

■ 2. Add § 165.T01–0992 to read as follows:

**§ 165.T01–0992 Safety Zone; Repair of High Voltage Transmission Lines to Logan International Airport; Saugus River, Saugus, MA.**

(a) *General.* A temporary safety zone is established for the event described in paragraph (a)(1):

(1) Repair of high voltage transmission lines to Logan International Airport; Saugus River, Saugus, MA.

(i) All waters of the Saugus River, from surface to bottom, within a 250-yard radius of position 42°26' 42" N; 070°58' 14" W.

(ii) *Effective Period.* This rule is effective May 9, 2011 to October 10, 2011.

(iii) *Enforcement Period.* This rule will be enforced during a consecutive 48 hour period to begin each day at 9 a.m. and end at 2 p.m. with notice of the enforcement of this safety zone to be made by all means to affect the widest publicity among the affected segments of the public, including publication of a Notice of Enforcement in the **Federal Register**, in the Local Notice to Mariners, and in the Safety Marine Information Broadcast.

(b) *Regulations.*

(1) In accordance with the general regulations in Section 165.23 of this part, entry into, transiting or anchoring within this regulated area is prohibited unless authorized by the COTP Boston, or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the COTP Boston or the designated on-scene representative.

(3) The “on-scene representative” of the Captain of the Port Boston is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port Boston to act on his behalf. The on-scene representative will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The COTP or the designated on scene representative may be contacted by telephone at 617–223–5750 or on VHF Channel 16.

(4) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may do so if they obtain permission from the COTP or the designated representative by contacting the COTP Sector Boston by telephone at 617–223–5750 or VHF radio channel 16.

Dated: March 25, 2011.

**John N. Healey,**

*Captain, U.S. Coast Guard, Captain of the Port Boston.*

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**BILLING CODE 9110–04–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA–HQ–OPP–2009–0988; FRL–8866–8]**

**Glyphosate (N-(phosphonomethyl) glycine); Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation replaces the established tolerance for residues of glyphosate in or on sweet corn, grain with corn, sweet, kernel plus cob with husk removed and reduces the established tolerance for residues of glyphosate and N-acetyl-glyphosate in or on poultry, meat. Monsanto Company requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 8, 2011. Objections and requests for hearings must be received on or before June 7, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0988. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:**

Kable Bo Davis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0415; e-mail address: [kable.davis@epa.gov](mailto:kable.davis@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 get electronic access to other related information?*

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0988 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 7, 2011. Addresses for mail

and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0988, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 24, 2010 (75 FR 14154-14157) (FRL-8815-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7644) by Monsanto Company, 1300 I St., NW., Suite 450 East, Washington, DC 20052. The petition requested that 40 CFR part 180 be amended by replacing the established tolerances for residues of the herbicide, glyphosate, in or on sweet corn, grain with the following: Corn, sweet, kernel plus cob with husk removed at a tolerance level of 3.0 parts per million (ppm) and corn, sweet, forage at a tolerance level of 9.0 ppm. The petition also requested a reduction in the established tolerance for residues of glyphosate and its metabolite (N-acetyl-glyphosate) in or poultry meat from 4.0 ppm to 0.1 ppm, as they believe the tolerance level was inadvertently increased when the poultry tolerances were moved from 40 CFR 180.364 (a)(1) to (a)(2). There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is revising the requested actions in several respects. EPA has concluded that a tolerance for residues of glyphosate in or on corn, sweet, kernel plus cob with husk removed should be set at 3.5 ppm, not 3.0 ppm. Since the proposed forage tolerance is less than the currently established tolerance for this commodity, EPA has concluded that a revision to the currently established forage tolerance is unnecessary. EPA is also modifying the tolerance expression for 40 CFR 180.364(a)(1) and (a)(2) to clarify the coverage of the tolerance and the compounds to be measured in determining compliance with tolerance levels. The reasons for these changes are explained in Unit IV.C.

## III. Aggregate Risk Assessment and Determination of Safety

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. \* \* \*

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for glyphosate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glyphosate 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.

Glyphosate is of low acute toxicity following oral, dermal, and inhalation exposure. It is a mild eye irritant, slight skin irritant, and is not a dermal sensitizer in guinea pigs. Inhalation risk assessments are not required based on the low toxicity of the formulation products (toxicity category III or IV) and the physical characteristics of the technical product. An acute dose and endpoint for assessing acute risk have not been selected for any population subgroups because no effect that could be attributed to a single exposure (dose) was observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits.

A chronic feeding/carcinogenicity study in rats found no systemic effects in any of the parameters examined (body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights, and histopathology). In a second chronic feeding/carcinogenicity study in rats tested at higher dietary levels, a lowest-observed-adverse-effect level (LOAEL) was identified at 940-milligrams/kilograms/day (mg/kg/day) & 1,183-mg/kg/day (male/female) based on decreased body-weight gains in females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. No evidence of carcinogenicity was found in rats or mice. In a chronic toxicity study in dogs, no systemic effects were found.

Acceptable developmental toxicity studies in the rat and rabbit are available, as is an acceptable 2-generation reproduction study in the rat. No significant reproductive and developmental toxic effects were found. A focal tubular dilation of the kidneys was observed in a 3-generation reproductive study on rats at the 30-mg/kg/day high dose treatment level (HDTL), however a 2-generational reproductive study on rats did not observe the same effect at the 1,500-mg/kg/day HDTL, nor were any adverse reproductive effects observed at any dose level. EPA concluded that the focal tubular dilation of the kidneys at the 30-mg/kg/day level was a spurious rather than a glyphosate-related effect.

In a prenatal developmental toxicity study in rats, maternal (systemic) effects observed included mortality, increased clinical signs, and reduced body-weight gain at the HDTL (3,500-mg/kg/day). Developmental (fetal) effects were observed only in the high-dose group

and included decreases in total implantations/dam and nonviable fetuses/dam, increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights. In a prenatal developmental toxicity study in rabbits, maternal (systemic) effects observed included mortality and clinical signs of toxicity at the HDTL (350-mg/kg/day). In the rabbits, developmental toxicity was not observed at any dose. On the basis of developmental studies in rats and rabbits and reproductive findings in rats, glyphosate exhibited no evidence of increased susceptibility of offspring.

Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate.

Specific information on the studies received and the nature of the adverse 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 can be found at <http://www.regulations.gov> in the document titled "Glyphosate. Section 3 Registration for Application of the Potassium Salt of Glyphosate to Glyphosate-Tolerant Sweet Corn. Human-Health Risk Assessment," pp. 26–27 in docket ID number EPA–HQ–OPP–2009–0988.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each

toxicological study to determine the dose at which the NOAEL the LOAEL. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) (a = acute c = chronic) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for glyphosate used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR GLYPHOSATE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary .....	An endpoint of concern (effect) attributable to a single dose was not identified in the database.		
Chronic dietary (All populations).	NOAEL= 175 ..... mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 1.75 mg/kg/day cPAD = 1.75 mg/kg/day.	Developmental Toxicity Study—Rabbit: Maternal LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals.
Incidental oral short-term (1 to 30 days).	NOAEL= 175 ..... mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = < 100 .....	Developmental Toxicity Study—Rabbit: Maternal LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 175 ..... mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = < 100 .....	Developmental Toxicity Study—Rabbit: Maternal LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals.
Dermal short-term (1 to 30 days) Dermal intermediate-term (1 to 6 months).	None .....	None .....	Based on the lack of toxicity up to the highest dose tested (1,000 mg/kg/day) in the 21 day dermal toxicity study in rabbits and the lack of concern for developmental and reproductive effects, the quantification of dermal risks was not conducted.
Inhalation short-term (1 to 30 days) Inhalation (1 to 6 months).	None .....	None .....	Based on the lack of toxicity up to the highest concentration tested (0.36 mg/L) in the 28-day inhalation toxicity study in rats, and the physical characteristics of the technical, the quantification of inhalation risks was not conducted.
Cancer (Oral, dermal, inhalation).	None .....	None .....	No evidence of carcinogenicity.

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>S</sub> = use of a short-term study for long-term risk assessment. UF<sub>DB</sub> = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to glyphosate, EPA considered exposure under the petitioned-for tolerances as well as all existing

glyphosate tolerances in 40 CFR 180.364. EPA assessed dietary exposures from glyphosate in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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.

No such effects were identified in the toxicological studies for glyphosate; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture Continuing Survey of Food Intake by Individuals (USDA CSFII) (1994–1996 and 1998). The chronic analysis assumed tolerance-level residues, 100 percent crop treated (PCT), and Dietary Exposure Evaluation Model (DEEM (version 7.81)) default processing factors and incorporated glyphosate drinking water monitoring data.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that glyphosate does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* The Agency used monitoring data from the United States Geological Survey (USGS) National Water-Quality Assessment Program (NAWQA) to calculate drinking water exposure. For chronic dietary risk assessment, the water concentration of value 13.5 parts per million (ppb) was used to assess the contribution to drinking 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).

The sweet corn use is not anticipated to result in residential exposure. However, residential exposure is anticipated from the registered broadcast and spot treatment to residential lawns, gardens, and recreational areas including parks and golf courses. Based on the registered residential use patterns, there is a potential for short-term and intermediate-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate. Since short- and intermediate-term dermal and inhalation endpoints were not selected, no residential handler/applicator exposure assessment was conducted. Post-application dermal and inhalation exposure assessments were not conducted since short- and intermediate-term dermal and inhalation endpoints were not selected. Based on registered use patterns, toddlers may have short-term post-application incidental oral exposure from hand-to-mouth, object to mouth,

and soil ingestion behavior on treated lawns and swimmers may have short-term post-application incidental oral exposures from treated surface water. Exposures and risks from these scenarios were assessed because an applicable endpoint was identified. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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.”

EPA has not found glyphosate to share a common mechanism of toxicity with 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 assumed that glyphosate does not have 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 EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rats or rabbit fetuses to *in utero* exposure in developmental studies. A focal tubular dilation of the kidneys was observed in a 3-generation reproductive study on rats at the 30-mg/kg/day

HDTL, however a 2-generational reproductive study on rats did not observe the same effect at the 1,500-mg/kg/day HDTL, nor were any adverse reproductive effects observed at any dose level. A clear NOAEL was established and the chronic reference dose was set at a level well below (~17-fold) this effect. Therefore, the endpoints selected for risk assessment are protective of the effects seen in the 3-generation rat reproduction study. There are no residual uncertainties for pre- or postnatal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database is complete with the exception of recently-required studies on acute and subchronic neurotoxicity and immunotoxicity. There is no evidence of neurotoxicity in any of the toxicology studies. Accordingly, although an acute and subchronic neurotoxicity studies are now required as part of new data requirements, EPA does not believe that conducting these studies will result in a lower POD than that currently used for overall risk assessment, and therefore, a database uncertainty factor is not needed to account for lack of these studies.

ii. The toxicology database for glyphosate does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. Accordingly, although an immunotoxicity study is required as a part of the new data requirements in the 40 CFR part 158 for conventional pesticide registration, EPA does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently use for overall risk assessment, and therefore, a data base uncertainty factor is not needed to account for lack of this study.

iii. There is no quantitative or qualitative evidence of increased susceptibility of rats or rabbit fetuses to *in utero* exposure in developmental studies.

iv. The dietary exposure analysis of exposure to glyphosate in food is conservative as it assumed tolerance level residues and 100 PCT. EPA made conservative (protective) assumptions in the water modeling used to assess exposure to glyphosate in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers.

These assessments will not underestimate the exposure and risks posed by glyphosate.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, glyphosate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to glyphosate from food and water will utilize 12% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of glyphosate is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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

Short-term incidental oral exposure may occur to young children (swimmer and turf non-dietary ingestion) and adults (swimmers). For young children, short-term aggregate exposure includes chronic dietary (food and water) and incidental oral ingestion exposure resulting from the turf use (highest exposure of all possible scenarios). For adults, short-term aggregate exposure includes chronic dietary exposure (food and water) and incidental oral ingestion exposure resulting from the aquatic use (highest exposure of all possible scenarios). See Table 6.0.1 in the document titled “Glyphosate. Section 3 Registration for Application of the

Potassium Salt of Glyphosate to Glyphosate-Tolerant Sweet Corn. Human-Health Risk Assessment” in docket ID number EPA–HQ–OPP–2009–0988 for a summary of the short-term aggregate exposures and risk estimates (the populations included represent those with the highest dietary exposures). For glyphosate, the LOC is for MOEs below 100. Since the aggregate MOEs are  $\geq 720$ , short-term aggregate exposure to glyphosate does not pose a risk of concern.

4. *Intermediate-term risk.* Since the short-/intermediate-term incidental oral endpoints are identical, the short-term risk assessments are protective of intermediate-term exposure.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, glyphosate is not expected to pose a cancer risk to humans.

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, or to infants and children from aggregate exposure to glyphosate residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high-performance liquid chromatography (HPLC) equipped with a fluorescence detector method; LOQ = 0.05 ppm) is available to enforce the tolerance expression.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for sweet corn commodities; however, it has established an MRL for residues of glyphosate, per se, in/on

poultry, meat at 0.05 ppm. The U.S. tolerance of 0.10 ppm for poultry, meat is necessarily higher than the Codex MRL to account for residues of both glyphosate and its metabolite N-acetyl glyphosate. N-acetyl glyphosate is found in genetically modified (GMO) glyphosate-resistant commodities, including corn and soybeans; that are used as feed items for poultry in the U.S. Therefore, it is included in the U.S. tolerance expression for poultry but not the Codex expression, accounting for the difference in the established MRLs.

##### *C. Revisions to Petitioned-For Tolerances*

EPA has concluded that a tolerance for residues of glyphosate in or on corn, sweet, kernel plus cob with husk removed at 3.5 ppm is needed because the highest residue from the field trials was 3.1 ppm. Since the proposed forage tolerance (9 ppm) is less than the currently established tolerance for this commodity (100 ppm), EPA has concluded that a revision to the currently established tolerance is unnecessary.

Finally, EPA is revising the tolerance expressions in 40 CFR 180.364(a)(1) and 40 CFR 180.364(a)(2) to clarify the chemical moieties that are covered by the tolerances and specify clearly how compliance with the tolerances is to be measured.

#### **V. Conclusion**

Therefore this regulation changes the established tolerance for residues of glyphosate in or on corn, sweet, grain (at 0.1 ppm) to 3.5 ppm for residues of glyphosate in or on corn, sweet, kernel plus cob with the husk removed. This regulation reduces the established tolerance for residues of glyphosate and N-acetyl-glyphosate in or on poultry, meat from 4.0 ppm to 0.10 ppm. This regulation also changes the tolerance expression for 40 CFR 180.364(a)(1) and (a)(2).

#### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May

22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: March 29, 2011.

**G. Jeffery Herndon,**

*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:

i. Revising the introductory text in paragraph (a)(1), and in the table, revise the entry for corn, sweet, grain 0.1 ppm; to corn, sweet, kernel plus cob with husk removed at 3.5 ppm; and

ii. Revising the introductory text in paragraph (a)(2), and in the table, revise the entry for poultry, meat 4.0 ppm to 0.10 ppm. The revisions read as follows:

**§ 180.364. Glyphosate; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of glyphosate, including its metabolites and degradates, in or on the commodities listed below resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate. Compliance with the following tolerance levels is to be determined by measuring only glyphosate (*N*-(phosphonomethyl)glycine).

Commodity	Parts per million
* * * * *	*
Corn, sweet, kernel plus cob with husk removed .....	3.5
* * * * *	*

(2) Tolerances are established for residues of glyphosate, including its metabolites and degradates, in or on the commodities listed below resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the dimethylamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate. Compliance with the following tolerance levels is to be determined by measuring only glyphosate (*N*-(phosphonomethyl)glycine) and its metabolite *N*-acetyl-glyphosate (*N*-acetyl-*N*-(phosphonomethyl)glycine; calculated as the stoichiometric equivalent of glyphosate).

Commodity	Parts per million
* * * * *	*
Poultry, meat .....	0.10
* * * * *	*

[FR Doc. 2011-8428 Filed 4-7-11; 8:45 am]

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**FEDERAL MARITIME COMMISSION**

**46 CFR Parts 520 and 532**

[Docket No. 10-03]

RIN 3072-AC38

**Non-Vessel-Operating Common Carrier Negotiated Rate Arrangements; Correction**

April 5, 2011.

**AGENCY:** Federal Maritime Commission.

**ACTION:** Final rule; correction.

**SUMMARY:** The Federal Maritime Commission is correcting a final rule that appeared in the **Federal Register** on March 2, 2011, exempting licensed non-vessel-operating common carriers that enter into negotiated rate arrangements from the tariff rate publication requirements of the Shipping Act of 1984. This correction clarifies that the negotiated rate arrangement must be agreed to prior to receipt of the cargo and removes the requirement that non-vessel-operating common carriers indicate their intention to move cargo under negotiated rate arrangements on their Form FMC-1 on file with the Commission.

**DATES:** Effective April 18, 2011.

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