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II. Background and Statutory Findings

In the **Federal Register** of January 28, 1998 (63 FR 4252) (FRL-5763-6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 5E4503) by Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167.

This notice included a summary of the petition prepared by Monsanto Company, the petitioner. There were no comments received in response to the notice of filing.

Previously, time-limited tolerances had been established (40 CFR 180.465) for the residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in or on corn commodities (April 14, 1993) (58 FR 19387). These tolerances expired on January 31, 1998.

In the above mentioned pesticide petition (5E4503) Monsanto Corporation requested permanent tolerances for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane in or on corn commodities at 0.005 ppm.

The petitioner asked in a letter dated January 15, 2002, that 40 CFR 180.465 be amended by establishing an import tolerance for residues of the herbicide safener 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in or on corn commodities at 0.005 parts per million (ppm) with no U.S. registrations.

In the United States a tolerance is the maximum residue level of a pesticide permitted in or on food or feed grown in the United States and food or feed imported into the United States from other countries. Typically, EPA would establish tolerance(s) or exemption(s) from the requirement of a tolerance at the same time that it registered the use of a pesticide for that commodity in the United States. Where no U.S. registration exists, interested persons may submit a petition requesting that EPA establish an import tolerance for a pesticide residue that would allow treated food to be legally imported into the United States. The term "import tolerance" is used as a convenience to refer to a tolerance that exists where there is no accompanying registration under the Federal Insecticide, Fungicide, Rhodenticide Act (FIFRA). There is no statutory or regulatory distinction between an "import tolerance" and any other tolerance issued by EPA. The same food safety standards apply to both domestically produced and imported food.

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 residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane on corn commodities at 0.005 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 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane are discussed in the following Table 1 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.