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II. Background and Statutory Findings

In the **Federal Register** of September 26, 1997 (62 FR 50610) (FRL-5740-2), 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 7F4850) by AgrEvo. Since 1997, by a series of mergers, AgrEvo became Aventis Crop Science and then Bayer CropScience. That notice included a summary of the petition prepared by AgrEvo, now doing business as Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.509 be amended by establishing permanent tolerances for the combined residues of the herbicide safener, mefenpyr-diethyl, 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1H-pyrazole-3,5-dicarboxylic acid, diethyl ester, in or on wheat and barley commodities.

In the **Federal Register** of August 8, 1997 (62 FR 42678) (FRL-5731-7), EPA, on its own initiative, pursuant to section 408(e) and (1)(6) of the FFDCA, established time-limited tolerances for the inert ingredient herbicide safener, mefenpyr-diethyl, and its 2,4-dichlorophenyl-pyrazoline metabolites in or on wheat grain and wheat straw. This action was in response to EPA's

granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of mefenpyr-diethyl on wheat grain and wheat straw in North Dakota and Montana.

Similarly, mefenpyr-diethyl time-limited tolerances were established by the Agency in the **Federal Register** of September 9, 1998 (63 FR 48116) (FRL-6024-7), in or on barley grain, barley hay, barley straw, and the processed by-products of barley grain: pearled barley, bran and flour. This action was in response to EPA's granting of an emergency exemption under FIFRA section 18 authorizing use of mefenpyr-diethyl on barley in North Dakota.

These time-limited tolerances have been extended as the petitioner has continued data generation. (See the **Federal Register** of May 6, 1998 (63 FR 24939) (FRL-5788-1); the **Federal Register** of November 22, 1999 (64 FR 63711) (FRL-6385-5); and the **Federal Register** of December 14, 2001 (66 FR 64768) (FRL-6814-2)). The extensions of these time-limited tolerances were consistent with the safety standard (FFDCA section 408(b)(2)) and FIFRA section 18. Currently, the time-limited tolerances under 40 CFR 180.509(b) expire on December 31, 2003. As the permanent tolerances are established, these emergency exemption time-limited tolerances are no longer necessary and will be revoked.

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 mefenpyr-diethyl on wheat and barley commodities. EPA's assessment of exposures and risks associated with establishing the tolerances 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 mefenpyr-diethyl 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	Subchronic feeding studies in mouse	NOAEL = 89.3/105.4 mg/kg/day (milligram/kilogram/day), male and female (M/F) LOAEL = 449.0/523.5 mg/kg/day (M/F) based on decreased body and kidney weight, increased liver weight and hepatocyte hypertrophy in males; decreased bilirubin and increased lactic acid dehydrogenase values in females