

Genetic Engineering Committee. A response to these comments is provided in Unit VI.

In the **Federal Register** of August 21, 2002 (67 FR 54196) (FRL-7190-9), 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 2E6404) by Interregional Research Project Number 4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petition prepared by IR-4, the petitioner. There were no comments received in response to the notice of filing.

In the **Federal Register** of August 15, 2003 (68 FR 48908) (FRL-7322-9), 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 amended pesticide petitions (PP 0F6140 and PP 0F6210) by Bayer CropScience, PO Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by Bayer CropScience. Two hundred and sixty five comments were filed. A response to these comments is provided in Unit VI.

The petitions requested that 40 CFR 180.473(a)(1) be amended by establishing tolerances for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolite, 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents in or on the raw agricultural commodities derived from cotton, undelinted seed at 3.5 parts per million (ppm) and gin byproducts at 12.0 ppm; and blueberry, lingonberry, junberry and salal at 0.10 ppm and that 40 CFR 180.473(a)(2) be amended by establishing tolerances for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolites, 3-methylphosphinico-propionic acid, and 2-acetamido-4-methylphosphinico-butanoic acid expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents in or on the raw agricultural commodities derived from transgenic cotton tolerant to glufosinate ammonium: undelinted seed at 3.5 ppm and gin byproducts at 12.0 ppm and transgenic rice tolerant to glufosinate ammonium: grain at 1.0 ppm, straw at 1.6 ppm.

IR-4 and Bayer CropScience subsequently amended the petitions to

request that 40 CFR 180.473(a)(1) be amended by establishing tolerances for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents, in or on the following food commodities: Bushberry subgroup, lingonberry, junberry and salal at 0.15 ppm, cattle, fat at 0.40 ppm, cattle, meat at 0.15 ppm, cattle, meat byproducts at 6.0 ppm, cotton, gin byproducts at 15 ppm, cotton, undelinted seed at 4.0 ppm, egg at 0.15 ppm, goat, fat at 0.40 ppm, goat, meat at 0.15 ppm, goat, meat byproducts at 6.0 ppm, hog, fat at 0.40 ppm, hog, meat at 0.15 ppm, hog, meat byproducts at 6.0 ppm, horse, fat at 0.40 ppm, horse, meat at 0.15 ppm, horse, meat byproducts at 6.0 ppm, Milk at 0.15 ppm, poultry, fat at 0.15 ppm, poultry, meat at 0.15 ppm, poultry, meat byproducts 0.6 ppm, sheep, fat at 0.40 ppm, sheep, meat at 0.15 ppm, and sheep, meat byproducts at 6.0 ppm.

Bayer CropScience subsequently amended the petitions to request that 40 CFR 180.473(a)(2) be amended by establishing tolerances for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents, in or on the following raw agricultural and processed commodities derived from transgenic cotton and rice that are tolerant to glufosinate ammonium: Cotton, gin byproducts at 15 ppm, cotton, undelinted seed at 4.0 ppm, rice, grain at 1.0 ppm, rice, straw at 2.0 ppm, and rice, hull at 2.0 ppm. These amendments were included in the August 15, 2003 notice of filing.

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 combined residues of glufosinate ammonium and its metabolites on bushberry subgroup, lingonberry, junberry and salal at 0.15 ppm, cattle, fat at 0.40 ppm, cattle, meat at 0.15 ppm, cattle, meat byproducts at 6.0 ppm, cotton, gin byproducts at 15 ppm, cotton, undelinted seed at 4.0 ppm, egg at 0.15 ppm, goat, fat at 0.40 ppm, goat, meat at 0.15 ppm, goat, meat byproducts at 6.0 ppm, hog, fat at 0.40 ppm, hog, meat at 0.15 ppm, hog, meat byproducts at 6.0 ppm, horse, fat at 0.40 ppm, horse, meat at 0.15 ppm, horse, meat byproducts at 6.0 ppm, milk at 0.15 ppm, poultry, fat at 0.15 ppm, poultry, meat at 0.15 ppm, poultry, meat byproducts at 0.60 ppm, sheep, fat at 0.40 ppm, sheep, meat at 0.15 ppm, and sheep, meat byproducts at 6.0 ppm, cotton, gin byproducts at 15 ppm, rice, grain at 1.0 ppm, rice, straw at 2.0 ppm, and rice, hull at 2.0 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