

enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

Dated: October 20, 1999.

**Laura Yoshii,**

*Deputy Regional Administrator, Region IX.*

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(256)(i)(A)(2) to read as follows:

##### § 52.220 Identification of plan.

\* \* \* \* \*

(c) \* \* \*  
(256) \* \* \*  
(i) \* \* \*  
(A) \* \* \*

(2) Rule 8–51, adopted on November 18, 1992 and amended on January 7, 1998.

\* \* \* \* \*

[FR Doc. 99–28723 Filed 11–3–99; 8:45 am]

BILLING CODE 6560–50–P

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP–300945; FRL–6391–5]

RIN 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 metabolite(s) (3-methylphosphinico-propionic acid and 2-acetamido-4-methylphosphinico-butanoic acid), expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid equivalents in or on almond hulls;

apples; bananas; cattle fat, meat and meat-byproducts; eggs; goat fat, meat, and meat-by-products; grapes; hog fat, meat, and meat-by-products; horse fat, meat, and meat-by-products; milk; potatoes, potato chips and granules/flakes; poultry fat, meat, and meat-by-products; sheep fat, meat, and meat-by-products; transgenic aspirated grain fractions, transgenic corn, field, forage; transgenic corn, field, grain; transgenic corn, field, stover; transgenic soybean hulls, transgenic soybeans, and tree nuts group. AgrEvo USA Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This regulation also corrects the existing regulation for time-limited tolerances for transgenic canola and sweet corn commodities.

**DATES:** This regulation is effective November 4, 1999. Objections and requests for hearings, identified by docket control number OPP–300945, must be received by EPA on or before January 3, 2000.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the “SUPPLEMENTARY INFORMATION” section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300945 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., 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 Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 in the “FOR FURTHER INFORMATION CONTACT” section.

##### 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–300945. 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 t2, 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 metabolite(s) 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.

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 almond hulls at 0.50 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 granule/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 nuts group at 0.1 ppm. The addition (a corrective action on the Administrator's own initiative under section 408(e)(A)(C) of a second metabolite (2-acetamido-4-methylphosphinico-butanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid equivalents) to the residues of glufosinate ammonium found in transgenic canola and sweet corn commodities is consistent with section 408(b)(2)(D) and is appropriate because the second metabolite consistently occurs in commodities derived from transgenic plants. The risk assessment included the second metabolite found in canola and sweet corn commodities. 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 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% active ingredient (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 milligrams/kilogram/day (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 observed 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 two 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 males/females (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 by gavage HOE 039866 (glufosinate ammonium, 96.9 a.i.) at doses of 0, 0.5, 2.24, 10, 50 and 250 mg/kg/day from days 7 to 16 of pregnancy. The 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 by gavage HOE 039866 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 Reference dose (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 2-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 were 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 Rule except those for potatoes at 0.8 ppm, potato chips at 1.6 ppm, potato granules/flakes at 2.0 ppm, were previously established as time-limited tolerances with expiration dates. This rule addresses a pending petition for these tolerances and the establishment of the time-limited tolerances as permanent tolerances for this pesticide. 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: 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; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and 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. The 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. The 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 pPAD (95th 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 drinking water level of concentration (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 (70kg/2L (adult male), 60kg/2L (adult female) and 10kg/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.

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) U.S. Population, (2) the other general subgroups for which the %cPAD is greater than that of the U.S. 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 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 parts per billion (ppb)) for the U.S. population and comparing it to conservative model estimates of concentrations of glufosinate ammonium 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 (consider 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" of this Rule. 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 section (See Unit III.A.8. and 9. of this Rule.).

iii. *Reproductive toxicity study.* A reproductive toxicity study was described in the Toxicology Profile (See Unit III.A.10. of this Rule.).

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 dermal 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 2-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.

#### IV. Other Considerations

##### A. 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.

##### B. 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 XAM-24A, which is a modification of method HRAV-5A is an adequate method for determining residues of glufosinate ammonium and its metabolites in or on transgenic field corn, and transgenic soybeans. The method describes an additional post-extraction cation exchange procedure to allow for separate detection and measurement of each residue component. Final determination is made by gas chromatography with flame photometric detection 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 potatoes. The method 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.

##### C. Magnitude of Residues

The residues established by this regulation are qualified and quantified in Unit V of this Rule.

##### D. International Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (CODEX MRLs) for the combined residues of glufosinate ammonium and 3-methylphosphinico propionic acid, expressed as glufosinate free acid equivalents, in or on potatoes at 0.5 ppm. Because the appropriate U.S. tolerance for potatoes (0.8 ppm) is greater than the CODEX MRL of 0.5 ppm and CODEX MRLs for residues in or on potato chips and potato granules and flakes do not exist, harmonization is not possible. The Codex Alimentarius Commission did not establish MRLs for glufosinate ammonium in processed potato commodities because earlier processing studies in cooked potatoes did not show any concentration of residues after cooking in water. The difference in residues represented by the CODEX MRL of 0.5 ppm and the 0.8 ppm tolerance for residues in or on potatoes established by this Rule was apparently due to differences in the methods used by the two Agencies in determining the level of residues that would be appropriate. The EPA sets tolerances based on the residue level from the highest average field trial where as the CODEX and European authorities use statistical calculations derived from all residue data covering one worst case label for the calculation of MRL proposals.

##### E. Rotational Crop Restrictions

A 120 day plant-back interval is required for all crops with the exceptions of buckwheat, barley, millet oats, rye, sorghum, triticale and wheat that requires a 70-day plant-back interval. Field corn and soybeans may be planted back any time.



## V. Conclusion

Therefore, permanent tolerances are established for combined residues of glufosinate ammonium and its metabolite(s) in or on almond hulls at 0.50 ppm, apples at 0.05 ppm, bananas at 0.3 (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-products 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 granule/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 nuts group at 0.1 ppm.

The time-limited tolerances for residues in transgenic canola and transgenic sweet corn commodities under Section 18 emergency exemptions (64 FR 44829-44836, August 18, 1999) are not replaced, These time-limited tolerances will expire December 1, 1999.

## VI. 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-300945 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 January 3, 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, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, 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." (cite). 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, 401 M St., SW., 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, 401 M St., SW., 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 VI.A. of this preamble, you should also send a copy of your request to the PIRB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP-300945, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PRIB described in Unit I.B.2. of this preamble. 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 5.1/6.1 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).

## VII. Regulatory Assessment Requirements

This final rule establishes tolerances under section 408(d) of the FFDCA 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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under 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 in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). 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). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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.

#### VIII. 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 rule in the **Federal Register**. This 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: October 26, 1999.

**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. By revising § 180.473 to read as follows:

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

(a) *General.* (1) Tolerances are established for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolite, 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid equivalents, in or on the following food commodities:

Commodity	Parts per million
Almond hulls .....	0.50
Apples .....	0.05
Bananas .....	0.30
Bananas, pulp .....	0.20
Cattle, fat .....	0.05
Cattle, meat .....	0.05
Cattle, mby .....	0.10
Eggs .....	0.05
Goats, fat .....	0.05
Goats, meat .....	0.05
Goats, mby .....	0.10
Grapes .....	0.05
Hogs, fat .....	0.05
Hogs, meat .....	0.05

Commodity	Parts per million
Hogs, mby .....	0.10
Horses, fat .....	0.05
Horses, meat .....	0.05
Horses, mby .....	0.10
Milk .....	0.02
Potatoes .....	0.80
Potato chips .....	1.60
Potato granules and flakes .....	2.00
Poultry, fat .....	0.05
Poultry, meat .....	0.05
Poultry, mby .....	0.10
Sheep, fat .....	0.05
Sheep, meat .....	0.05
Sheep, mby .....	0.10
Tree nuts group .....	0.10

(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 raw agricultural commodities derived from transgenic field corn and transgenic soybeans and that are tolerant to the herbicide glufosinate ammonium as follows:

Commodity	Parts per million
Aspirated Grain Fractions .....	25.0
Corn, field, forage .....	4.0
Corn, field, grain .....	0.2
Corn, field, stover .....	6.0
Soybean hulls .....	5.0
Soybeans .....	2.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide (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 raw agricultural commodities derived from transgenic canola and transgenic sweet corn in connection with use of section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/Revocation Date
Canola meal .....	1.1	12/1/99
Canola Seed .....	0.4	12/1/99
Corn, sweet, forage ..	4.0	12/1/99
Corn, sweet, kernels and cobs with husks removed .....	4.0	12/1/99
Corn, sweet, stover ..	6.0	12/1/99

(c) *Tolerances with regional restrictions.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 99-28887 Filed 11-3-99; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[FRL-6468-2]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of deletion of the Joseph Forest Products site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA), Region 10, announces the deletion of the Joseph Forest Products Site from the National Priorities List (NPL). The NPL constitutes appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended. EPA and the State of Oregon Department of Environmental Quality have determined that no further cleanup under CERCLA is appropriate and that the selected remedy has been protective of human health and the environment.

**EFFECTIVE DATE:** November 4, 1999.

**FOR FURTHER INFORMATION CONTACT:** Chip Humphrey, U.S. Environmental Protection Agency, Region 10, 811 SW Sixth Avenue, Portland, Oregon 97204, (503) 326-2678.

**SUPPLEMENTARY INFORMATION:** The site to be deleted from the NPL is: Joseph Forest Products, Joseph, Oregon.

A Notice of Intent to Delete for this site was published on August 31, 1999, (64 FR 47478). The closing date for comments was September 30, 1999. The only comment EPA received was a

comment letter from the Department of Interior, Fish and Wildlife (the Department) requesting information about the impact of contamination on the Department's trust resources, e.g., migratory birds. EPA is providing the information requested by the Department. EPA believes that the remedial actions performed at the site are protective of trust resources. Further remedial activities are not necessary.

EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substance Response Trust Fund-financed remedial actions. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425 of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede Agency efforts to recover costs associated with response efforts.

#### List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: October 21, 1999.

**Chuck Clarke,**

*Regional Administrator, Region 10.*

For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

#### PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

**Authority:** 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601-9657; E.O. 12777, 56 FR 54757, 3 CFR 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

#### Appendix B—[Amended]

2. Table 1 of Appendix B to part 300 is amended by removing—Joseph Forest Products, Joseph, Oregon.

[FR Doc. 99-28543 Filed 11-3-99; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[FRL-6468-3]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of deletion of the McCarty's/Pacific Hide & Fur Recycling Co. site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA), Region 10, announces the deletion of the McCarty's/Pacific Hide and Fur Site from the National Priorities List (NPL). The NPL constitutes appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended. EPA and the State of Idaho Division of Environmental Quality have determined that no further cleanup under CERCLA is appropriate and that the selected remedy has been protective of human health and the environment.

**EFFECTIVE DATE:** November 4, 1999.

**FOR FURTHER INFORMATION CONTACT:** Beverly Gaines, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Mail Stop ECL-110, Seattle, Washington 98101, (206) 553-1066.

**SUPPLEMENTARY INFORMATION:** The site to be deleted from the NPL is: Pacific Hide & Fur Recycling Co., Pocatello, Idaho.

A Notice of Intent to Delete for this site was published on August 31, 1999, (64 FR 47481). The closing date for comments was September 30, 1999. The only comment EPA received was a comment letter from the Department of Interior, Fish and Wildlife (the Department) requesting information about the impact of contamination on the Department's trust resources, e.g., migratory birds. EPA is providing the information requested by the Department. EPA believes that the remedial actions performed at the site are protective of trust resources. Further remedial activities are not necessary.

EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substance Response Trust Fund-financed remedial