Exhibit 5

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300469; FRL–5598–6]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes permanent tolerances for residues of the herbicide glyphosate [*N*-(phosphonomethyl)glycine] in or on the raw agricultural commodities (RACs) corn, field, grain; corn, field, stover; corn, field, forage; aspirated grain fractions; sorghum, grain; sorghum, grain, stover; and oats. The residues from the treatment of field corn include residues in or on field corn varieties which have been genetically modified to be tolerant of glyphosate. Monsanto Company submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub L. 104–179) requesting the tolerances.

EFFECTIVE DATES: These regulations become effective April 11, 1997. Written objections must be submitted by June 10, 1997.

ADDRESSES: Written objection and hearing requests, identified by the docket control number, [OPP–300469; PP 8F3672, 8F3673, 5F4555, 6E4645], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing request filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to: Rm. 1132, CM#2, 1921 Jefferson Davis Highway., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300469; PP 8F3672, 8F3673, 5F4555, 6E4645]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submission can be found in Unit XIII. of this document.

FOR FURTHER INFORMATION CONTACT: By mail, Philip V. Errico, Product Manager, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 241, CM #2, 1921 Jefferson Davis Highway., Arlington, VA, (703)–305–6027; e-mail: errico.philip@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 24, 1996 (61 FR 67804)(FRL–5576–6), EPA issued a Notice of Filing amending petitions PP 8F3672, 8F3673, 5F4555, 6E4645 to bring the petitions into conformity with the Food Quality Protection Act (FQPA of 1996). The notice contained a summary of the petitions prepared by the petitioner and the summary contained conclusions and arguments to support its conclusion that the petitions complied with FPQA. In that notice Monsanto Company, 700 14th Street, NW., Suite 1100, Washington, DC 20005 proposed amending 40 CFR 180.364 by establishing a regulation to permit residues of the herbicide glyphosate (*N*-(phosphonomethyl)glycine) resulting from the application of the isopropylamine salt and/or the monoammonium salt of glyphosate in or on the raw agricultural commodities (RACs) field corn grain at 1.0 ppm; field corn forage at 1.0 ppm; field corn fodder at 100 ppm; aspirated grain fractions at 200 ppm; grain sorghum at 15 ppm; grain sorghum fodder at 40 ppm; and oats at 20 ppm. The notice stated that PP 5F4555 specifically related to field corn which had been genetically modified to be tolerant to glyphosate.

The Agency received one comment opposing the tolerances. The commentor‘s objection was based on concerns of (1) Enhanced exposure of the public to glyphosate and other ingredients of the Roundup formulations, (2) greater use of Roundup/glyphosate which will result in adverse effects to the environment and human health, and (3) exposure of the public to Roundup from consumption of the corn or the animal product from animals fed corn. EPA‘s response to this comment is provided below.

The Agency determined that the terminology for field corn grain, field corn, forage; field corn, fodder; aspirated grain fractions; grain sorghum, and grain sorghum, fodder; should be corrected to read corn, field, grain; corn, field, stover; corn, field, forage; aspirated grain fractions; sorghum, grain; and sorghum, grain, stover; The subject regulation is therefore amended accordingly.

The data submitted in the petitions and other relevant material have been evaluated. The glyphosate toxicological data listed below were considered in support of these tolerances.

I. Toxicological Profile

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

2. A 1–year feeding study with dogs fed dosage levels of 0, 20, 100, and 500 milligrams/kilogram/day (mg/kg/day) with a no-observable-effect level (NOEL) of 500 mg/kg/day.

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

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

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

4. *Acute illnesses and skin and eye irritation—EPA response.* Data indicate that technical-grade glyphosate is in Toxicity Category III and Toxicity Category IV and that technical glyphosate is not a dermal sensitizer. Some formulations of glyphosate are in Category I and II where skin and eye irritation were associated with acute illnesses. Some of these formulations are being phased out of the U.S. market. Handlers and users of remaining formulations in Category I and II are expected to be adequately protected by the protective clothing requirements of the Worker Protection Standards (WPS). Data reviewed by the Agency on current formulations place these formulations in Toxicity Category III and IV.

5. *Carcinogen, mutagen and reproductive toxicity—EPA response.* Data indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans, causes no pre- or post-natal effects in any study absent maternal toxicity, and is not a mutagen (refer to toxicology discussion above for a detailed discussion of carcinogenicity, reproductive, developmental and mutagenicity testing).

6. *Formaldehyde—EPA response.* Available rat metabolism data, residue data, and environmental data indicate that the major metabolite of glyphosate is AMPA which is further degraded by soil microbes to CO_2. The Agency has determined that AMPA is not of toxicological concern. (Glyphosate Reregistration Eligibility Decision (RED) issued by EPA September 1993). Available data do not indicate that formaldehyde is a metabolite or a degradate of glyphosate.

7. *Decreased lung function—EPA response.* Data reviewed by the Agency for glyphosate formulations for acute inhalation place most glyphosate formulations in Toxicity Category III and IV for acute inhalation. The Agency believes that handlers of these formulations and any formulations that may be Toxicity Category I or II are expected to be adequately protected by the protective clothing required by WPS.

8. *Interference with enzymes—EPA response.* The mode of action for glyphosate does involve interference with enzymes that result in the death of plants by inhibiting the biosynthesis of aromatic amino acids which along with other biochemical changes results in the death of plants. This is a common mode of action for various pesticides, but the Agency has no information that indicates that the handling or ingestion of glyphosate in small amounts result in interference with enzymes in the human body.

9. *Inert Ingredients.* The commentor also contended that EPA must examine the toxicity of the inert ingredients in glyphosate products in setting these tolerances.

EPA response. These tolerances establish maximum legal levels of residues of the active ingredient glyphosate that can be present in certain foods. These tolerances do not legalize any inert ingredients in glyphosate products. If a pesticide product also contains inert ingredients, those inert ingredients must have tolerances or exemptions from the requirement or their presence in food will render the food adulterated. Before approving a pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., EPA checks to make sure that all needed tolerances or exemptions are in place. All inerts present in current glyphosate formulations for use on food crops either have tolerances or exemptions from tolerances. Additionally, under the FIFRA registration process, EPA evaluates the potential risks posed by inert ingredients. The Agency requires a full disclosure of inert ingredients for each Roundup formulation to determine acute toxicity such as acute eye, skin, inhalation, and dermal sensitization. Refer to previous discussions on skin, eye, and acute inhalation for discussion of formulations.

10. *Persistence in soil.* The commenter claimed that glyphosate persists in soils from 3 to 141 days.

EPA response. Data from background field dissipation trials from eight sites show that the median half-life (DT50) for glyphosate applied at maximum use rates was 13.9 days with a range of 2.6 (Texas) to 140.6 (Iowa) days. Acceptable aerobic soil, aerobic aquatic, and anaerobic aquatic metabolism studies demonstrate that under those conditions at 25 °C in the laboratory, glyphosate degrades rapidly with half-lives of approximately 2,7, and 8 days respectively. The reported half-lives from the field studies conducted in the coldest climates, i.e. Minnesota, New York, and Iowa, were the longest at 28.7 days, 127.8 days, and 140.6 days respectively indicating that glyphosate residues in the field are somewhat more persistant in cooler climates as opposed to milder ones (Georgia, California, Arizona, Ohio, and Texas. AMPA was the major degradate in all studies. AMPA has been determined to not be of toxicological concern. (Glyphosate Reregistration Eligibility Decision (RED) issued by EPA September, 1993).

11. *Environmental effects.* The commenter also claimed that data was lacking regarding glyphosate's toxicity to soil invertebrates, reptiles, and amphibians.

EPA response. Environmental Effects are considered under FIFRA. In examining glyphosate under FIFRA the Agency required several tests with mammals; acute tests to birds, fish, aquatic invertebrates, and bees; subacute dietary testing on birds; avian reproduction; and chronic testing on freshwater fish and freshwater invertebrates. Data submitted to and reviewed by the Agency indicate that effects to birds, mammals, fish, and invertebrates are minimal. (Glyphosate Registration Eligibility Decision (RED) issued by EPA September, 1993).

XII. Objections and Hearing Requests

The new FFDCA section 408 (g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under the new section 408 (e) and (1)(6) as was provided in the old section 408 and section 409. However, the period for filing objections is 60 days rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person adversely affected by this regulation may, by June 10, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given below (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which the hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and