

Exhibit 7

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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.gov/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., 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,

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 than 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 exposure 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-(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 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