pressure gasoline program, and rules for industrial cleanup solvents, plastic parts coating, and wood furniture coating.

(i) Incorporation by reference.

(A) State of Michigan House Bill No. 4165 signed by the Governor and effective on November 13, 1993.

(B) State of Michigan House Bill No. 726 signed by the Governor and effective on November 13, 1993.

(C) State of Michigan House Bill No. 4898 signed by the Governor and effective on November 13, 1993.

3. Section 52.1174 is amended by adding paragraph (r) to read as follows:

§ 52.1174 Control strategy: Ozone.

* * * * *

(r) Approval—On March 9, 1995, the Michigan Department of Environmental Quality submitted a request to redesignate the Muskegon County ozone nonattainment area to attainment. As part of the redesignation request, the State submitted a maintenance plan as required by 175A of the Clean Air Act, as amended in 1990. Elements of the section 175A maintenance plan include a contingency plan, and an obligation to submit a subsequent maintenance plan revision in 8 years as required by the Clean Air Act. If the area records a violation of the 1-hour ozone NAAQS, determined not to be attributable to transport from upwind areas, Michigan will implement one or more appropriate contingency measure(s) which are in the contingency plan. The menu of contingency measures includes a motor vehicle inspection and maintenance program, stage II vapor recovery, a low Reid vapor pressure gasoline program, and rules for industrial cleanup solvents, plastic parts coating, and wood furniture coating.

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7871 *et seq.*

2. In § 81.323 the table entitled ''Michigan—Ozone (1-hour standard)'' is amended by revising the entry for ''Muskegon Area: Muskegon County'' to read as follows:

§ 81.323 Michigan.

* * * * *

MICHIGAN—OZONE

[1-Hour Standard]

Designated areas	Designation		Classification	
	Date[1]	Type	Date[1]	Type
* * *	*	*	*	*
Muskegon Area:				
Muskegon County	October 18, 2000	Attainment.		
* * *	*	*	*	*

[1] This date is October 18, 2000, unless otherwise noted.

* * * * * * *

[FR Doc. 00–21913 Filed 8–29–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301034; FRL–6736–6]

RIN 2070–AB78

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of glyphosate (*N*-(phosphonomethyl)glycine in or on certain raw agricultural commodities resulting from application of the ethanolamine salt and revises the headers for 40 CFR 180.364. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 30, 2000. Objections and requests for hearings, identified by docket control number OPP–301034, must be received by EPA on or before October 30, 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–301034 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, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–5697; and e-mail address: 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	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed 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–301034. 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 January 10, 2000 (65 FR 1370) (FR–6394–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Monsanto Company, 600 13th Street NW. Suite 660, Washington DC 20005. This notice included a summary of the petition prepared by Monsanto Company, 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 establishing a tolerance for residues of the herbicide glyphosate, *N*-(phosphonomethy) glycine from application of the ethanolamine salt of glyphosate. The petition (0F6071) notice requested that the 180.364(a) introductory text be revised.

It also proposed that 40 CFR 180.364(a) be amended so that the introductory text for paragraphs (a)(2) and (a)(3) are removed and the commodity tolerances listed in paragraphs (a)(2) and (a)(3) are reorganized into section (a) in alphabetical order in the table. It is further that 40 CFR 180.364(d) be revised.

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 a tolerance for residues of glyphosate by revising the existing regulation to include the ethanolamine salt of glyphosate and to revise the introductory text, remove the introductory text for paragraphs (a)(2) and (a)(3), and the commodity tolerances listed in paragraphs (a)(2) and (a)(3) are reorganized into paragraph (a) in alphabetical order in the table, and revising the text in paragraph (d).

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 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

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 F_3b 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 F_0 and F_1 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

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD=NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE)= NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

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 UF.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.364 or the residues 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 in food as follows:

i. *Acute exposure*. 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 one 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*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA [1989–1992] nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 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. Neither percent crop treated nor anticipated residues were used for this risk assessment.

iii. *Cancer*. A cancer risk assessment was not performed because glyphosate has been classified as a Group E chemical no evidence of carcinogenicity in two acceptable aninal species. The Agency concludes with reasonable certaintly that glyphosate does not elict a toxicological cancer response. A cancer risk assessment is not needed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for glyphosate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of glyphosate.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) 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.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead 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, and from residential uses. Since DWLOCs address total aggregate exposure to glyphosate they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of glyphosate in surface water and ground water for acute exposures are estimated to be 1.64 parts per billion (ppb) for surface water and 0.000852 ppb for ground water. The EECs for chronic exposures are estimated to be 0.19 ppb for surface water and 0.00111 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Glyphosate is currently registered for use on the following residential non-dietary sites: around ornamentals, shade trees, shrubs, walks driveways, flower beds, and home lawns. Based on the registered uses for glyphosate, the potential for residential exposure 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. This risk assesment was not conducted. Exposures from residenitial uses are not expected to pose undue risks or harm to the public health.

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. Safety Factor for Infants and Children

1. *In general*. 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 on toxicity and exposure 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.

2. *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.

3. *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. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because there was no indication of increased susceptablilty of rats or rabbits to in utero and/or postnatal exposure to glyphosate. In the prenatal developmental toxicity studies in rats and rabbits and the 2–generation reproductions study in rats, effects in the offspring were observed only at or above treatment levels whichresulted in evidence of appreciable parental toxicity. The use of generally high quality data, conservative models and/or assumptions in the exposure assessment provide adequate protection of infants and childern.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking 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 and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day)= cPAD – (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An acute risk assessment is not applicable because 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.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to glyphosate from food will utilize 1.5 % of the cPAD for the U.S. population, 3.3 % of the cPAD for non-nursing infants (less than one–year old) and 3.2 % of the cPAD for childern (1–6 years old). Based the use pattern, chronic residential exposure to residues of the glyphosate is not expected to pose undue risks to the general population, including infants and childern. In addition, there is potential for chronic dietary exposure to glyphosate in drinking water. After calculating the DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO GLYPHOSATE

Population subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.029960	1.5	0.19	0.0011	69000
Non-nursing infants < 1	0.065430	3.3	0.19	0.0011	19000
Childern (1–6)	0.064388	3.2	0.19	0.0011	19000

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Though residential exposure could occur with the use of glyphosate, no toxicological effects have been identified for short-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure

takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Though residential exposure could occur with the use of glyphosate, no toxicological effects have been identified for intermediate-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Glyphosate has been classified as a Group E chemical no evidence of carcinogenicity for humans in two animal species. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to glyphosate residues.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to glyphosate residues.

IV. Other Considerations

A. 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).

B. 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.

C. Conditions

There are no conditons of registration associated with this action.

V. Conclusion

Therefore, the tolerance is established for residues of glyphosate, *N*-(phosphonomethyl)glycine by revising the existing regulation to include the ethanolamine salt of glyphosate and to revise the introductory text, remove the introductory text for paragraphs (a)(2) and (a)(3), and the commodity tolerances listed in paragraphs (a)(2) and (a)(3) are reorganized into paragraph (a) in alphabetical order in the table, and revising the text in paragraph (d).

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–301034 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 October 30, 2000.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

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

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit 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–301034, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. 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(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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: August 15, 2000.

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 180.364 is amended by revising paragraphs (a) and (d) to read as follows:

§180.364 Glyphosate; tolerances for residues.

(a) *General.* Tolerances are established for residues of glyphosate, (*N*-(phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate and the ammonium salt of glyphosate in or on the following food commodities:

Commodity	Parts per million
Acerola	0.2
Alfalfa	200.0
Alfalfa, forage	75.0
Alfalfa, fresh and hay	0.2
Alfalfa, hay	200.0
Almonds, hulls	1
Almond hulls	25
Artichokes, Jerusalem	0.2
Asparagus	0.5
Aspirated grain fractions	200.0
Atemoya	0.2
Avocados	0.2
Bahiagrass	200.0
Bananas	0.2
Barley, bran	30
Barley, grain	20
Beets	0.2
Beets, sugar, dried pulp	25
Beets, sugar, roots	10
Beets, sugar, tops	10
Bermudagrass	200.0
Bluegrass	200.0
Breadfruit	0.2
Bromegrass	200.0
Canistel	0.2
Canola, meal	15
Canola, seed	10
Carambola	0.2
Carrots	0.2
Cattle, kidney	4.0
Cattle, liver	0.5
Celeriac	0.2
Cherimoya	0.2

Commodity	Parts per million
Chickory	0.2
Citrus, fruits	0.5
Citrus pulp, dried	1.5
Clover	200.0
Cocoa beans	0.2
Coconut	0.1
Coffee beans	1
Corn, field, forage	1.0
Corn, field, grain	1.0
Corn, field, stover	100.0
Cotton gin byproducts	100.0
Cottonseed	15
Cranberries	0.2
Dates	0.2
Durian	0.2
Fescue	200.0
Figs	0.2
Fish	0.25
Forage grasses	0.2
Forage legumes (except soybeans and peanuts)	0.4
Fruits, small, and berries	0.2
Genip	0.2
Goats, kidney	4.0
Goats, liver	0.5
Grain crops (except wheat, oats, grain sorghum and barley)	0.1
Grapes	0.2
Grasses, forage	0.2(N)
Guavas	0.2
Hogs, kidney	4.0
Hogs, liver	0.5
Horseradish	0.2
Horses, kidney	4.0
Horses, liver	0.5
Jaboticaba	0.2
Jackfruit	0.2
Kiwifruit	0.2
Leafy vegetables	0.2(N)
Legume vegetables (succculent and dried) group (except soybeans)	5
Longan	0.2
Lychee	0.2
Mamy sapote	0.2
Mangoes	0.2
Mangosteen	0.2
Molasses, sugarcane	30.0
Nuts	0.2
Oats, grain	20.0
Oil, palm	0.1
Olives	0.2
Olives, imported	0.1
Orchardgrass	200.0
Papayas	0.2
Parsnips	0.2
Passion fruit	0.2
Peanut, forage	0.5
Peanut, hay	0.5
Peanuts	0.1
Peppermint	200
Persimmons	0.2
Pineapple	0.1
Pistachio nuts	0.2
Pome fruits	0.2
Pomegranates	0.2
Potatoes	0.2
Poultry, kidney	0.5
Poultry, liver	0.5
Radishes	0.2
Rambutan	0.2
Rutabagas	0.2
Ryegrass	200.0
Salsify	0.2
Sapodilla	0.2
Sapote, black	0.2
Sapote, white	0.2
Seed and pod vegetables	0.2(N)
Seed and pod vegetables, forage	0.2(N)
Seed and pod vegetable, hay	0.2(N)
Sheep, kidney	4.0
Sheep, liver	0.5
Shellfish	3.0
Sorghum, grain	15.0
Sorghum, grain, stover	40.0
Soursop	0.2
Soybean, hulls	100.0
Soybeans	20.0
Soybeans, aspirated grain fractions	50.0
Soybeans, forage	100.0
Soybeans, grain	20.0
Soybeans, hay	200.0
Spearmint	200
Stone fruit	0.2
Sugar apple	0.2
Sugarcane	2.0
Sunflower seed	0.1
Sweet potatoes	0.2
Tamarind	0.2
Tea, dried	1.0
Tea, instant	7.0
Timothy	200.0
Tree nut crop group	1.0
Turnips	0.2
Vegetables, bulb	0.2
Vegetables, cucurbit	0.5
Vegetables, fruiting (except cucurbits) group	0.1
Vegetables, leafy, Brassica (cole)	0.2
Wheat, grain	5.0
Wheat, straw	85.0
Wheat milling fractions (excluding flour)	20.0
Wheatgrass	200.0
Yams	0.2

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of glyphosate *N*-(phosphonomethyl glycine) per se resulting from the use of irrigation water containing residues of 0.5 ppm following applications on or around aquatic sites, at 0.1 ppm on the crop groupings citrus, cucurbits, forage grasses, forages legumes, fruiting vegetables, grain crops, leafy vegetables, nuts, pome fruits, root crop vegetables, seed and pod vegetables, stone fruits, and the individual commodities cottonseed, hops, and avocados. Where tolerances are established at higher levels from other uses of glyphosate in or on the subject crops, the higher tolerances should also apply to residues from the aquatic uses cited in this paragraph.

[FR Doc. 00–22168 Filed 8–29–00; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 213

[Docket No. RST–94–3, Notice No. 2]

Policy on the Safety of Railroad Bridges

AGENCY: Federal Railroad Administration (FRA), Department of Transportation, (DOT).

ACTION: Final Statement of Agency Policy.

SUMMARY: FRA issues a final statement of policy for the safety of railroad bridges. FRA establishes suggested criteria for railroads to use to ensure the structural integrity of bridges that carry railroad tracks. This final statement of policy reflects minor changes following public comment on the interim statement of policy published April 27, 1995, at 60 FR 20654.

DATES: *Effective Date:* The final statement of policy is effective September 29, 2000.

FOR FURTHER INFORMATION CONTACT: Gordon A. Davids, P.E., Bridge Engineer, Office of Safety Assurance and Compliance, Federal Railroad Administration, 1120 Vermont Avenue, NW., Mail Stop 25, Washington, DC 20590, (Telephone: 202–493–6320), or Nancy Lummen Lewis, Trial Attorney, Office of Chief Counsel, Federal Railroad Administration, 1120 Vermont Avenue, NW., Mail Stop 10, Washington, DC 20590, (Telephone 202–493–6047).

SUPPLEMENTARY INFORMATION: On April 27, 1995, FRA issued an interim statement of policy on the safety of railroad bridges. Published in the **Federal Register** at 60 FR 20654, the interim statement included a request for comments to be submitted to FRA during a 60-day period following publication. The interim statement detailed the reasons which prompted FRA to adopt this policy, as well as the background information behind its adoption. The notice stated that FRA intended to incorporate the policy statement as an appendix to 49 CFR part 213, reflecting any changes warranted by comments submitted during the comment period. FRA's original intent was to publish the final statement of policy at the same time it issued a final rule to revise the Federal Track Safety Standards found at 49 CFR Part 213. However, because the final statement of policy addresses certain unique issues not shared by the final rule to revise the track standards, FRA decided to publish this final statement of policy separately.