SUPPLEMENTARY INFORMATION: The Coast Guard received a letter from the Consolidated Rail Corporation (CONRAIL) on October 20, 1999 requesting a temporary deviation from the current operating schedule of the bridge contained in 33 CFR 117.741. CONRAIL intends to conduct maintenance and repair work that involves the installation of new rails and ties on the bridge deck and superstructure. This work requires completely immobilizing the operation of the bascule span during this phase of the work. In the event of an emergency, openings of the span will be provided as quickly as possible, but may take two hours or longer to accomplish. Requests for emergency openings can be made my contacting CONRAIL's resident engineer at (609) 820–7784.

In accordance with 33 CFR 117.35, the District Commander approved Conrail's request for a temporary deviation from the governing regulations in a letter dated October 25, 1999.

The Coast Guard has informed the known commercial users of the waterway of the bridge closure so that these vessels can arrange their transits to minimize any impact caused by the temporary deviation.

The temporary deviation allows the CONRAIL Railroad Bridge across Raccoon Creek, mile 2.0, in Bridgeport, New Jersey to remain closed from 7 a.m. on November 22, until 5 p.m. on December 6, 1999.

Dated: November 9, 1999.

Thomas E. Bernard,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 99–30659 Filed 11–23–99; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300946; FRL–6390–5]

RIN 2070–AB78

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for glyphosate (*N*-(phosphonomethyl)glycine) in or on certain raw agricultural commodities from application of glyphosate in its acid form. Entek Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective November 24, 1999. Objections and requests for hearings, identified by docket control number OPP–300946, must be received by EPA on or before January 24, 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.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300946 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.james@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:

Categories	NAICS Codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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 under ''*FOR FURTHER INFORMATION CONTACT.*''

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

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

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300946. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 25, 1999 (64 FR 46382) (FRL–6093–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 9F5095) for a tolerance by Entek Corporation, 6835 Deerpath Road, Suite E, Elkridge, MD 21075. This notice included a summary of the petition prepared by Entek, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.364 be amended by revising the existing tolerance regulation for glyphosate to allow application of glyphosate (in its acid form) on raw agricultural commodities (RACs).

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 tolerances for glyphosate by revising the existing tolerance regulation for glyphosate to allow application of glyphosate (in its acid form) on raw agricultural commodities (RACs). EPA's assessment of the dietary exposures and risks associated with establishing the 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 glyphosate are discussed in this unit.

1. Several acute toxicology studies placing technical-grade glyphosate in Toxicity Category III and Toxicity Category IV. Technical glyphosate is not a dermal sensitizer.

2. A 21–day dermal toxicity study in which rabbits were exposed to glyphosate at levels of 0, 10, 1,000, or 5,000 milligrams/kilogram/day (mg/kg/day). The systemic no observed adverse effect level (NOAEL) was 1,000 mg/kg/day and the lowest observed adverse effect level (LOAEL) was 5,000 mg/kg/day based on decreased food consumption in males. Although serum lactate dehydrogenase was decreased in both sexes at the high dose, this finding was not considered to be toxicologically significant.

3. A 1–year feeding study with dogs fed dosage levels of 0, 20, 100, and 500 mg/kg/day with a NOAEL of 500 mg/kg/day.

4. A 2–year carcinogenicity study in mice fed dosage levels of 0, 150, 750, and 4,500 mg/kg/day with no carcinogenic effect at the highest dose tested (HDT) of 4,500 mg/kg/day.

5. A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 3, 10, and 31 mg/kg/day (males) and 0, 3, 11, or 34 mg/kg/day (females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 31 mg/ kg/day (HDT) (males) and 34 mg/kg/day (HDT) (females) and a systemic NOAEL of 31 mg/kg/day (HDT) (males) and 34 mg/kg/day (HDT) (females). Because a maximum tolerated dose (MTD) was not reached, this study was classified as supplemental for carcinogenicity.

6. A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 89, 362, and 940 mg/kg/day (males) and 1, 113, 457, and 1,183 mg/kg/day (females) with no carcinogenic effects noted under the conditions of the study at dose levels up to and including 940/1,183 mg/kg/day (males/females) (HDT) and a systemic NOAEL of 362 mg/kg/day (males) based on an increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased liver weight and increased liver weight/brain ratio (relative liver weight) at 940 mg/kg/day (males) (HDT) and 457 mg/kg/day (females) based on decreased body weight gain 1,183 mg/kg/day (females) (HDT).

7. A developmental toxicity study in rats given doses of 0, 300, 1,000, and 3,500 mg/kg/day with a developmental (fetal) NOAEL of 1,000 mg/kg/day based on an increase in number of litters and fetuses with unossified sternebrae, and decrease in fetal body weight at 3,500 mg/kg/day, and a maternal NOAEL of 1,000 mg/kg/day based on decrease in body weight gain, diarrhea, soft stools, breathing rattles, inactivity, red matter in the region of nose, mouth, forelimbs, or dorsal head, and deaths at 3,500 mg/kg/day (HDT).

8. A developmental toxicity study in rabbits given doses of 0, 75, 175, and 350 mg/kg/day with a developmental NOAEL of 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity); a maternal NOAEL of 175 mg/kg/day based on increased incidence of soft stool, diarrhea, nasal discharge, and deaths at 350 mg/kg/day (HDT).

9. A multi-generation reproduction study with rats fed dosage levels of 0, 3, 10, and 30 mg/kg/day with the parental NOAEL/LOAEL 30 mg/kg/day (HDT). The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F3b pups. Since the focal tubular dilation of the kidneys was not observed at the 1,500 mg/kg/day level (HDT) in the rat reproduction study discussed below, but was observed at the 30 mg/kg/day level (HDT) in the 3–generation rat reproduction study, the latter was a spurious rather than glyphosate-related effect. Therefore, the parental and reproductive (pup) NOAELs are 30 mg/kg/day.

10. A 2–generation reproduction study with rats fed dosage levels of 0, 100, 500, and 1,500 mg/kg/day with a systemic NOAEL of 500 mg/kg/day based on soft stools in F0 and F1 males and females at 1,500 mg/kg/day (HDT) and a reproductive NOAEL 1,500 mg/kg/day (HDT).

11. Mutagenicity data included chromosomal aberration *in vitro* (no aberrations in Chinese hamster ovary cells were caused with and without S9 activation); DNA repair in rat hepatocyte; *in vivo* bone marrow cytogenic test in rats; rec-assay with *B. subtilis*; reverse mutation test with *S. typhimurium*; Ames test with *S. typhimurium*; and dominant-lethal mutagenicity test in mice (all negative).

B. Toxicological Endpoints

1. *Acute toxicity*. No toxicological endpoint attributable to a single dose was identified in oral studies including the rat and rabbit developmental studies. There are no data requirements for acute or subacute neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses.

2. *Short- and intermediate-term toxicity*. No short- or intermediate-term dermal or inhalation endpoints were

identified. In a 21–day dermal toxicity study with rabbits, no systemic or dermal toxicity was seen following repeated applications of glyphosate at 0, 100, 1,000, or 5,000 mg/kg/day. The NOAEL was 1,000 mg/kg/day and the LOAEL was 5,000 mg/kg/day based on decreased food consumption in males. In addition, the use of 3% dermal absorption rate (estimated) in conjunction with the oral NOAEL of 175 mg/kg/day established in the rabbit development study yields a dermal equivalent dose of greater than 5,000 mg/kg/day.

Based on the low toxicity of the formulation product (Toxicity Category III and IV) and the physical characteristics of the technical product, there is minimal concern for potential inhalation exposure or risk. The acute inhalation study was waived for technical glyphosate. Some glyphosate end-use products are in Toxicity Category I or II for eye or dermal irritation. The Reregistration Eligibility Decision Document for Glyphosate (September 1993) indicates that the Agency is not adding any additional personal protective equipment (PPE) requirements to labels of end-use products, but that it continues to recommend the PPE and precautionary statements required for end-use products in Toxicity Categories I and II.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for glyphosate at 2.0 mg/kg/day. This RfD is based on the maternal NOAEL of 175 mg/kg/day from a rabbit developmental study and a 100-fold uncertainty factor.

4. *Carcinogenicity*. Glyphosate has been classified as a Group E chemical - no evidence of carcinogenicity in two acceptable animal species.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.364) for the residues of glyphosate (*N*-(phosphonomethyl)glycine and its metabolite aminomethylphosphonic acid resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate, in or on a variety of raw agricultural commodities. Tolerances are established on kidney of cattle, goats, hogs, horses, and sheep at 4.0 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.5 ppm; and liver and kidney of poultry at 0.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from glyphosate 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. An acute dietary risk assessment was not performed because no endpoints attributable to single dose were identified in the oral studies including rat and rabbit developmental studies. There are no data requirements for acute and subchronic neurotoxicity studies and no evidence of neurotoxicity in any of the toxicity studies at very high doses. The Agency concludes with reasonable certainty that glyphosate dose not elicit an acute toxicological response. An acute dietary risk assessment is not needed.

ii. *Chronic exposure and risk*. The chronic dietary exposure analysis was conduced using the (RfD) of 2.0 mg/kg/day based on the maternal NOAEL of 175 mg/kg/day from a developmental study and an uncertainty factor of 100 (applicable to all population groups). The Dietary Exposure Evaluation Model (DEEM) analysis assumed tolerance levels residues and 100% of the crop treated. These assumptions resulted in the following theoretical maximum residue contributions (TMRCs) and percent of the RfDs for certain population subgroups. The TMRC for the US population (48 states) was 0.029960 or 1.5% of the RfD, 0.026051 or 1.3% of the RfD for nursing infants (less than 1 year old), 0.065430 or 3.3% of the RfD for non-nursing infants less than 1 year old; 0.064388 or 3.2% of the RfD for children (1–6 years old); 0.043017 or 2.2% of the RfD for children (7–12 years old); 0.030928 or 1.5% of the RfD for females (13+/nursing); 0.030241 or 1.5% of the RfD for non-Hispanic whites; and 0.030206 or 1.5% of the RfD for non-Hispanic blacks.

2. *From drinking water*. Generic expected environmental concentration (GENEEC) and Screening concentration and ground water (SCI-GROW) models were run to produce estimates of glyphosate concentrations in surface and ground water, respectively. The drinking water exposure for glyphosate from the ground water screening model, SCI-GROW, yields a peak and chronic Estimated Environmental Concentration (EEC) of 0.0011 parts per billion (ppb) in ground water. The GENEEC values represent upper-bound estimates of the concentrations that might be found in surface water due to glyphosate use. Thus, the GENEEC model predicts that glyphosate surface water concentrations range from a peak of 1.64 ppb to a 56–day average of 0.19 ppb. The model estimates are compared to chronic drinking water levels of comparison (DWLOC (chronic)). The DWLOC (chronic) is the theoretical concentration of glyphosate in drinking water so that the aggregate chronic exposure (food + water + residential) will occupy no more than 100% of the RfD. Glyphosate is registered for residential products, however, a residential exposure assessment is not required, since there are no endpoints selected for either dermal or inhalation exposure. The Agency's default body weights and consumption values used to calculate DWLOCs are as follows: 70 kilograms/liter (kg/2L) (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

i. *Acute exposure and risk*. An acute dietary endpoint and dose was not identified in the toxicology data base. Adequate rat and rabbit developmental studies did not provide a dose or endpoint that could be used for acute dietary risk purposes. Additionally, there were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses.

ii. *Chronic exposure and risk*. The DWLOC (chronic) (non-cancer) risk is calculated by multiplying the chronic water exposure (mg/kg/day) x (body weight) divided by the consumption (L) x 10^{-3} mg/µg. The DWLOCS are 69,000 µg/L for the U.S. population in 48 states, males (13+), non-Hispanic whites, and non-Hispanic blacks; and 19,000 µg/L for non-nursing infants (less than 1 year old) and children (1–6 years). The GENEEC and SCI-GROW estimated that average concentrations of glyphosate in the surface and ground water are less than the DWLOC (chronic). Therefore, taking into account present uses and uses proposed in this action, the Agency concludes with reasonable certainty that no harm will result from chronic aggregate exposure to glyphosate.

3. *From non-dietary exposure*. Glyphosate is currently registered for use on the following residential non-food sites: Around ornamentals, shade trees, shrubs, walk, driveways, flower beds and home lawns. Based on the registered uses of glyphosate, the potential for residential exposures exists. However, based on the low acute toxicity and lack of other toxicological concerns, glyphosate does not meet the Agency's criteria for residential data requirements. Exposures from residential uses are not expected to pose undue risks or harm to public health.

i. *Acute exposure and risk*. There are no acute toxicological concerns for glyphosate. Glyphosate has been the subject of numerous incident reports, primarily for eye and skin irritation injuries, in California. Some glyphosate end-use products are in Toxicity

Categories I and II for eye and dermal irritation. The Reregistration Eligibility Decision Document for Glyphosate (September 1993) indicates the Agency is not adding additional PPE requirements to labels of end-use products, but that it continues to recommend the PPE and precautionary statements required for end-use products in Toxicity Categories I and II.

ii. *Chronic exposure and risk*. Although there are registered residential uses for glyphosate, glyphosate does not meet the Agency's criteria for residential data requirements, due to the lack of toxicological concerns. Incidental acute and/or chronic dietary exposures from residential uses of glyphosate are not expected to pose undue risks to the general population, including infants and children.

iii. *Short- and intermediate-term exposure and risk*. EPA identified no toxicological concerns for short-intermediate-and long-term dermal or inhalation routes of exposures. The Agency concludes that exposures from residential uses of glyphosate are not expected to pose undue risks.

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 glyphosate 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, glyphosate 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 glyphosate 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*. There was no acute dietary endpoint identified, therefore there are no acute toxicological concerns for glyphosate.

2. *Chronic risk*. Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to glyphosate from food will utilize 1.5% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non- nursing infants (less than 1 year old) and children (1–6 years) as discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD 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 exposure to glyphosate in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to glyphosate residues.

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. Short- and intermediate-term dermal and inhalation risk is not a concern due to the lack of significant toxicological effects observed with glyphosate under these exposure scenarios.

4. *Aggregate cancer risk for U.S. population*. Glyphosate has been classified as a Group E chemical, with no evidence of carcinogenicity for humans in two acceptable animal studies.

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 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 glyphosate, 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 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 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. *Prenatal and postnatal sensitivity*. The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to in utero and postnatal exposure to glyphosate.

iii. *Conclusion*. There is a complete toxicity data base for glyphosate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on these data, there is no indication that the developing fetus or neonate is more sensitive than adult animals. No developmental neurotoxicity studies are being required at this time. A developmental neurotoxicity data requirement is an upper tier study and required only if effects observed in the acute and 90–day neurotoxicity studies indicate concerns for frank neuropathy or alterations seen in fetal nervous system in the developmental or reproductive toxicology studies. The Agency believes that reliable data support the use of the standard 100-fold uncertainty factor, and that a tenfold (10x) uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk*. There are no acute toxicological endpoints for glyphosate. The Agency concludes that establishment of the proposed tolerances would not pose an unacceptable aggregate risk.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to glyphosate from food will utilize 3.3% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD 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 exposure to glyphosate in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. Short-term and intermediate-term dermal and inhalation risk is not a concern due to the lack of significant toxicological effects observed with glyphosate under these exposure scenarios.

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 glyphosate residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

The qualitative nature of the residue in plants is adequately understood. Studies with a variety of plants including corn, cotton, soybeans, and wheat indicate that the uptake of glyphosate or its metabolite, aminomethylphosphonic acid (AMPA), from soil is limited. The material which is taken up is readily translocated. Foliarly applied glyphosate is readily absorbed and translocated throughout the trees or vines to the fruit of apples, coffee, dwarf citrus (calamondin), pears and grapes. Metabolism via *N*-methylation yields *N*-methylated glycines and phosphonic acids. For the most part, the ratio of glyphosate to AMPA is 9 to 1 but can approach 1 to 1 in a few cases (e.g., soybeans and carrots). Much of the residue data for crops reflect a detectable residue of parent (0.05 – 0.15 ppm) along with residues below the level of detection (<0.05 ppm) of AMPA. The terminal residue to be regulated in plants is glyphosate *per se*.

The qualitative nature of the residue in animals is adequately understood. Studies with lactating goats and laying hens fed a mixture of glyphosate and AMPA indicate that the primary route of elimination was by excretion (urine and feces). These results are consistent with metabolism studies in rats, rabbits, and cows. The terminal residues in eggs, milk, and animal tissues are glyphosate and its metabolite AMPA; there was no evidence of further metabolism. The terminal residue to be regulated in livestock is glyphosate *per se*.

B. Analytical Enforcement Methodology

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant commodities. These methods include GLC (Method I in Pesticides Analytical Manual (PAM) II; the limit of detection is 0.05 ppm) and High Performance Liquid Chromatography (HPLC) with fluorometric detection. Use of the GLC method is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion in PAM II. A GC/MS method for glyphosate in crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL).

C. Magnitude of Residues

The available crop field trial residue data support established tolerances for glyphosate. Application of glyphosate as the acid will not result in residues which exceed currently established tolerances.

D. International Residue Limits

Codex Maximum Residue Levels (MRLs) exist for barley, dry peas, dry beans, and canola seed at 20, 5, 2, and 10 pp, respectively for glyphosate. Canadian glyphosate MRLs exist for barley, barley milling fractions, peas, beans, and lentils at 10, 15, 5, 2, and 4 ppm, respectively. Mexican glyphosate MRLs exist for barley, peas, and beans at 0.1, 0.2, and 0.2 ppm, respectively. Application of glyphosate as the acid in the United Sates will not cause any new conflicts with existing MRLs.

E. Rotational Crop Restrictions

Glyphosate labels currently bear a 30–day minimum plant back interval for crops on which the use of glyphosate is not registered.

V. Conclusion

Therefore, the tolerances are established for residues of glyphosate (*N*-(phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate in or on the raw agricultural commodities.

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–300946 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 24, 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 Rm. 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.'' 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, 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., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300946, 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 PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.* , as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 9, 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. In §180.364, by revising paragraph (a)(1) introductory text, paragraph (a)(2) introductory text, and paragraph (a)(3) introductory text to read as follows:

§180.364 Glyphosate; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of glyphosate, (*N*-

(phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, and/or the monoammonium salt of glyphosate in or on the following food commodities:

* * * * *

(2) Tolerances are established for the residues of glyphosate, (*N*-(phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, and/or the monoammonium salt of glyphosate in or on the following food commodities:

* * * * *

(3) Tolerances are established for the residues of glyphosate, (*N*-(phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, and/or the monoammonium salt of glyphosate in or on the following food commodities:

* * * * *

[FR Doc. 99–30408 Filed 11–23–99; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

I.D. 111899C

Atlantic Highly Migratory Species (HMS) Fisheries; Large Coastal Shark Species

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Fishing season notification.

SUMMARY: NMFS notifies eligible participants of the opening and closing of fishing seasons for Atlantic large coastal sharks (LCS), small coastal sharks (SCS), and pelagic sharks.

DATES: The fishery opening for LCS is effective January 1, 2000; the LCS closure is effective from 11:30 p.m. local time March 31, 2000, through June 30, 2000. The fishery opening for SCS and pelagic sharks are January 1, 2000; no closure dates for these fisheries are included in this document.

FOR FURTHER INFORMATION CONTACT: Steve Meyers or Margo Schulze, 301–713–2347; fax 301–713–1917.

SUPPLEMENTARY INFORMATION: The Atlantic shark fishery is managed under the Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks (HMS FMP), and its implementing regulations found at 50 CFR part 635 issued under authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

On June 30, 1999, NMFS received a Court Order from Judge Steven D. Merryday relative to the May, 1997, lawsuit challenging commercial harvest quotas for Atlantic sharks. Specifically, the order states: '' ... the Court hereby preliminarily, and until further order of the Court, expressly ENJOINS the defendant and his designees from enforcing the 1999 regulations, 64 Fed. Reg. 29090 (May, 28, 1999) with respect to Atlantic shark commercial catch quotas and fish-counting methods (including the counting of dead discards and state commercial landings after federal closures) that are different from the quotas and fish counting methods prescribed by the 1997 Atlantic shark regulations, 62 Fed. Reg. 16648 (April 7, 1997).''

As such, the annual 2000 LCS quota continues at the 1997 level of 1,285 mt dw for all species of LCS, (Table 1 of appendix A to part 635), with no minimum size on ridgeback LCS. The SCS and pelagic shark quotas also revert to their annual 1997 levels, of 1,760 and 580 mt dw, respectively. The 1997 prohibited species list now applies to only five prohibited species: white, basking, whale, sand tiger and bigeye sand tiger. The limited access provisions for commercial harvests still apply, including trip limits for directed and incidental shark permit holders.

The first semiannual fishing season of the 2000 fishing year for the commercial fishery for LCS in the Western North Atlantic Ocean, including the Gulf of Mexico and the Caribbean Sea will open January 1, 2000. Catch rate data from the first semiannual fishing season from 1997 and 1998 for LCS species indicate that the LCS quota of 642.5 mt dw will be attained within 90 days. Accordingly, the Assistant Administrator for Fisheries (AA) has determined, based on these projected catch rates and the available quota, that the quota for the 2000 first semiannual season for LCS in or from the Western North Atlantic Ocean, including the Gulf of Mexico and Caribbean Sea, will be attained as of March 31, 2000. The LCS fishery will close March, 31, 2000, at 11:30 p.m. local time.

During a closure, retention of, fishing for, possessing or selling LCS are prohibited for persons fishing aboard vessels issued a limited access permit under § 635.4. The sale, purchase, trade, or barter of carcasses and/or fins of LCS harvested by a person aboard a vessel that has been issued a permit under § 635.4 are prohibited, except for those that were harvested, offloaded, and sold, traded, or bartered prior to the closure and were held in storage by a dealer or processor.

The first semiannual quota for SCS is 880 mt dw. The first semiannual quota for pelagic sharks is 290 mt dw. When quotas are projected to be reached for these fisheries, the AA will file notification of closure at the Office of the Federal Register at least 14 days before the effective date.

Those vessels that have not been issued a limited access permit under § 635.4 may not sell sharks and are subject to the recreational retention limits and size limits specified at §§ 635.22(c) and 635.20(d). The recreational fishery is not affected by any closure in the commercial fishery.

Classification

This action is taken under 50 CFR part 635 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 18, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–30667 Filed 11–23–99; 8:45 am]

BILLING CODE 3510–22–F