

population utilizing 0.1% of the RfD. A Tier 3 chronic analysis was done using the DEEM™ software, Version 7.76 (Novigen Sciences, Inc.). The 1994–96, 1998 CSFII consumption data from USDA were used. Average anticipated residue values were calculated from the appropriate field trial studies conducted for pyrimethanil. The average residue values were adjusted by the projected PCT at product maturity. Concentration factors derived from processing studies were included where appropriate. Secondary residues were calculated using theoretical dietary burdens derived from sensible diets for beef and dairy cattle and tissue to feed ratios from the ruminant feeding study.

ii. *Drinking water.* U.S. EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was followed to perform the Tier 1 drinking water assessment. This SOP uses a variety of tools to conduct drinking water assessments, including water models such as Screening Concentration in Ground Water (SCI-GROW), FIRST, Pesticide Root Zone Model (PRZMS)/EXAMS, and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface and ground water and the highest levels (whether ground or surface) are assumed to be the drinking water residue. In the case of pyrimethanil, monitoring data are not available. SCI-GROW and FIRST were used to estimate a drinking water residue. Calculation of the Drinking Water Estimate Concentration (DWECC) for surface water for the worst case pyrimethanil use scenario results in an acute DWECC of 122 parts per billion (ppb) and a chronic DWECC of 37 ppb. DWLOCs calculated based on the acute and chronic risk assessments described above are many fold higher than these conservative DWECCs. The adult acute and chronic DWLOCs are 10,146 ppb and 5,944 ppb respectively. Children's acute and chronic DWLOCs are 2,762 ppb and 1,695 ppb respectively.

2. *Non-dietary exposure.* Pyrimethanil products are not labeled for residential uses (food or non-food), thereby eliminating the potential for residential exposure or non-occupational 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." There are no available data to determine

whether pyrimethanil 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, pyrimethanil does not appear to form a toxic metabolite produced by other substances. For the purposes of the tolerance petition and this reduced risk rationale, therefore, it has been assumed that pyrimethanil does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Using the assumptions and data described above, based on the completeness and reliability of the toxicity data, it is concluded that dietary risk from the proposed uses of pyrimethanil are acceptable for all populations examined. Chronic exposure for the U.S. population utilizes 0.1% (0.00015 mg/kg bwt/day) of the cRfD. Acute exposure for the U.S. population utilizes 3.4% (0.01012 mg/kg bwt/day) of the aRfD. The most highly exposed population of children 1–6 utilizes only 0.3% of the cRfD and 7.9% of the aRfD. The actual exposures are likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD (acute or chronic), because the RfD represents the level at or below which exposure will not pose appreciable risk to human health. DWLOC for adults both acute (10,146 ppb) and chronic (5,944 ppb) are several orders of magnitude above the conservative DWECC for acute (122 ppb) and chronic (37 ppb) worst case scenarios. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to residues of pyrimethanil.

2. *Infants and children.* The relevant toxicity studies as discussed in the toxicology section above show no extra sensitivity of infants and children to pyrimethanil, therefore, the FQPA safety factor can be removed. Using the assumptions and data described in the exposure section above, it is concluded that dietary risk from the proposed uses of pyrimethanil are acceptable for all infant and children sub-populations examined. The most highly exposed sub-population was children 1–6 for both the chronic and acute analyses. The sub-population children 1–6 utilizes 0.3% (0.00047 mg/kg bwt/day) of the cRfD and 7.9% (0.02377 mg/kg bwt/day) of the aRfD. All other infant

and children populations have less exposure. The chronic and acute drinking water levels of concern for children (1,695 ppb and 2,762 ppb respectively) are well above the conservative DWECC for chronic and acute scenarios. The chronic DWECC is 37 ppb and the acute DWECC is 122 ppb. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of pyrimethanil.

F. International Tolerances

Maximum residue limits for pyrimethanil have not been established by the Codex Alimentarius Commission.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0027; FRL–7291–1]

Imidacloprid; 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–2003–0027, must be received on or before April 4, 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**.

FOR FURTHER INFORMATION CONTACT: Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5409; e-mail address: daniel.dani@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to: