/day) was based on reduced fetal body weight and increased fetal death. The FQPA safety factor of 10x was reduced to 3x because there was no qualitative or quantitative indication of increased susceptibility in the prenatal developmental toxicities in rats and rabbits or in the two generation reproductive study in rats with parent compound, the isomer or metabolites of concern. Toxicological studies showed neurological effects in short term studies described as aggressive behavior, piloerection and a high startle response at dosages of 300 mg/kg/day. Based on these effects, EPA determined that a 3x FQPA safety factor was appropriate for the risk assessment for the food and feed used of glufosinate ammonium. Using the 3x FQPA safety factor, the acute population adjusted dose (aPAD) for glufosinate ammonium is 0.021 mg/kg/day.

2. *Short- intermediate- and long-term toxicity—i. Dermal.* Short- and intermediate-term dermal toxicity risk assessments were recommended based on neurological clinical signs (hyperactivity, aggressive behavior, piloerection) observed in the 21- day dermal study at 300 mg/kg/day (LOAEL). The NOAEL was 100 mg/kg/day. A long-term dermal risk assessment was recommended based on the NOAEL of 2.1 mg/kg/day established in the 2-year chronic study in rats (see chronic dietary; 50% dermal absorption).

ii. *Inhalation.* With the exception of an acute inhalation study, no other inhalation studies were available.

Therefore, oral NOAELs were selected for inhalation risk assessments. Because an oral dose was used, the exposure assessments was conducted by converting the application rate to oral equivalents and assuming 100% absorption.

Short-term inhalation risk assessments were recommended based on the developmental NOAEL of 6.3 mg/kg/day in the rabbit (see acute dietary endpoint). Intermediate-term inhalation risk assessments were recommended based on the NOAEL of 2.1 mg/kg/day from the 2- year chronic rat study (see chronic dietary endpoint below).

3. *Chronic toxicity.* EPA has established the RfD for glufosinate ammonium at 0.021 mg/kg/day based on the NOAEL of 2.1 mg/kg/day in the 2-year chronic study in rats and a 100x uncertainty factor (10x inter- 10x intra-species extrapolation). The LOAEL in the study was based on increased kidney weight and kidney/brain weight in males at 52 weeks (6.8 mg/kg/day) and decreased survival in females at 130 weeks (8.2 mg/kg/day). Using the 3x FQPA safety factor, the chronic population adjusted dose (cPAD) for glufosinate ammonium is 0.007 mg/kg/day.

4. *Carcinogenicity.* Based on a lack of mutagenic potential as assessed in a battery of mutagenicity assays and the absence of treatment-related tumors in rats and mice at dose levels adequate for assessment, the EPA has determined that glufosinate ammonium is not likely a carcinogen; and has classified it as a "Group E—Evidence of Non-Carcinogenicity for Humans" chemical.

#### C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.473 for the combined residues of glufosinate ammonium and its metabolites, in or on a variety of raw agricultural commodities. All tolerances listed under Unit III of this preamble, except those for canola meal at 1.1 ppm, canola seed at 0.4 ppm, sugar beet, molasses at 5.0 ppm; sugar beet, roots at 0.9 ppm and sugar beet tops (leaves) at 1.5 ppm, were established as permanent tolerances on November 4, 1999 (64 FR 60112–61121). This rule addresses the pending petition for establishing permanent tolerances in these commodities. Risk assessments were conducted by EPA to assess dietary exposures from tolerance levels of residue as follows:

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of crop treated (PCT) for assessing chronic dietary risk only if the

Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue, Condition 2, that the exposure estimate does not underestimate exposure for any significant sub-population group and Condition 3, that if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT. The Agency used PCT information as follows:

The chronic dietary exposure analysis assumed tolerance level residues for all registered and proposed commodities. The weighted average percent crop treated was incorporated for all registered commodities. Sweet corn and proposed commodities were maintained at 100% crop treated.

The Agency believes that the three conditions listed above have been met. With respect to (Condition 1), percent of crop treated estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average percent crop treated for chronic dietary exposure estimates. This weighted average percent crop treated figure is derived by averaging state-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the percent crop treated reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average

percent crop treated over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum percent crop treated. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Condition 2 and Condition 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which pesticide glufosinate ammonium may be applied in a particular area.

i. *Acute exposure and risk.* The acute dietary exposure analysis for females 13+ (no acute dietary endpoint was identified for the general U.S. population including infants and children) assumed tolerance level residues and 100% crop treated for all registered and proposed commodities (Tier 1 analysis). The most highly exposed population was females 13+/nursing at 58% of the aPAD (95<sup>th</sup> percentile). Acute dietary food exposure to glufosinate ammonium is below EPA's level of concern.

ii. *Chronic exposure and risk.* The chronic dietary exposure analysis assumed tolerance level residues for all registered and proposed commodities.

The weighted average percent crop treated was incorporated for all registered commodities. Sweet corn and proposed commodities were maintained at 100% crop treated. The most highly exposed population was children 1–6 years old at 71% of the cPAD (0.004974 mg/kg/day). Chronic dietary food exposure to glufosinate ammonium is below EPA's level of concern.

2. *From drinking water.* Aggregate exposures are generally calculated by summing dietary (food and water) and residential exposures. If the aggregate exposure is less than the specified PAD, the exposure is not expected to be a concern. Because EPA does not have ground and surface water monitoring data to calculate a quantitative aggregate exposure, a DWLOC was calculated. The DWLOC is the upper limit of a chemical's concentration in drinking water that will result in an acceptable aggregate exposure. The DWLOC is used as a point of comparison against model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have indirect regulatory impact through aggregate exposure and risk assessments.

To calculate the acceptable acute and chronic exposure to glufosinate ammonium in drinking water, the dietary food exposure estimate was subtracted from the appropriate PAD (only short-term residential exposure). A DWLOC was then calculated by using default body weights and drinking water consumption figures (70 kg/2L (adult male), 60 kg/2L (adult female) and 10 kg/1L (infant/child)).

The estimated maximum and average concentration of glufosinate ammonium in ground and surface water are less than EPA's DWLOC for glufosinate ammonium as a contribution to acute and chronic aggregate exposure (for all population subgroups).

i. *Acute exposure and risk.* The Agency's analysis based on the information available is presented in the following table 1:

TABLE 1.—ACUTE DWLOCs

Population Subgroup <sup>1</sup>	aPAD mg/ kg/ day	Food Ex- posure mg/kg/ day	Maximum Water Ex- posure <sup>2</sup> mg/kg/ day	DWLOC <sup>3</sup> ppb	SCI- GROW ppb	PRZM- EXAMS ppb
Females (13+, nursing) .....	0.021	0.012131	0.008869	270	1.16	34.1

<sup>1</sup> Highest exposed subgroup among females 13+

<sup>2</sup> Maximum water exposure (mg/kg/day) = 0.021 mg/kg/day - acute food exposure (mg/kg/day)

<sup>3</sup> DWLOC = [(maximum water exposure mg/kg/day)/(body weight kg)/(water consumption liters)] \* 1,000

ii. *Chronic exposure and risk.* The Agency's analysis based on the

information available is presented in the following table 2:

TABLE 2.—CHRONIC (NON-CANCER) DWLOC

Population Subgroup <sup>1</sup>	cPAD mg/ kg/ day	Food Ex- posure mg/kg/ day	Maximum Water Ex- posure <sup>2</sup> mg/kg/ day	DWLOC <sup>3</sup> ppb	SCI- GROW ppb	PRZM- EXAMS ppb
U.S. Population .....	0.007	0.002120	0.004880	170	1.16	0.79
Non-Hispanic blacks .....	0.007	0.002246	0.004754	170	1.16	0.79
Non-Hispanic/non-white/non-black .....	0.007	0.002256	0.004744	170	1.16	0.79
Non-Hispanic whites .....	0.007	0.002132	0.004868	170	1.16	0.79
Children 1–6 yrs .....	0.007	0.004974	0.002026	20	1.16	0.79
Females 13+ nursing .....	0.007	0.002035	0.004965	150	1.16	0.79
Males 13–19 yrs .....	0.007	0.002449	0.004551	160	1.16	0.79

<sup>1</sup> The subgroups listed above are the following: (1) US Population, (2) the other general subgroups for which the %cPAD is greater than that of the US Population and (3) the most highly exposed population among infants and children, females, and males.

<sup>2</sup> maximum water exposure (mg/kg/day) = (0.007 mg/kg/day - acute food exposure, (mg/kg/day)); no residential exposure

<sup>3</sup> DWLOC = [(maximum water exposure mg/kg/day)(body weight kg)/(water consumption liters)]\* 1,000

### 3. From non-dietary exposure.

Glufosinate ammonium is currently registered for use on the following non-food sites: areas around ornamentals, shade trees, Christmas trees, shrubs, walks, driveways, flower beds, farmstead buildings, in shelter belts, and along fences. It is also registered for use as a post-emergent herbicide on farmsteads, areas associated with airports, commercial plants, storage and lumber yards, highways, educational facilities, fence lines, ditch banks, dry ditches, schools, parking lots, tank farms, pumping stations, parks, utility rights-of-way, roadsides, railroads, and other public areas and similar industrial and non-food crop areas. It is also registered for lawn renovation uses.

In a pharmacokinetics study with dermal application in rats radioactive glufosinate ammonium was used at levels of 0.1, 1.0, or 10.0 mg/rat on 6 cm square of shaved skin and exposed for 0.5, 1, 2, 4, 10, 24, or 168 hrs. At the low dose (0.1 mg), 42.5 to 50.8% of the applied radioactivity was absorbed whereas at the high dose (10.0 mg) 26% was absorbed. After removal and washing of the treated skin a substantial amount of the radioactivity still remained in the skin. and it was gradually absorbed and eliminated. Radioactivity was found in both feces and urine samples, but the majority of glufosinate ammonium was eliminated in the urine. In all organs/tissues examined, radioactivity was found to reach a maximum level either at 4 or 10 hours after exposure. Subsequently, the radioactivity dropped rapidly. The amount of radioactivity found in the brain was minimal relative to that of kidneys and liver. Based on this study, a 50% dermal absorption factor was determined based on the range of 42.5%

to 50.8% of radioactivity absorbed at 0.10 mg/kg.

i. *Acute exposure and risk.* There are no acute non-dietary exposure scenarios.

ii. *Chronic exposure and risk.* There are no chronic non-dietary exposure scenarios.

iii. *Short- and intermediate-term exposure and risk.* It is not appropriate to aggregate short- and intermediate-term non-dietary exposure with dietary exposures in this risk assessment because the end-points are different.

iv. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether glufosinate ammonium has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, glufosinate ammonium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that glufosinate ammonium has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for

Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

### D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute dietary exposure analysis assumed tolerance level residues and 100% crop treated for all commodities derived from glufosinate ammonium treated crops. For the most highly exposed subgroup among females 13+ (nursing females), 58% of the aPAD is occupied by dietary (food) exposure, an acute RfD was not established for the general population including infants and children. The estimated glufosinate ammonium concentration in surface and ground water are less than EPA's DWLOC (for all population subgroups). Acute aggregate exposure to glufosinate ammonium and related metabolites, as a result of all registered and proposed uses, is below EPA's level of concern.

2. *Chronic risk.* There are no chronic non-dietary exposure scenarios. Therefore, only food and water are included in the chronic aggregate risk. The chronic dietary exposure analysis assumed tolerance level residues for all commodities derived from the crop use of glufosinate ammonium and incorporated the weighted average percent crop treated for all commodities derived from glufosinate ammonium treated crops, except for sweet corn, registered under section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended. For the most highly exposed subgroup (children, 1–6 years), 71% of the cPAD is occupied by dietary (food) exposure. The estimated glufosinate ammonium concentrations in surface and ground water are less than EPA's DWLOC for all population subgroups. Chronic

aggregate exposure to glufosinate ammonium as a result of all registered and proposed uses is below EPA's level of concern. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a life time will not pose appreciable risks to human health. Despite the potential for chronic exposure to glufosinate ammonium in drinking water, after calculating a DWLOC (236 ppb) for the U.S. population and comparing it to conservative model estimates of concentrations of glufosinate ammonium in surface and ground water (59.43 ppb and 1.16 ppb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. There are registered residential uses for glufosinate ammonium. The potential dermal exposures were not aggregated because the toxic effects for short- and intermediate-term exposure (neurological clinical signs) and chronic exposure (increases in absolute and relative kidney weights) are different.

4. *Aggregate cancer risk for U.S. population.* There is no cancer concern based on negative results observed in three guideline studies available for the carcinogenicity screen: a chronic feeding study in rats, a carcinogenicity study in rats and a carcinogenicity study in mice, each described under the "Toxicology Profile", Unit III.A. of this preamble. Glufosinate ammonium has been classified as a "not likely" carcinogen according to the EPA Proposed Guidelines for Carcinogen Risk Assessment. Therefore, a cancer risk assessment was not necessary.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to glufosinate ammonium residues.

#### *E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of glufosinate ammonium, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on

the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals, and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* Two studies were described in the Toxicology Profile, Unit III.A.8. and 9. of this preamble.

iii. *Reproductive toxicity study.* A reproductive toxicity study was described in the Toxicology Profile, Unit III.A.10. of this preamble.

iv. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for glufosinate ammonium is complete with respect to current data requirements. There are no prenatal or postnatal susceptibility concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproduction study.

v. *Other studies.* Based on clinical signs of neurological toxicity in short- and intermediate-term toxicity studies with rats, EPA has determined that an added FQPA safety factor of 3x is appropriate for the risk assessment for the tolerances in the commodities listed in this Final Rule. The FQPA safety factor of 10x was reduced to 3x because there were no qualitative or quantitative indications of increased susceptibility in the prenatal developmental toxicities in rats and rabbits, or in the two-generation reproductive studies in rats with the parent compound, the isomer or metabolites of concern.

vi. *Conclusion.* There is a complete toxicity database for glufosinate ammonium, and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* The acute dietary exposure analysis assumed tolerance level residues and 100% crop treated for all registered and proposed commodities. For the most highly exposed subgroup among females 13–50 (nursing females), 58% of the aPAD is occupied by dietary (food) exposure (no acute RfD was established for the general population including infants and children). The estimated glufosinate ammonium concentration in surface and ground water are less than EPA's DWLOC (for all population subgroups). Acute aggregate exposure to glufosinate ammonium and related metabolites, as a result of all registered and proposed uses, is below EPA's level of concern.

3. *Chronic risk.* Based on exposure assumptions described above, EPA has concluded that aggregate exposure to glufosinate ammonium from food will utilize 71% of the cPAD for children 1–6 years of age, the most highly exposed subgroup. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for chronic exposure to glufosinate ammonium in drinking water, after calculating a DWLOC (64 ppb) for non-nursing infants and comparing it to conservative model estimates of concentrations of glufosinate ammonium in surface and ground water (59.43 ppb and 11.16 ppb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. There are registered residential uses for glufosinate ammonium, however, the potential dermal exposures were not aggregated because the toxic effects for short- and intermediate-term exposure (neurological clinical signs) and chronic exposure (increases in absolute and relative kidney weights) are different.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues of glufosinate ammonium residues.



#### *F. Metabolism in Plants and Animals*

1. *Plants.* The nature of the residues of glufosinate ammonium is considered to be understood. The Agency has concluded that the residues of concern are glufosinate ammonium and its metabolites 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid expressed as glufosinate ammonium free acid equivalents.

2. *Animals.* A rat metabolism study with dermal application indicated that about 50% of the given radioactivity was absorbed 48 hours after a single dose application. In other metabolism studies, it was shown that over 80% of administered radioactivity is excreted within 24 to 48 hours as the parent compound in the feces and kidneys. Highest tissue levels were found in liver, kidney and gonads. The nature of glufosinate ammonium residues in lactating goats and hens is considered to be understood. Glufosinate ammonium and its metabolite (3-methylphosphinico propionic acid) are largely excreted and do not accumulate too any great degree in animal tissues. The only identifiable compounds in feces, urine, milk, eggs and tissues were the parent and 3-methylphosphinico propionic acid. EPA has concluded that the residues of concern in commodities derived from ruminants and poultry are glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid, expressed as glufosinate ammonium free acid equivalents.

#### *G. Analytical Enforcement Methodology*

In Pesticide Analytical Manual II (PAM II), method HRAV-5A describes an adequate analytical method for determining residues of glufosinate ammonium and its metabolite 3-methylphosphinico propionic acid in or on apples, bananas, grape, potatoes and tree nuts. In PAM II, method HRAV-12, is an adequate method for determining residues of glufosinate ammonium and its metabolite 3-methylphosphinico-propionic acid in or on milk, eggs and tissues of ruminants and poultry. Method BK/01/99 is an adequate method for determining residues of glufosinate ammonium and its metabolites in or on commodities derived from transgenic canola, transgenic field corn, transgenic soybeans and transgenic sugar beets. This method detects and measures total residues of parent and metabolites and allows detection and measurement of parent compound residues separately from residues of the metabolites. Final determination is made by gas chromatography with flame photometric

detection (GC/FPD) operating in the phosphorus selective mode (p-mode). Residues are expressed as glufosinate ammonium free acid equivalents.

Adequate enforcement methodology (gas chromatography with mass spectrophotometry) is available to enforce the tolerances for commodities derived from transgenic canola and transgenic sugar beets. These methods may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

#### *H. Magnitude of Residues*

The residues established by this regulation are qualified and quantified in Unit IV. of this preamble.

#### *I. International Residue Limits*

The Codex Alimentarius Commission has established maximum residue limits (CODEX MRLs) for the combined residues of glufosinate ammonium and metabolites 3-methylphosphinico-propionic acid and, when used in culture of genetically modified glufosinate ammonium tolerant crops, *N*-acetyl glufosinate (2-acetamido-4-methylphosphinico-butanoic acid) expressed as glufosinate free acid equivalents. A CODEX MRL is established in or on rape seed (canola seed) at 5 ppm. Canada has established a maximum residue limit (MRL) for the combined residues of glufosinate ammonium and 3-methylphosphinico-propionic acid in/on canola seed at 3.0 ppm. Because the CODEX and Canadian MRLs for canola seed are significantly greater than the appropriate U.S. tolerance for canola seed established by this Final Rule, and because there are no MRLs for canola meal harmonization is not possible. CODEX MRLs are established in or on sugar beets at 0.05 ppm and sugar beet leaves or tops at 0.1 ppm. There is no CODEX MRL for sugar beet molasses and there are no Canadian MRLs for sugar beet commodities. Because the appropriate tolerances for sugar beet roots and tops (leaves) established by this Final Rule are greater than the CODEX MRLs and there is no CODEX MRL for molasses, harmonization is also not possible. As this Rule establishes tolerances for transgenic canola and transgenic sugar beet commodities and includes the metabolite 2-acetamido-4-methylphosphinico-butanoic acid expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid equivalents, harmonization is also not possible. These differences in

residues are due to differences in the use-patterns represented in the data bases used in establishing these different levels of residues found in the raw agricultural commodities derived from transgenic canola and transgenic sugar beets, cultured with the use of glufosinate ammonium as a herbicide for weed control.

#### **IV. Conclusion**

Therefore, permanent tolerances are established for combined residues of glufosinate ammonium and its metabolites in or on transgenic canola meal at 1.1 ppm, transgenic canola seed at 0.4 ppm, transgenic sugar beet tops (leaves) at 1.5 ppm, transgenic sugar beet root at 0.9 ppm and transgenic sugar beet molasses at 5.0 ppm.

#### **V. Objections and Hearing Requests**

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

##### *A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300986 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 30, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). Information submitted in connection with an objection or hearing request 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 information 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit V.A., you should also send a copy of your request to the PIRIB for its

inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-300986, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### *B. When Will the Agency Grant a Request for a Hearing?*

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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### **VI. Regulatory Assessment Requirements**

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special

considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

#### **VII. Submission to Congress and the Comptroller General**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General

of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

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

Dated: March 17, 2000

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), (346a), and 371.

2. In § 180.473 by revising paragraph (a)(2) and by removing and reserving paragraph (b) to read as follows:

#### § 180.473 Glufosinate ammonium; tolerances for residues.

(a) \* \* \*

(2) Tolerances are established for the combined residues of glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt) and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid equivalents, in or on the following food commodities derived from transgenic canola, transgenic field corn, transgenic soybeans and transgenic sugar beets that are tolerant to the herbicide glufosinate ammonium as follows:

Commodity	Parts per million
Aspirated grain fractions .....	25.0
Canola meal .....	1.1
Canola seed .....	0.4
Corn, field, forage .....	4.0
Corn, field, grain .....	0.2
Corn, field, stover .....	6.0
Soybean hulls .....	5.0
Soybeans .....	2.0
Sugar beet, molasses .....	5.0
Sugar beet, roots .....	0.9
Sugar beet, tops (leaves) .....	1.5

(b) *Section 18 emergency exemptions.*  
[Reserved]

\* \* \* \* \*

[FR Doc. 00-8000 Filed 3-30-00; 8:45 am]

BILLING CODE 6560-50-F

#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 73

[DA 00-585; MM Docket No. 99-280; RM-9672]

#### Radio Broadcasting Services; Elaine, AR

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 238A to Elaine, Arkansas, as that community's first local aural transmission service in response to a petition for rule making filed on behalf of Phillips County Broadcasting. *See* 64 FR 51285, September 22, 1999. Coordinates used for Channel 238A at Elaine, Arkansas, are 34-22-52 NL and 90-45-56 WL. With this action, the proceeding is terminated.

**DATES:** Effective May 1, 2000. A filing window for Channel 238A at Elaine, Arkansas, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent Order.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418-2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 99-280, adopted March 8, 2000, and released March 17, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY-A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857-3800.

#### List of Subjects in 47 CFR Part 73

Radio broadcasting.  
Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

#### PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334, 336.

#### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Arkansas, is amended by adding Elaine, Channel 238A.

Federal Communications Commission.

**John A. Karousos,**

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 00-7827 Filed 3-30-00; 8:45 am]

BILLING CODE 6712-01-P

#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 73

[DA 00-585; MM Docket No. 99-281; RM-9684]

#### Radio Broadcasting Services; Ringgold, LA

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 253C3 to Ringgold, Louisiana, as that community's first local aural transmission service in response to a petition for rule making filed on behalf of Black Lake Broadcasting. *See* 64 FR 51285, September 22, 1999. Coordinates used for Channel 253C3 at Ringgold, Louisiana, are 32-19-49 NL and 93-12-33 WL. With this action, the proceeding is terminated.

**DATES:** Effective May 1, 2000. A filing window for Channel 253C3 at Ringgold, Louisiana, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent Order.

**FOR FURTHER INFORMATION CONTACT:** Nancy Joyner, Mass Media Bureau, (202) 418-2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 99-281, adopted March 8, 2000, and released March 17, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center (Room CY-A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857-3800.

#### List of Subjects in 47 CFR Part 73

Radio broadcasting.