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II. Background and Statutory Findings

In the **Federal Register** of November 20, 2002 (67 FR 70073) (FRL-7184-7), 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 (1F6428) by Nichino America Incorporated, 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. That notice included a summary of the petition prepared by Nichino America Incorporated, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.585 be amended by establishing tolerances for combined residues of the herbicide pyraflufen-ethyl (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetate) and its acid metabolite, E-1 (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid), expressed as the ester equivalent in or on field corn forage, field corn grain, and field corn stover at 0.01 parts per million (ppm); potato at 0.02 ppm; and soybean forage, soybean hay, and soybean seed at 0.01.

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 pyraflufen-ethyl on field corn forage, field corn grain, and field corn stover at 0.01 ppm; potato at 0.02 ppm; and soybean forage, soybean hay, and soybean seed at 0.01. 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 pyraflufen-ethyl 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 = 5,000 ppm (456–499 milligram/kilogram/day (mg/kg/day)). LOAEL = 15,000 ppm (1,489–1,503 mg/kg/day) based on clinical signs, death, effects on erythrocytes, changes in clinical chemicals for liver function and splenomegaly.
870.3150	90-Day oral toxicity in dogs	NOAEL = 1,000 mg/kg/day. LOAEL not established; no effects observed.
870.3200	28-Day dermal toxicity in rats	NOAEL = 1,000 mg/kg/day. LOAEL not established; no effects observed.
870.3700	Prenatal developmental in rats	Maternal NOAEL ≥ 1,000 mg/kg/day. Maternal LOAEL not determined; no effects observed. Developmental NOAEL ≥ 1,000 mg/kg/day. Developmental LOAEL not determined; no effects observed.
870.3700	Prenatal developmental in rabbits	Maternal NOAEL = 20 mg/kg/day. Maternal LOAEL = 60 mg/kg/day based on mortality. Developmental = 60 mg/kg/day. Developmental LOAEL = 150 mg/kg/day based on increased incidence of abortion.
870.3800	Reproduction and fertility effects	Parental NOAEL = 1,000 ppm (70.8–82.3 mg/kg/day (M); 80.1–91.2 mg/kg/day (F)). Parental LOAEL = 10,000 ppm (721–844 and 813–901 mg/kg/day) based on decreased body weight (bwt) and bwt gains of F ₀ and F ₁ (M) and F ₁ (F), gross and microscopic liver lesions of (M) and (F) both generations. Reproductive NOAEL ≥ 10,000 ppm (721–844 and 813–901 mg/kg/day). Reproductive LOAEL not determined; no effects observed. Offspring NOAEL = 1,000 ppm (70.8–82.3 mg/kg/day (M); 80.1–91.2 (F)). Offspring LOAEL = 10,000 ppm (721–844 and 813–901 mg/kg/day) based on decreased bwt and bwt gains of the F ₁ and F ₂ pups.