Dated: August 4, 1999.

Peter Caulkins,

Acting 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), 346(a), and 371.

§ 180.510 [Amended]

2. In § 180.510, by amending the table in paragraph (b) by changing the date ''7/31/99'' to read ''1/31/01'' for the entries for citrus fruit; citrus juice; citrus oil; citrus pulp, dried; and pears.

[FR Doc. 99–21427 Filed 8–17–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300900; FRL–6092–8]

RIN 2070–AB78

Glufosinate Ammonium; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt and its metabolite, 3-methylphosphinico-propionic acid in or on sweet corn (kernels and cob with husk removed), sweet corn forage, sweet corn stover, canola meal and canola seed. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on sweet corn and canola. This regulation establishes a maximum permissible level for residues of glufosinate ammonium in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 1, 1999.

DATES: This regulation is effective August 18, 1999. Objections and requests for hearings must be received by EPA on or before October 18, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300900], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300900], must also be submitted 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, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300900]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 284, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6463; e-mail: madden.barbara@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt and its metabolite, 3-methylphosphinico-propionic acid, in or on sweet corn (kernels and cob with husk removed) at 4.0 part per million (ppm), sweet corn forage at 4.0 ppm, sweet corn stover at 6.0 ppm, canola meal at 1.1 ppm and canola seed at 0.4 ppm. These tolerances will expire and are revoked on December 1, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preeamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations

governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Glufosinate Ammonium on Sweet Corn and Canola and FFDCA Tolerances

The Wisconsin Department of Agriculture, Trade, and Consumer Protection requested an emergency exemption for use of glufosinate ammonium on sweet corn to control weeds. The applicant states that only a limited number of broadleaf herbicides are registered for use in sweet corn. Traditionally, triazine herbicides have been widely used. However, Wisconsin's ground water law restricts the use of atrazine, and in sensitive areas, cyanazine and simazine may also contribute to problems and are best not used. Approximately 36,900 acres of Wisconsin's sweet corn production is located in ground water-sensitive areas. Additionally, approximately 24,700 acres of Wisconsin's cropland used to grow sweet corn are infested with triazine-resistant weeds. 2,4-D, registered for use on sweet corn to control weeds, often injures sweet corn hybrids resulting in reduction of crop yields. Bentazon is also registered but fails to control the two most serious annual broadleaf weeds (common lambsquarters and pigweed species). Other alternatives such as ametryne, linuron or paraquat require specialized application equipment not available to most Wisconsin sweet corn growers. In addition, sweet corn is frequently infested by two difficult-to-control annual grasses, wild-proso millet and woolly cupgrass. Registered soil applied grass herbicides are largely ineffective against these species.

Weather in North Dakota and Minnesota was responsible for serious losses in wheat due to disease and to serious losses due to water damage and to inability to harvest wet fields. Even good revenue years for wheat have netted less than those for canola. This use of Liberty on canola is needed to maintain grower solvency. The ''above-average'' returns from alternative crops such as canola are urgently needed to maintain economic viability for producers in North Dakota and Minnesota.

EPA has authorized under FIFRA section 18 the use of glufosinate ammonium on sweet corn in Wisconsin and on canola in North Dakota and Minnesota for control of weeds. After having reviewed these submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of glufosinate ammonium in or on sweet corn and canola. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 1, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sweet corn and canola after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether glufosinate ammonium meets EPA's registration requirements for use on sweet corn and canola or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of glufosinate ammonium by a State for special local needs under FIFRA section 24(c). Nor does these tolerances serve as the basis for any State other than Wisconsin, North Dakota, and Minnesota to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for glufosinate ammonium, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has sufficient data to assess the hazards of glufosinate ammonium and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt and its metabolite, 3-methylphosphinico-propionic acid on sweet corn (kernels and cob with husk removed) at 4.0 ppm, sweet corn forage at 4.0 ppm, sweet corn stover at 6.0 ppm, canola meal at 1.1 ppm and canola seed at 0.4 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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.

B. Toxicological Endpoint

1. *Acute toxicity.* An acute reference dose (aRfD) of 0.50 milligrams/kilograms/day (mg/kg/day) has been identified for females 13+ years old. The aRfD is derived from a no observable adverse effect level (NOAEL) of 50 mg/

kg/day, based on developmental toxicity characterized as dilated renal pelvis and/or hydroureter, from a rat developmental toxicity study, and an uncertainty factor (UF) of 100 (10x for interspecies extrapolation and 10x for intraspecies variability). The 10x FQPA Safety factor to account for enhanced sensitivity of infants and children (as required by FFDCA section 408 (b)(2)(C)) was reduced to 3x for acute exposures. The acute Population Adjusted Dose (aPAD) is a modification of the aRfD to accommodate the FQPA Safety Factor. The aPAD is equal to the aRfD divided by the FQPA Safety Factor. Therefore, the dietary aPAD is 0.167 mg/kg/day. The dietary aPAD applies only to the female 13+ years old subgroups since the endpoint of concern is based on developmental toxicity. No acute dietary endpoint was identified for the general population including infants and children.

2. *Short- and intermediate-term toxicity.* For short- and intermediate-term exposure scenarios for dermal exposure, the dermal NOAEL of 100 mg/kg/day from the 21–day dermal toxicity study in rats, based on neurological clinical signs (hyperactivity, aggressive behavior, piloerection) at the lowest observed adverse effect level (LOAEL) of 300 mg/kg/day, has been identified as the endpoint for risk assessment. A margin of exposure (MOE) of 100 is required (10x for interspecies extrapolation and 10x for intraspecies variability). Short-term inhalation exposure should be converted to an oral equivalent dose (using 100% inhalation absorption) and compared to the NOAEL of 50 mg/kg/day from the oral rat developmental toxicity study. Intermediate-term inhalation exposure should be converted to an oral equivalent dose (using 100% inhalation absorption) and compared to the NOAEL of 2.1 mg/kg/day from the 2–year chronic feeding study in rats. MOEs of 100 are required to account for interspecies extrapolation (10x) and intraspecies variability (10x).

3. *Chronic toxicity.* EPA has established the chronic RfD (cRfD) for glufosinate ammonium at 0.021 mg/kg/day. This RfD is derived from a NOAEL of 2.1 mg/kg/day, based on increases in absolute and relative kidney weights in males at the LOAEL of 7.6 mg/kg/day in a 2–year chronic feeding study in rats and an UF of 100 (10x for interspecies extrapolation and 10x for intraspecies variability). The 10x FQPA Safety factor to account for enhanced sensitivity of infants and children (as required by FFDCA section 408(b)(2)(C)) was reduced to 3x for chronic exposures. The chronic Population Adjusted Dose (cPAD) is a modification of the cRfD to accommodate the FQPA Safety Factor. The cPAD is equal to the cRfD divided by the FQPA Safety Factor. Therefore, the dietary cPAD is 0.007 mg/kg/day.

4. *Carcinogenicity.* There is no cancer concern based on negative results observed in three guideline studies available for the carcinogenicity screen (the chronic feeding study in rats, carcinogenicity study in rats and the carcinogenicity study in mice).

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 (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt and its metabolite, 3-methylphosphinico-propionic acid, in or on a variety of raw agricultural commodities. Time-limited tolerances have also been established as a result of secondary residues in/on eggs and meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep. Risk assessments were conducted by EPA to assess dietary exposures and risks from glufosinate ammonium as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–91 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. At the 95th percentile exposure level, assuming 100% crop treated and tolerance level residues for all commodities, 6% of the aPAD was utilized for females (13+ nursing), the subgroup with the highest exposure. The results of the acute analyses indicate that the acute dietary risk associated with the existing and proposed uses of glufosinate ammonium is below the Agency's current level of concern.

ii. *Chronic exposure and risk.* The chronic DEEM analysis assumed tolerance level residues for all commodities except for milk. Anticipated residues were used for milk. Maximum percent crop treatment data were incorporated into the chronic dietary estimate. Percent crop treated (PCT) data for sweet corn was incorporated by determining the amount of sweet corn produced in Wisconsin versus that produced in the United States. Assuming tolerance level residues for all commodities except milk where anticipated residues were used and PCT values, 4% of the cPAD was utilized for the U.S. Population and 9% of the cPAD was utilized for non-nursing infants, the subgroup with the highest exposure. The results of this analysis indicate that the acute dietary risk associated with existing uses and the proposed use of glufosinate ammonium is below the Agency's level of concern.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual 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 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 the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

A routine chronic dietary exposure analysis for glufosinate ammonium was based 1% of apples, 4% of field corn, and less than 1% of soybeans were treated. PCT data for sweet corn was incorporated by determining the amount of sweet corn produced in Wisconsin versus that produced in the United States. Based on this information the time-limited tolerance for sweet corn only supports a section 18 for use in Wisconsin.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. EPA finds that the PCT information is reliable and has a valid basis. Before the petitioner can increase production of product for treatment of greater than 30,000 acres of sweet corn, permission from the Agency must be obtained. 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 consumption of food bearing glufosinate ammonium in a particular area.

2. *From drinking water.* The Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for glufosinate ammonium. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on GENEEC and PRZM/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and SCI-GROW, which predicts pesticide concentrations in ground water. None of these models include consideration of the impact processing of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern. Based on the GENEEC and SCI-GROW models, the acute drinking water concentration values are estimated to be 237 parts per billion (ppb) for surface water and 1.16 ppb for ground water. The chronic drinking water concentration values are estimated to be 59.43 ppb for surface water and 1.16 pbb for ground water.

In the absence of monitoring data for pesticides, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to glufosinate ammonium, they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Glufosinate ammonium is currently registered for use on the following residential non-food sites: spot spraying around trees, shrubs, fences, walks, patios, driveways, sidewalks, in flower beds, around houses, buildings, wooded lots, storage and recreational areas, and for spot-kill weeds in lawns. The risk estimates indicate that the potential risks from the registered residential uses of glufosinate ammonium do not exceed the Agency's level of concern. These risk estimates are based on the Agency's Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments, December 18, 1998.

i. *Acute exposure and risk.* Acute dietary exposure and risks are not expected from use of glufosinate ammonium as a result of non-dietary, non-occupational exposure.

ii. *Chronic exposure and risk.* Chronic-term residential exposures are not expected from the proposed section 18 use of glufosinate ammonium, therefore a risk assessment was not conducted.

iii. *Short- and intermediate-term exposure and risk.* There are potential short-term exposures from the registered residential uses of glufosinate ammonium. Therefore, a risk assessment was conducted to estimate the potential risks from garden uses. The estimated MOEs from residential uses ranged from 190 (dermal exposures to homeowner/handler) to 330,000 (inhalation exposures).

4. *Cumulative exposure to substances with a 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 more 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.* An acute dietary endpoint was identified only for the females 13+ years old subpopulations. Using the exposure assumptions of 100% crop treated and tolerance level residues for all commodities, at the 95th percentile, 6% of the aPAD was utilized for females (13+, nursing) the subgroup with the highest exposure. EPA generally has no concern for exposures below 100% of the aPAD. Despite the potential for exposure to glufosinate ammonium in drinking water, after calculating a DWLOC (4730 ppb) for the females (13+ nursing) and comparing it to conservative model estimates of acute concentrations of glufosinate ammonium in surface and ground water (237 ppb and 1.16 pbb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions of tolerance level residues for all commodities except milk where anticipated residues were used and PCT values, 4% of the cPAD was utilized for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants. 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 (236 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 pbb, 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 estimated MOEs from residential uses ranged from 190 (dermal exposures to homeowner/handler) to 330,000 (inhalation exposures). These estimates indicate that the potential inhalation exposures will not be a significant contribution to the aggregate risk. 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. Therefore, based on the best available data and current policies, potential risks do not exceed the Agency's level of concern.

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: the chronic feeding study in rats, carcinogenicity study in rats and the carcinogenicity study in mice.

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 prenatal-and postnatal 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 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 MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies 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.* In the developmental study in rats, the maternal (systemic) NOAEL was 10 mg/kg/day, based on vaginal bleeding and hyperactivity at the LOAEL of 50 mg/kg/day. The developmental (fetal) NOAEL was 50 mg/kg/day, based on dilated renal pelvis and/or hydroureter at the LOAEL of 250 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 2 mg/kg/day, based on decreases in body weight, body weight gain and food consumption and increased kidney weight at the LOAEL of 6 mg/kg/day. The developmental (pup) NOAEL was 2 mg/kg/day based on absent/incomplete ossification, with fetal death at 20 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2–generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 2 mg/kg/day based on increased kidney weights in males and females ate 6 mg/kg/day. The reproductive/developmental NOAEL was 6 mg/kg/day based on decreased pup viability in all generations at 18 mg/kg/day.

iv. *Prenatal and postnatal 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. *Conclusion.* There is a complete toxicity data base for glufosinate ammonium and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Although the data indicate that there is no additional sensitivity to young rats or rabbits following prenatal and/or postnatal exposure to glufosinate ammonium in the developmental and reproductive toxicity studies; the Agency has determined that the FQPA Safety Factor should not be removed but instead reduced to 3x due to the presence of neurotoxicity in several studies in the toxicology data base, and the absence of acute neurotoxicity data, subchronic neurotoxicity data, and developmental neurotoxicity data.

2. *Acute risk.* An acute dietary RfD was not identified for any subpopulation other than female 13+ years old.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to glufosinate ammonium from food will utilize 9% of the cPAD for non-nursing infants, the major identifiable subgroup with the highest aggregate exposure. 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 1.16 pbb, 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, based on the use patterns (spot treatments), potential post application exposures to infants and children from these uses will not contribute significantly to the overall risks. The estimated MOE from post application exposures was 330 (based on conservative estimates). Therefore, the Agency concludes that there is a reasonable certainty that no harm will result to infants and children from short- and intermediate-term

aggregate exposures to residues of glufosinate ammonium.

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 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 free acid equivalents.

2. *Animals.* The nature of the residues of glufosinate ammonium in/on animals is considered to be understood. The Agency has concluded that the residues of concern in ruminants and hens are glufosinate ammonium and its metabolite 3-methylphosphinico-propionic acid expressed as glufosinate free acid equivalents.

B. Analytical Enforcement Methodology

Method AE-24 is an adequate tolerance enforcement method for determination of glufosinate ammonium related residues. This method is a modification of the current enforcement Analytical Method HRAV-5A. Method AE-24, includes 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 (GC/FPD) operating in the phosphorus selective mode (P-mode). Residues are expressed as glufosinate-ammonium free acid equivalents.

C. Magnitude of Residues

Residues of glufosinate ammonium are not expected to exceed 4.0 ppm in/on sweet corn (kernels and cob with husk removed), sweet corn forage at 4.0 ppm, sweet corn stover at 6.0 ppm, canola seed at 0.4 ppm and canola meal at 1.1 ppm as a result of these section 18 uses. Secondary residues in animal commodities are not expected to exceed the previously established tolerances as a result of this section 18 use.

D. International Residue Limits

There are no Canadian or Mexican MRLs established for glufosinate ammonium in/on sweet corn.

E. Rotational Crop Restrictions

A 120–day plant back interval is required for all crops.

V. Conclusion

Therefore, the tolerance is established for combined residues of glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt and its metabolite, 3-methylphosphinico-propionic acid in sweet corn (kernels and cobs with husk removed) at 4.0 ppm, sweet corn forage at 4.0 ppm, sweet corn stover at 6.0 ppm, canola seed at 0.4 ppm and canola meal at 1.1 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by October 18, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300900] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. 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 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 in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), 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. If the mandate is unfunded, EPA must provide 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 officials 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 rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. 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 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.** 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: July 29, 1999.

Peter Caulkins,

Acting 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. Section 180.473, is amended as follows:

i. By redesignating (b)(1), and (b)(2) as paragraphs (a)(3) and (a)(4).

ii. By adding a new paragraph (b).

§ 180.473 Glufosinate Ammonium; tolerances for residues.

* * * * *

(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 metabolite, 3-methylphosphinico-propionic acid 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

* * * * *

[FR Doc. 99–20869 Filed 8–17–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6424–1]

Texas: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The State of Texas has applied for final authorization to revise its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The EPA has determined that these changes satisfy all requirements needed to qualify for final authorization. The EPA reviewed Texas's application, and now makes an immediate final decision, subject to receipt of adverse written comment, that Texas' Hazardous Waste Program revision satisfies all of the requirements necessary to qualify for final authorization. Consequently, EPA intends to grant Texas final authorization for the program modifications contained in the revision.

DATES: This action is effective on October 18, 1999 without further notice, unless EPA receives relevant adverse comments by September 17, 1999. If adverse comments are received, EPA will publish a timely withdrawal of the immediate final rule or identify the issues raised, respond to the comments, and affirm that the immediate final rule will take effect as scheduled.

ADDRESSES: Mail written comments to Alima Patterson, Region 6, Regional Authorization Coordinator, Grants and Authorization Section (6PD–G), Multimedia Planning and Permitting Division, at the address shown below. You can examine copies of the materials submitted by the State of Louisiana during normal business hours at the following locations: EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6444; or Louisiana Department of Environmental Quality, H.B. Garlock Building, 7290 Bluebonnet, Baton Rouge, Louisiana, 70810, (504) 765–0617.

FOR FURTHER INFORMATION CONTACT: Alima Patterson (214) 665–8533.

SUPPLEMENTARY INFORMATION:

A. What is Resource Conservation and Recovery Act (RCRA) State Authorization?

The RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), provides for authorization of State hazardous waste programs under subtitle C. Under RCRA Section 3006, EPA may authorize a State to administer and enforce the RCRA hazardous waste program. *See* 40 Code of Federal Regulations (CFR) part 271. In fact, Congress designed RCRA so that the entire subtitle C program would eventually be administered by the States in lieu of the Federal Government. This is because the States are closer to, and more familiar with, the regulated community and therefore are in a better position to administer the programs and respond to local needs effectively.

After receiving authorization, the State administers the program in lieu of the Federal government, although EPA retains enforcement authority under RCRA sections 3008, 3013, and 7003. Authorized States are required to revise their programs when EPA promulgates Federal Standards that are more stringent or broader in scope than existing Federal standards. States are not required to modify their programs to address Federal changes that are less stringent than the existing Federal program or that reduce the scope of the existing Federal program. These changes are optional and are noted as such in the **Federal Register** (FR) documents. However, EPA encourages States to adopt optional rules because they provide benefit to environmental protection.

B. Why are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal Hazardous Waste Program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 CFR parts 124, 260–266, 268, 270, 273, and 279.

C. What is the Effect of This Authorization?

This authorization should have little impact because the State's requirements are already effective. However, upon approval of the revisions, Texas will be authorized to administer federal rules referred by EPA as RCRA Cluster V (these rules are listed in a chart in this FR document). Currently, federal cluster V rules are administered by the EPA.

D. What is the History of Texas' Final Authorization and Its Revisions

Texas received final authorization to implement its hazardous waste management program on December 12, 1984, effective December 26, 1984 (49 FR 48300). This authorization was clarified in a notice published in the FR on March 26, 1985 (50 FR 11858). Texas received final authorization for revisions to its program in notices published in the FR on January 31, 1986, effective October 4, 1985 (51 FR 3952), on December 18, 1986, effective February 17, 1987 (51 FR 45320). We authorized the following revisions: March 1, 1990, effective March 15, 1990 (55 FR 7318), on May 24, 1990, effective July 23, 1990 (55 FR 21383), on August 22, 1991, effective October 21, 1991 (56 FR 41626), on October 5, 1992, effective December 4, 1992 (57 FR 45719) and on April 11, 1994, effective June 27, 1994, (59 FR 16987); on April 12, 1994, effective (59 FR 17273), September 12, 1997, effective November 26, 1997, (62 FR 47947), and on September 19, 1997, effective December 3, 1997, (62 FR 49163). Effective December 3, 1997 (62 FR 49163), EPA incorporated by reference the State of Texas Base Program into CFR. On February 11, 1999, Texas submitted a final complete program revision application, seeking authorization of its program revision in accordance with 40 CFR 271.21.

In 1991, Texas Senate Bill 2 created the TNRCC which combined the functions of the former Texas Water Commission and the former Texas Air Control Board. The transfer of functions to the TNRCC from the two agencies became effective on September 1, 1993.

Under the Texas Solid Waste Disposal Act (codified in Chapter 361 of the Texas Health and Safety Code), the