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II. Background and Statutory Findings

In the **Federal Register** of August 14, 2002 (67 FR 52996) (FRL-7191-9), 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 2E6441 by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing. In the **Federal Register** of March 21, 2003 (68 FR 13917) (FRL-7297-1), 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 pesticide petitions (3E6527, 3E6528, and 3E6533) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.544 be amended by establishing tolerances for residues of the insecticide methoxyfenozide, benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide, in or on cranberry at 0.5 parts per million (ppm); okra at 2.0 ppm; pea, blackeyed, seed at 4.0 ppm; pea, southern, seed at 4.0 ppm; turnip, greens at 30 ppm; and vegetable, cucurbit, group 9 at 0.3 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 November 26, 1997 (62 FR 62961) (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 residues of methoxyfenozide on cranberry at 0.5 ppm; okra at 2.0 ppm; pea, blackeyed, seed at 4.0 ppm; pea, southern, seed at 4.0 ppm; turnip, greens at 30 ppm; and vegetable, cucurbit, group 9 at 0.3 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

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 methoxyfenozide is discussed in Unit II.A. of the **Federal Register** of September 20, 2002 (67 FR 59193) (FRL-7198-5).

B. Toxicological Endpoints

The dose at which no observed adverse effects levels are (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern. However, the lowest dose observed at which adverse effects levels of concern are identified (the LOAEL) is sometimes used for risk assessment if no

NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure/exposures}$) is calculated. A summary of the toxicological endpoints for methoxyfenozide used for human risk assessment is discussed in Unit II.B. of the **Federal Register** of September 20, 2002 (67 FR 59193).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.544) for the