

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/fedrgstr/A> frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.html/>.

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 May 14, 2003 (68 FR 25883) (FRL-7301-3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 9F6050) by Dow AgroSciences LLC, 9330 Zionville Road, Indianapolis, IN 46268. That notice included a summary of the petition prepared by Dow AgroSciences LLC, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.535 be amended by establishing tolerances for combined residues of the herbicide fluroxypyr 1-methylheptyl ester [(4-amino-3,5-dichloro-6-fluoro-2-

pyridinyl)oxy) acetic acid, 1-methylheptyl] and its metabolite fluroxypyr [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy) acetic acid], free and conjugated, all expressed as fluroxypyr, in or on the following raw agricultural commodities: Sweet corn at 0.02 parts per million (ppm) for kernels plus cob with husk removed, and forage and stover at 1.0 ppm. Tolerances for residues of fluroxypyr in or on field corn are being proposed in support of this registration as follows: grain, 0.02 ppm; forage, 1.0 ppm; and stover, 0.5 ppm. Tolerances for residues of fluroxypyr in or on sorghum as follows: Grain, 0.02 ppm; forage, 2.0 ppm; and stover, 4.0 ppm. Tolerances for residues of fluroxypyr in or on grasses as follows: Forage, 120 ppm; hay, 160 ppm; and grass silage, 100 ppm. Increased tolerances are also proposed for fluroxypyr in or on the following animal commodities: Milk of cattle, goats, hogs, horses and sheep at 0.3 ppm; and kidney of cattle, goats, hogs, horses and sheep at 1.5 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 tolerances for combined residues of fluroxypyr on or in field corn, grain at 0.02 ppm; field corn, forage at 1.0 ppm; field corn, stover at 0.5 ppm; on or in sweet corn, kernels plus cob with husks removed at 0.02 ppm; sweet corn, forage at 1.0 ppm; sweet corn, stover at 2.0 ppm; on or in sorghum, grain at 0.02 ppm; sorghum, forage at 2.0 ppm; sorghum, stover (fodder) at 4.0 ppm; on or in grass, forage at 120 ppm; grass, hay at 160 ppm; and a tolerance for combined residues of fluroxypyr on cattle, milk; goat, milk; hog, milk; horse, milk; and sheep, milk at 0.3 ppm; and on cattle, kidney; goat, kidney; hog, kidney; horse, kidney; and sheep, kidney at 1.5 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 fluroxypyr are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity—Rats	NOAEL = 700 milligram/kilogram/day (mg/kg/day) LOAEL = 1,000 mg/kg/day based on decreased body weight gain & testis weight (M), decreased brain weight (F), and increased kidney weight (M/F).
870.3100	90-Day oral toxicity—Mice	NOAEL = 1,342 mg/kg/day (Males)/ 1,748 mg/kg/day (Females) LOAEL not established.