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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0323; FRL–7683–9]

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of glyphosate, N-(phosphonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on cotton, gin byproducts and cotton, undelinted seed. 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 November 10, 2004. Objections and requests for hearings must be received on or before January 10, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0323. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: James A.Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 18, 2004 (69 FR 51301) (FRL–7364–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 0F6195, 1F6274, 2F6487, and 3F6570) by Monsanto Company, 600 13th St., NW., Suite 660, Washington, DC 20005. The petition requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate, N-(phosphonomethyl)glycine, in or on alfalfa seed at 0.5 parts per million (ppm) (PP 2F6487); increasing the current tolerance for cotton, gin byproducts from 100 ppm to 150 ppm (PP 3F6570); rice, bran at 30 ppm; rice, grain at 15 ppm; and rice, hulls at 25 ppm (PP 1F6274); wheat, forage at 10.0 ppm; wheat, hay at 10.0 ppm (PP 0F6195). Monsanto Company also proposed to revise the entry for grain, cereal group tolerance ''except rice'' to read as grain, cereal group 15 except barley, field corn, grain sorghum, oats, rice, and wheat at 0.1 ppm (PP 1F6274). Monsanto Company also amended PP 0F6195 to delete the proposal for wheat grain at 6 ppm that was announced in the **Federal Register** of April 17, 2002 (67 FR 18894) (FRL–6830–5). The notice stated that tolerances for alfalfa, rice, wheat, and cotton gin byproducts include both conventional and genetically altered crops.

The notice also proposed that the tolerances for alfalfa, forage at 175 ppm and alfalfa, hay at 400 ppm be deleted from § 180.364. Also proposed was to amend § 180.364 by replacing the current listing vegetable, legume, group 6 except soybean at 5.0 ppm with the current crop group pea and bean, dried and shelled, subgroup 6C at 5.0 ppm. That notice included a summary of the petition prepared by Monsanto Company, the registrant. One comment was received in response to the notice of filing from B. Sachau, 15 Elm St., Florham Park, NJ 07932. The commenter objected to allowing any tolerance, wavier, or exemption for glyphosate. The commenter also objected to animal testing and stated that a more reliable method of testing should be developed. This comment is discussed further in Unit V.

During the course of the review the Agency decided to correct the company address to read Monsanto Company, 1300 I St., NW., Suite 450 East, Washington, DC 20005. The Agency also determined the tolerance proposed for cotton, gin byproducts should be raised to 175 ppm and that the current tolerance for cotton, undelinted seed be increased to 35 ppm.

The Agency has determined that based on available data, the current tolerances for alfalfa, forage and alfalfa, hay are to be maintained and that the current listing for vegetable, legume,

group 6 except soybean at 5 ppm is correct; therefore, these proposed changes are not made at this time. Also, even though the proposed tolerances for alfalfa, seed; rice, bran; rice, grain; rice, hulls; wheat, forage; and wheat, hay are included in the risk assessment discussed in Units III.C., D., and E., these tolerances are not being issued at this time.

The Agency is also correcting the proposed tolerance expression to agree with the current tolerance expression by including references to the salts. Therefore, the tolerance expression is corrected to read: Tolerances are established for residues of glyphosate, N-(phosophonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on cotton, gin byproducts at 175 ppm and cotton, undelinted seed at 35 ppm.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of FFDCA 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) of FFDCA, 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) of FFDCA, for a tolerance for residues of glyphosate, N-(phosophonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate on cotton, gin byproducts at 175 ppm and cotton, undelinted seed at 35 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by glyphosate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2).

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.

Three other types of safety or UFs may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children, primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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.

A summary of the toxicological endpoints for glyphosate used for human risk assessment is discussed in

Unit V.B. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.364) for the residues of glyphosate, in or on a variety of raw agricultural commodities. 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 1-day or single exposure.

A review of the toxicity database, including developmental toxicity studies in rats and rabbits, did not provide an endpoint that could be used to quantitate risk to the general population and to females 13–50 years old from a single-dose administration of glyphosate. Therefore, no acute dietary analysis was conducted for glyphosate.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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: Tolerance level residues, DEEM default factors and 100% crop treated. PCT and/or anticipated residues were not used.

iii. *Cancer.* Glyphosate is classified as a Group E chemical, negative for carcinogenicity in humans, based on the absence of carcinogenicity in male and female rats as well as male and female mice.

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 Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration and Ground Water (SCI-GROW) model, 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water in quantitative risk assessments. EECs derived from these models are used 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, Unit III.E.

Based on the GENEEC, and SCI-GROW models, the EECs of glyphosate for acute exposures are estimated to be 21.0 parts per billion (ppb) for surface water and 0.0038 ppb for ground water. The EECs for chronic exposures are estimated to be 0.83 ppb for surface water. The EEC resulting from the registered use of direct glyphosate application to surface water is 230 ppb. Because the glyphosate water-application estimate is greater than the crop-application estimate, 230 ppb is the appropriate value to use in the chronic risk assessment. The EEC for chronic exposure in ground water is 0.0038 ppb.

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).

i. *Non-occupational (recreational) exposures.* Glyphosate is currently registered for use on the following residential non-dietary sites: Recreational areas, including parks and golf courses for control of broadleaf weeds and grasses, and lakes and pond, including reservoirs for control of nuisance aquatic weeds. Based on the registered uses, adult and child golfers are anticipated to have short-term post-application dermal exposure at golf courses. Swimmers (adults, children, and toddlers) are anticipated to have short-term post-application dermal and incidental ingestion exposures. However, since the Agency did not select dermal endpoints, no post-application dermal assessment was performed.

A post-application incidental ingestion exposure assessment for swimmers was performed. This assessment assumed 100% of applied concentration available at maximum application rate in the top one foot of water column; an ingestion rate of 0.05 Liter/hour (L/hr), and an exposure duration of 5 hrs/day (although a toddler is unlikely to be exposed for 5 hrs/day). Adult and toddler swimmers were included in this assessment as they are anticipated to represent the upper and lower bound of swimmer exposures. The respective body weights are 60 kilogram (kg) for adult-females (since NOAEL is based on developmental study) and 15 kg for toddlers. This exposure assessment is fully discussed in Unit V.C. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2). MOEs for incidental exposure for incidental ingestion by swimmers were 7,600 for toddler and to 36,000 for adult females and therefore, do not exceed the Agency's level of concern (LOC) for short-term non-occupational (recreational) exposures (MOEs of less than 100).

ii. *Residential exposures.* Glyphosate is also registered for broadcast and spot treatments on home lawns and gardens by homeowners and by lawn care operators (LCOs). Based on the registered residential use pattern, there is a potential for short-term dermal and inhalation exposures to homeowners who apply products containing

glyphosate (residential handlers). Additionally, based on the results of the environmental fate studies, there is a potential for incidental ingestion by toddlers. However, since the Agency did not select short- or intermediate-term dermal or inhalation endpoints, no residential handler or post-application dermal assessment was performed.

A post-application toddler assessment for incidental ingestion exposure assessment was performed. The *SOPs For Residential Exposure Assessments*, Draft, 17-DEC-1997 and Exposure Science Advisory Committee (ExpoSAC) Policy No. 11, 22-FEB-2001: *Recommended Revisions to the SOPs for Residential Exposure* were used to estimate post-application incidental ingestion exposures and risk estimates for toddlers. The following assumptions were used to assess exposures to toddlers after contact with treated lawns: Toddler body weight of 15 kg; toddler hand-surface area is 20 centimeter squared $(cm)^2$, and a toddler performs 20 hand-to-mouth events per hr for short-term exposures; exposure duration of 2 hrs per day; 5% of application rate represents fraction of glyphosate available for transfer to hands and a 50% saliva extraction factor for hand-to-mouth exposures; surface area of a object (for toddler object-to-mouth exposures; surface area of an object (for toddler object-to-mouth exposures) is approximately 25 cm^2; 20% of application rate available as dislodgeable residues for object-to-mouth exposures; 100% of application rate is avaible in the top 1 cm of soil for soil ingestion exposures; and that a toddler can ingest 100 milligram (mg) soil/day. This risk assessment is fully discussed in Unit V.C. of the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2). MOEs for toddler post-application incidental ingestion exposures were 7,200 for hand-to-mouth, 29,000 for object-to-mouth and greater than 10^6 for soil ingestion, and therefore, do not exceed the Agency's level of concern for residential exposures (MOEs) less than 100.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to glyphosate and any other substances and 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of FFDCA 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Based on the acceptable developmental studies, the Agency has determined that there is no evidence of either a quantitative or qualitative increased susceptibility following *in utero* glyphosate exposure to rats or rabbits, or following prenatal/postnatal exposure in the 2-generation reproduction study in rats.

3. *Conclusion*. There is a complete toxicity database for glyphosate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The impact of glyphosate on the nervous system has not been specifically evaluated in neurotoxicity studies. However, there was no evidence of neurotoxicity seen in either acute, subchronic, chronic, or reproductive studies. and there are no concerns for potential developmental neurotoxicity. Therefore, neurotoxicity studies are not required for glyphosate. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because the toxicology database is complete; a developmental neurotoxicity study is not required; there is no evidence of quantitative or qualitative increased susceptibility of the young demonstrated in the prenatal developmental studies in rats or rabbits and pre-/postnatal reproduction study in rats; and the dietary (food and drinking water) exposure assessments will not underestimate the potential exposure for infants and children.

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 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 EPA's Office of Water are used to calculate DWLOCs: 2 L/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*. Glyphosate is not expected to pose an acute risk because no toxicological endpoints attributable to a single exposure (dose), including maternal toxicity in developmental toxicity studies, were identified in the available data.

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 2.2% of the cPAD for the U.S. population, 3.9% of the cPAD for all infants < 1 year old, and 5.4% of the cPAD for children 1–2 years old. Based the use pattern, chronic residential exposure to residues of glyphosate is not expected. In addition, there is potential for chronic dietary exposure to glyphosate in drinking water. After calculating 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, as shown in Table 1 of this unit:

TABLE 1.—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	1.75	2.2	230	0.0038	60,000
All infants < 1 year old	1.75	3.9	230	0.0038	16,800
Children 1–2 years old	1.75	5.4	230	0.0038	16,600
Females 13–49 years old	1.75	1.7	230	0.0038	51,600
Youth 13–19 years old	1.75	2.1	230	0.0038	51,400
Adults 20–49 years old	1.75	1.9	230	0.0038	60,100

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).

Glyphosate is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for glyphosate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,800 for all infants < 1 year old, 1,500 for children 1–6 years old, and 2000 for children 7–12 years old. Because the incidental oral ingestion exposure estimates for toddlers from residential turf exposures exceeded the incidental oral exposure from post-application swimmer exposures, the Agency conducted this risk assessment using exposure estimates from the worst case situation. No attempt was made to combine exposures from swimmer and residential turf scenarios due to the low probability of both occurring. See Tables 5 and 6 from the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2) for detailed discussion. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of glyphosate in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO GLYPHOSATE

Population subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
All infants < 1 year old	1,800	100	230	0.0038	16,500
Children 1–6 years old	1,500	100	230	0.0038	16,300
Children 7–12 years old	2,000	100	230	0.0038	16,600

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).

Glyphosate is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for glyphosate.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,800 for all infants < 1 year old, 1,500 for children 1–6 years old, and 2,000 for

children 7–12 years old. Because the incidental oral ingestion exposure estimates for toddlers from residential turf exposures exceeded the incidental oral exposure from post-application swimmer exposures, the Agency conducted this risk assessment using exposure estimates from the worst case situation. No attempt was made to combine exposures from swimmer and residential turf scenarios due to the low probability of both occurring. See Tables 5 and 6 from the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL–7200–2) for detailed discussion. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of glyphosate in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO GLYPHOSATE

Population subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
All infants < 1 year old	1,800	100	230	0.0038	16,500
Children 1–6 years old	1,500	100	230	0.0038	16,300
Children 7–12 years old	2,000	100	230	0.0038	16,600

5. *Aggregate cancer risk for U.S. population*. Glyphosate has no carcinogenic potential.

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 analytical methods are available for the enforcement of tolerances for glyphosate in plant and livestock commodities. These methods include gas liquid chromatography (GLC) (*Method I in Pesticides Analytical Manual* (PAM II)) and High Performance Liquid Chromatography (HPLC) with fluorometric detection. Use of GLC is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion into PAM II. A Gas Chromatography Spectrometry (GC/MS) method for glyphosate in crops has also been validated by EPA.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Codex and Mexican maximum residue levels (MRLS) are established for residues of glyphosate per se and Canadian MRLs are established for combined residues of glyphosate and aminomethylphosphonic acid (AMPA) in a variety of raw agricultural commodities. Codex MRLs exist for dry peas and dry beans at 5 ppm and 2 ppm, respectively. Canadian MRLs exist for peas, beans, and lentils at 5 ppm, 2 ppm, and 4 ppm, respectively. Mexican MRLs of 0.2 ppm exist for both peas and beans. Codex and Canadian MRLs for beans and lentils, and Mexican MRLs for peas and beans are lower then necessary to cover residues from the use patterns in the United States. The proposed U. S. tolerance for the crop group peas and beans, dried and shelled, except soybeans, is in agreement with the Codex and Canadian MRLs for dry peas and peas, respectively, and are necessary to cover use patterns in the United States.

Currently no Codex MRL for cotton, gin byproducts or cotton, undelinted seed are established.

C. Conditions

There are no conditions of registration for the establishment of tolerances on cotton, gin byproducts or cotton, undelinted seed.

V. Comments

One comment was received in response to the notice of filing from B. Sachau, 15 Elm St., Florham Park, NJ 07932. The commenter objected to the allowance of any tolerances, waiver, or exemption from tolerance for glyphosate because there are bad effects from glyphosate. The commenter also objected to animal testing, because testing on rabbit or dog constitutes animal abuse, and stated that a more reliable method of testing should be developed.

The comment contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate expose to glyphosate, including all anticipated dietary exposure and all other exposures for which the is reliable information.

Health Effects Guidelines (Series 870) recommends that dog or rabbit be used for various acute, subchronic, and longer term chronic, carcinogenic, developmental, and reproductive studies. Information derived from these tests serve to indicate the presence of possible hazards likely to arise from exposure to the test substance. Currently, there are not *in vitro* studies that can address the questions these studies answer. The EPA is currently working with the Interagency Coordinating Committee on the Validation or Alternative Methods (ICCVAM) to investigate alternative *in vitro* methods.

VI. Conclusion

Therefore, the tolerance is established for residues of glyphosate, N-(phosophonomethyl)glycine, resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on cotton, gin byproducts at 175 ppm and cotton, undelinted seed at 35 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2004–0323 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 10, 2005.

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 issue(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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0323, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule

does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of 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: October 25, 2004.

Betty Shackleford,

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, paragraph (a) is amended by:

■ i. Revising the chemical name ''(N-phosphomethyl)glycine)'' in the introductory text to read ''N-(phosphonomethyl)glycine.''

■ ii. Revising in the table the entries ''cotton, gin byproducts'' and ''cotton, undelinted seed'' to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cotton, gin byproducts	175
Cotton, undelinted seed	35
* * *	* *

* * * * *

[FR Doc. 04–25098 Filed 11–9–04; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF DEFENSE

48 CFR Parts 209 and 252

[DFARS Case 2003–D011]

Defense Federal Acquisition Regulation Supplement; Contractor Qualifications Relating to Contract Placement

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has issued a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to delete text pertaining to contractor qualification requirements. This rule is a result of a transformation initiative undertaken by DoD to dramatically change the purpose and content of the DFARS.

DATES: *Effective Date:* November 10, 2004.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Schulze, Defense Acquisition Regulations Council, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–0326; facsimile (703) 602–0350. Please cite DFARS Case 2003–D011.

SUPPLEMENTARY INFORMATION:

A. Background

DFARS Transformation is a major DoD initiative to dramatically change the purpose and content of the DFARS. The objective is to improve the efficiency and effectiveness of the acquisition process, while allowing the acquisition workforce the flexibility to innovate. The transformed DFARS will contain only requirements of law, DoD-wide policies, delegations of FAR authorities, deviations from FAR requirements, and policies/procedures that have a significant effect beyond the internal operating procedures of DoD or a significant cost or administrative impact on contractors or offerors. Additional information on the DFARS Transformation initiative is available at *http://www.acq.osd.mil/dpap/dfars/transf.htm.*

This final rule is a result of the DFARS Transformation initiative. The DFARS changes include—

- Deletion of text at DFARS 209.103, 209.103–70, and 252.209–7000 pertaining to obsolete Intermediate Range Nuclear Forces (INF) Treaty inspection requirements.
- Deletion of text at DFARS 209.106–1, 209.106–2, and 209.202 containing internal DoD procedures relating to requests for pre-award surveys and approval for use of product qualification requirements. This text has been relocated to the new DFARS companion resource, Procedures, Guidance, and Information (PGI), available at *http://www.acq.osd.mil/dpap/dars/pgi.*
- Deletion of unnecessary first article testing and approval requirements in DFARS subpart 209.3.

DoD published a proposed rule at 69 FR 8150 on February 23, 2004. DoD received no comments on the proposed rule. Therefore, DoD has adopted the proposed rule as a final rule. An additional change has been made at DFARS 209.202 to reflect the qualification requirements for aviation critical safety items added to the DFARS on September 17, 2004 (69 FR 55987).

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule deletes DFARS text that is obsolete, unnecessary, or procedural, but makes no significant change to contracting policy.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*