

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 (NAIC 111)
- Animal production (NAIC 112)
- Food manufacturing (NAIC 311)
- Pesticide manufacturing (NAIC 32532)

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0155. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgrstr/>. A frequently updated electronic version of 40 CFR part 180 is available at <http://www.access.gpo.gov/nara/cfr/>

www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select “search,” then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of April 17, 2002 (67 FR 18894) (FRL-6830-5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170), announcing the filing of a number of pesticide petitions by Monsanto, 600 13th St., NW., Suite 660, Washington, DC 20005. The notice included a summary of the petition prepared by Monsanto, the registrant. Comments received in the public docket with respect to the Notice of Filing were addressed in the final rule publication in the **Federal Register** of September 27, 2002 (67 FR 60934) (FRL-7200-2), and will not be presented again here in this final rule.

The petitions requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate in or on corn, field, forage at 6 ppm; by reducing the tolerance on aspired grain fractions from 200 ppm to 100 ppm. In addition, the Agency is taking this opportunity to change the commodity definition from aspired grain fractions to grain, aspired fractions; deleting the existing tolerance for soybean, aspired grain fractions at 50.0 ppm since these soybean fractions are included in the “grain, aspired fractions” tolerance described above; and by deleting the existing tolerance for animal, feeds, nongrass group, except alfalfa at 200 ppm, which is now included in the established tolerance for animal feed, nongrass, group at 400 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of the 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 the 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 the 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 the 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 the FFDCA, for a tolerance for residues of glyphosate on grain, aspired fractions at 100 ppm and corn, field, forage at 6.0 ppm. EPA's assessment of exposures and risks associated with establishing glyphosate tolerances for a number of feed commodities was performed previously and was presented in detail in the final rule on Glyphosate Pesticide Tolerances (67 FR 60934, September 27, 2002) (FRL-7200-2). Given that higher tolerances for glyphosate are currently established for other significant animal feed commodities, the dietary burden for cattle, poultry, and hogs will be unaffected by a glyphosate tolerance for aspired grain fractions at 100 ppm and corn, field, forage at 6.0 ppm. EPA estimates a worst-case dietary burden for livestock animals by assuming an animal consumes dietary feeds bearing the highest permitted residues. In the case of glyphosate, the dietary feed bearing the highest permitted residue is alfalfa hay as the roughage component of the diet with a tolerance of 400 ppm whereas only 6 ppm of glyphosate is permitted in corn forage and 100 ppm in grain, aspired fractions.