

iv. *Pet treatment.* Human exposure from the use of imidacloprid to treat dogs and cats for fleas has been addressed by EPA with the conclusion that due to the fact that imidacloprid is not an inhalation or dermal toxicant and that while dermal absorption data are not available, imidacloprid is not considered to present a hazard via the dermal route.

D. Cumulative Effects

Imidacloprid is a chloronicotinyl insecticide. At this time, EPA has not made a determination that imidacloprid and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore, for these tolerance petitions, it is assumed that imidacloprid does not have a common mechanism of toxicity with other substances and only the potential risks of imidacloprid in its aggregate exposure are considered.

E. Safety Determination

1. *U.S. population.* EPA has considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. These studies are discussed under section A (Toxicology Profile) above. The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to *in utero* exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study did not identify any increased sensitivity of rats to *in utero* or post-natal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 MOS will be safe for infants and children. MOS are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors (UF) in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard UF (usually 100 for combined 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/UF.

Although developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, no increased sensitivity in pups as compared to adults was seen in the 2-generation reproduction toxicity study in rats, and the toxicology data base is complete as to core requirements, EPA has determined that the additional safety factor for the protection of infants and children will be retained but reduced to 3x based on the following weight-of-the-evidence considerations relating to potential sensitivity and completeness of the data:

i. There is concern for structure activity relationship. Imidacloprid, a chloronicotinyl compound, is an analog to nicotine and studies in the published literature suggests that nicotine, when administered causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed *in utero*.

ii. There is evidence that imidacloprid administration causes neurotoxicity following a single oral dose in the acute study and alterations in brain weight in rats in the 2-year carcinogenicity study.

iii. The concern for structure activity relationship along with the evidence of neurotoxicity dictates the need of a developmental neurotoxicity study for assessment of potential alterations on functional development. Because a developmental neurotoxicity study potentially relates to both acute and chronic effects in both the mother and the fetus, EPA has applied the additional UF for FQPA for all population subgroups, and in both acute and chronic risk assessments.

Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that the dietary exposure estimates from all label and pending uses of imidacloprid are 7.73% of the aPAD at the 99.9th percentile and 1.4% of the cPAD for the U.S. population. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

2. *Infants and children.* Based on the exposure assessments described above for the safety determination of the U.S. population and on the completeness

and reliability of the toxicity data, it can be concluded that the dietary exposure estimates from all label and pending uses of imidacloprid are 16.42% of the aPAD at the 99.9th percentile and 3.0% of the cPAD for the most sensitive population subgroup, children 1–6 years. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

F. International Tolerances

No CODEX Maximum Residue Levels have been established for residues of imidacloprid on any crops pending in EPA's 2003 work plan.

[FR Doc. 03–5034 Filed 3–4–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0047; FRL–7294–5]

Trifloxystrobin; 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–2003–0047, 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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: jackson.sidney@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: