

petition was transferred to Nippon Soda Company, Ltd., 220 East 42nd Street, Suite 3002, New York, NY 10017.

The petition requested that 40 CFR 180.578 be amended by establishing a tolerance for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on canola seed and mustard seed at 0.01 parts per million (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 (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 acetamiprid on canola seed and mustard seed at 0.01 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 acetamiprid are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity in rats	NOAEL: 12.4/14.6 mg/kg/day (M/F) LOAEL: 50.8/56.0 mg/kg/day (M/F: decreased BW, BW gain and food consumption).
870.3100	90-Day oral toxicity in mice	NOAEL: 106.1/129.4 mg/kg/day (M/F) LOAEL: 211.1/249.1 mg/kg/day (reduced BW and BW gain, decreased glucose and cholesterol levels, reduced absolute organ weights).
870.3150	90-Day oral toxicity in dogs	NOAEL: 13/14 mg/kg/day (M/F) LOAEL: 32 mg/kg/day (reduced BW gain in both sexes).
870.3200	21-Day dermal toxicity in rabbits	NOAEL: 1,000 mg/kg/day (HDT) LOAEL: >1,000 mg/kg/day
870.3700	Developmental toxicity in rats	Maternal NOAEL: 16 mg/kg/day Maternal LOAEL: 50 mg/kg/day (reduced BW and BW gain and food consumption, increased liver weights). Developmental NOAEL: 16 mg/kg/day Developmental LOAEL: 50 mg/kg/day (increased incidence of shortening of the 13 th rib)
870.3700	Developmental toxicity in rabbits	Maternal NOAEL: 15 mg/kg/day Maternal LOAEL: 30mg/kg/day (BW loss and decreased food consumption). Developmental NOAEL: 30 mg/kg/day (HDT) Developmental LOAEL: > 30 mg/kg/day