

water, respectively. The modeling was conducted based on the environmental profile and the maximum seasonal application rate proposed for methoxyfenozide (1.0 lb active ingredient/acre/season). PRZM/EXAMS was used to generate the surface water EECs, because it can factor the persistent nature of the chemical into the estimates.

The EECs for assessing chronic aggregate dietary risk used by the Agency are 6 parts per billion (ppb) in ground water, based on SCI-GROW and 98.5 ppb in surface water, based on the PRZM/EXAMS, long-term mean.

2. Non-dietary exposure.

Methoxyfenozide is not currently registered for use on any residential non-food sites. Therefore, there is no non-dietary acute, chronic, short-term or intermediate-term exposure.

D. Cumulative Effects

Section (408)(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA does not have, at this time, available data to determine whether methoxyfenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, it is assumed that methoxyfenozide does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Using the DEEMTM exposure assumptions described in this unit, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 18.9% of the chronic pollution adjusted dose (cPAD) for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1–6 years old at 37.6% of the cPAD and is discussed below. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential

for exposure to methoxyfenozide in drinking water, the aggregate exposure is not expected to exceed 100% of the cPAD. Dow AgroSciences concludes that there is a reasonable certainty that no harm will result from aggregate exposure to methoxyfenozide residues.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (UF) usually 100 for combine inter-species and intra-species variability and not the additional tenfold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

The toxicology data base for methoxyfenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a 2-generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methoxyfenozide. There is a complete toxicity data base for methoxyfenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the data base and the lack of prenatal and postnatal toxicity, EPA determined that an additional safety factor was not needed for the protection of infants and children.

Since no toxicological endpoints were established, acute aggregate risk is considered to be negligible. Using the exposure assumptions described in this unit, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 37.6% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

Drinking water. The back-calculated drinking water levels of concern (DWLOCs) for assessing chronic aggregate dietary risk range from 624 ppb for the most highly exposed population subgroup children (1 to 6) years old to 2,839 ppb for the U.S. population (48 contiguous States) (all seasons). Despite the potential for exposure to methoxyfenozide in drinking water, Dow AgroSciences does not expect the aggregate exposure to exceed 100% of the cPAD. Short-term and intermediate-term risks are judged to be negligible due to the lack of significant toxicological effects observed. Based on these risk assessments, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to methoxyfenozide residues.

F. International Tolerances

There are no Codex or Canadian maximum residue levels (MRL's) established for residues of methoxyfenozide. Mexican MRL's are established for residues of methoxyfenozide in cottonseed 0.05 ppm and maize 0.01 ppm. The U.S. tolerances on these commodities are 2.0 ppm and 0.05 ppm, respectively. Based on the current use patterns, the U.S. tolerance levels cannot be reduced to harmonize with the Mexican MRL's, so incompatibility will exist.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0049; FRL–7295–5]

Tralkoxydim; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0049, must be received on or before April 21, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.