

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 7, 2003 (68 FR 24458) (FRL-7303-7), 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 9F6060) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide, thiacloprid, in or on apple, wet pomace; cattle, meat and meat byproducts; cotton, gin byproducts;

cotton, undelinted seed; fruit, pome, group 11; and milk at 0.6; 0.2; 11.0; 1.0; 0.3; and 0.1 parts per million (ppm), respectively. Upon review and evaluation of the data submitted in support of the petition, the Agency determined that the residues of concern are thiacloprid plus metabolites retaining the thiazolidine ring intact. Excluded from the residues of concern are metabolites such as 6-nicotinic acid (6-CNA) for which the thiazolidine ring is broken. These metabolites are excluded based on the finding that the toxic effects of thiacloprid are considered to be associated with the entire thiacloprid molecule (with both the thiazolidine ring and the chloropyridine ring intact). Because metabolism and degradation studies have shown that the thiazolidine ring is less stable than the chloropyridine ring, it is understood that metabolites retaining the thiazolidine ring also retain the chloropyridine ring intact.

Metabolites retaining the thiazolidine ring generally constitute most of the residue in foods and feeds. The petition was subsequently revised to:

1. Request that 40 CFR part 180 be amended by establishing tolerances for the insecticide thiacloprid in or on the commodities: Meat, meat byproducts, liver, fat, and kidney of sheep, goat and horse; liver; fat and kidney of cattle; and

2. Lowering the previously proposed tolerance levels for the food commodities, cattle, meat from 0.2 ppm to 0.03 ppm; cattle, meat byproducts from 0.2 ppm to 0.05 ppm; cotton, undelinted seed from 1.0 ppm to 0.02 ppm and milk from 0.1 ppm to 0.03 ppm based on measurement of thiacloprid per se rather than measurement of the common moiety, 6-nicotinic acid (6-CNA) upon which the original proposed tolerances were based; as summarized in Table 1 of this unit.

TABLE 1—PROPOSED TOLERANCE LEVELS FOR FOOD COMMODITIES.

Commodity	Original, Measured as 6-CNA (ppm)	Revised, Measured as Thiacloprid (ppm)
Apple, wet pomace	0.6	0.6
Cattle, meat	0.2	0.03
Cattle, meat byproducts	0.2	0.05
Cotton, gin byproducts	11.0	11.0
Cotton, undelinted seed	1.0	0.02
Cattle, sheep, goat and horse fat		0.02
Cattle, sheep, goat and horse kidney		0.05
Cattle, sheep, goat and horse liver		0.15
Fruit, pome, group 11	0.3	0.3
Milk	0.1	0.03
Sheep, goat and horse meat		0.03
Sheep, goat and horse meat byproducts		0.05

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 tolerances for combined residues of thiacloprid and metabolites