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II. Background and Statutory Findings

In the **Federal Register** of December 6, 2002 (67 FR 72678) (FRL-7283-3) and the **Federal Register** of January 3, 2003 (68 FR 370) (FRL-7283-4), EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of pesticide petitions (PP 6F4746 and PP 1E6286, respectively) by BASF. The notices included a summary of the petitions prepared by BASF, the registrant. There were no comments received in response to the notices of filing.

Petition 6F4746 requested that 40 CFR 180.447 be amended by establishing a tolerance for combined residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid as its ammonium salt, and its metabolite 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid both free and conjugated, in or on non-grass animal feed crops, forage, hay, and seed at 3.0 parts per million (ppm). Petition 1E6286 requested that 40 CFR 180.447 be amended to establish a tolerance for the sum of the residues of the herbicide imazethapyr 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridinecarboxylic acid as its free acid or its ammonium salt (calculated as the acid), and its metabolite 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridinecarboxylic acid on canola seed at 0.1 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).

After analysis of the submitted residue chemistry data, EPA determined that appropriate tolerances for nongrass animal feed differ from those proposed by the registrant. EPA determined that available field trial data support the following tolerances for the combined residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, and its metabolites 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid and 5-[1-(beta-D-glucopyranosyloxy)ethyl]-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid, applied as its free acid or ammonium salt, in or on the following raw agricultural commodities: Animal feed, nongrass, group, forage - 3.0 ppm; animal feed, nongrass, group, hay - 5.5 ppm; alfalfa, seed - 0.15 ppm; and alfalfa, seed screenings - 0.15 ppm. The currently established alfalfa forage and alfalfa hay tolerances will be removed since they will be covered by the new nongrass animal feed forage and hay group tolerances. The tolerance for canola seed will be established for residues of the parent compound, imazethapyr, only. Finally, EPA determined that tolerances of 0.10 ppm for imazethapyr and the metabolite 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid need to be established for meat byproducts of cattle, goat, hog, horse, and sheep; the registrant did not propose tolerances for these commodities. EPA determined that tolerances are not needed for eggs; milk; meat and fat of cattle, goat, hog, horse, and sheep; and poultry commodities because there is no reasonable expectation of finite residues based on the calculated maximum total dietary burdens and the results of the poultry metabolism study.

The data for nongrass animal feeds and canola were used in the aggregate risk assessment that was calculated to

support establishing tolerances for rice commodities, and the risk discussion in the following Unit III. will frequently refer back to that final rule (FR notice dated August 29, 2002, 67 FR 55323) (FRL-7193-4).

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 residues of imazethapyr in/on canola seed at 0.10 ppm, and for combined residues of imazethapyr on nongrass animal feed at 3 ppm for forage, 5.5 ppm for hay, and additional tolerances of 0.15 ppm for alfalfa seed and alfalfa seed screenings. 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 imazethapyr are discussed in Unit III. A. of the final rule that established imazethapyr tolerances in or on rice, crayfish, and meat byproducts of certain cattle (FR notice dated August 29, 2002, 67 FR 55323).

B. Toxicological Endpoints

The toxicological endpoints for imazethapyr are discussed in Unit III. B. of the final rule that established imazethapyr tolerances in or on rice, crayfish, and meat byproducts of certain cattle (FR notice dated August 29, 2002, 67 FR 55323).

C. Exposure Assessment

The exposure assessment for imazethapyr are discussed in Unit III. C. of the final rule that established imazethapyr tolerances in or on rice, crayfish, and meat byproducts of certain cattle (FR notice dated August 29, 2002, 67 FR 55323).

D. Safety Factor for Infants and Children

The safety factors for infants and children for imazethapyr are discussed in Unit III. D. of the final rule that