

under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summaries of the petitions were prepared by the petitioner and represent the views of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 (IR-4)

PP 3E6519

EPA has received a pesticide petition (3E6519) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of combined residues of fenpyroximate benzoic acid, 4-[[[(E)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[(Z)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-, 1,1-dimethylethyl ester]] in or on the raw agricultural commodity fruit, pome, group 11 at 0.3 parts per million (ppm). Nichino America, Incorporated.

PP 2F6437

EPA has also received a pesticide petition (2F6437) from Nichino America, Inc., 4550 New Linden Hill Road, Wilmington, DE 19808 proposing, pursuant to section 408(d) of the

FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of combined residues of fenpyroximate benzoic acid, 4-[[[(E)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[(Z)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-, 1,1-dimethylethyl ester]] in or on the following raw agricultural commodities: Cotton, undelinted seed at 0.1 ppm, cotton, gin byproducts at 9.0 ppm, apple, fruit at 0.08 ppm, and grape at 0.3 ppm. Additionally, EPA has received request for tolerances for the combined residues of fenpyroximate benzoic acid, 4-[[[(E)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[(Z)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-, 1,1-dimethylethyl ester]] and the acid metabolite ((E)-4-[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)-methyleneamino]oxymethyl benzoic acid (M-3)), all expressed as fenpyroximate in or on milk at 0.01 ppm; meat at 0.02 ppm; fat at 0.8 ppm; kidney at 0.5 ppm; liver at 0.5 ppm; and meat byproducts at 0.01 ppm of cattle, goats, hogs, horses and sheep. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This summary has been prepared by the Nichino American, Inc., Wilmington, DE 19808, the registrant.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of fenpyroximate and z-isomer has been studied in cotton, apples, grapes, and citrus and is adequately understood.

2. *Analytical method.* As a result an enforcement method has been developed which involves extraction of fenpyroximate from crops with acetone, filtration, partitioning and cleanup, and analysis by gas chromatography using a nitrogen/phosphorous detector. This method allows detection of residues at or above the proposed tolerances. The method has undergone independent laboratory validation as required by PR Notices 88-5 and 96-1.

3. *Magnitude of residues—i. Magnitude of residues in crops field residue trials meeting.* EPA study requirements have been conducted at the maximum label rate for cotton, grapes, and pome fruit. Results from

these trials demonstrate that the highest fenpyroximate and z-isomer residues found will not exceed the proposed tolerances when the product is applied following the proposed use directions.

ii. *Magnitude of the residue in animals—*a. *Ruminants.* Maximum residues of fenpyroximate, z-isomer, and acid metabolite in a cattle feeding study demonstrate that the highest fenpyroximate, z-isomer, and acid metabolite, combined as fenpyroximate, will not exceed the proposed tolerances in or on milk (0.01 ppm); meat (0.02 ppm), fat (0.8) ppm, kidneys and liver (0.5) ppm, and meat byproducts (0.01) ppm in cattle, goats, hogs, horses, sheep.

b. *Poultry.* The maximum poultry dietary burden results from a diet composed of cotton meal for a total dietary burden that is significantly lower than the levels that would require the proposal of tolerances in poultry. This conclusion is based on the exaggerated rate field crop studies carried out on fenpyroximate and the z-isomer. Therefore, an exemption from tolerances in poultry meat, poultry meat by-products, fat and eggs under 40 CFR 180.6(a)(3) and (b) is proposed as it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

B. Toxicological Profile

A full description of the studies describing the toxicity of fenpyroximate can be found in the posting for the import tolerances on hops and wine grapes in the **Federal Register** of April 10, 2001 (66 FR 18561) (FRL-6773-2).

1. *Animal metabolism.* The qualitative nature of the residues of fenpyroximate and z-isomer and acid metabolite, in animals is adequately understood. Fenpyroximate was not metabolized to volatiles to any significant degree. The majority of either benzyl or pyrazole labels (approximately 70% to 92%) is excreted in the feces. Urinary excretion accounts for less (approximately 9% to 18%) of the label. Thus, feces and urine are the major routes of excretion for fenpyroximate. Tissue did not accumulate fenpyroximate or its metabolites to any great extent. The greatest levels of label were in liver, kidneys, adrenals, and fat (to a lesser degree). In blood, nearly all the label is in the plasma.

2. *Endocrine disruption.* Chronic, lifespan, and multigenerational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal any endocrine effects for fenpyroximate. Any endocrine-related effects would have been detected in this