

Dated: February 6, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioners summaries of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Bayer CropScience, and represents the view 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.

Bayer CropScience

Interregional Research Project Number 4 (IR-4)

PP 0F6122, PP 3E6518, and PP 3E6538

EPA has received pesticide petitions (OF6122 and 3E6538) from Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709 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 tolerances for residues of spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine in or on the raw agricultural commodities as follows:

1. PP 0F6122 proposes tolerances for grape at 1.0 parts per million (ppm) and grape, raisin at 1.3 ppm.

2. PP 3E6538 proposes a tolerance for banana at 3.0 ppm.

In addition, EPA has received a pesticide petition (3E6518) from the Interregional Research Project Number 4 (IR-4), Technology Centre of New Jersey, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing tolerances for residues of spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine in or on the raw agricultural commodity hop at 11.0 parts per million (ppm).

EPA has determined that the petitions contains 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 notice includes a summary of all three petitions prepared by Bayer CropScience, the manufacturer of spiroxamine.

A. Residue Chemistry

1. *Plant metabolism.* Banana and grape plant metabolism studies have been conducted, and the nature of the residue is adequately understood. Animal metabolism studies are not required since none of the proposed crops to be treated with spiroxamine are fed to livestock per EPA's Table 1. Raw Agricultural and Processed Commodities and Feedstuffs Derived from Crops.

2. *Analytical method.* A method to determine the total residues of spiroxamine using gas chromatography has been submitted to EPA. In addition, spiroxamine has been evaluated using the multi-residue methodologies as published in the Food and Drug Administration (FDA) Pesticide Analytical Manual, Volume I.

3. *Magnitude of residues*—i. *Grape.* Field trials were conducted at 12 locations to evaluate the quantity of spiroxamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine, residues in grape (fruit) following treatment of grape vines with KWG 4168 300 CS. In the 11 harvest experiments conducted, duplicate treated and single control samples of grape (fruit) were collected at 26 to 29 days following the final application of KWG 4168 300 CS. In the single decline experiment, duplicate samples of treated grape (whole fruit) were collected at 21–28–, 34–, and 42–day pre-harvest intervals (PHIs). In all trials, the highest average field trial (HAFT) residue of spiroxamine observed in grape was 0.61 ppm.

A study to evaluate the quantity of the residues of spiroxamine in grape processed commodities following two foliar spray applications of KWG 4168 300 CS was conducted in which KWG 4168 300 CS was applied to the grape vines at 50% fruit maturity (56–day PHI), and at 80% fruit maturity (28–day PHI), using an airblast sprayer. Control and treated grapes were harvested at 28 days after the second application of KWG 4168 300 CS. The grape juice and raisins were evaluated for the residues. Total spiroxamine residues in the processed commodities were 0.434 ppm in grape juice and 0.831 ppm in raisins. The concentration factor for spiroxamine residues in raisins was 1.3X. No concentration of spiroxamine residues occurred in grape juice. Therefore, a tolerance of 1.3 ppm is being proposed for residues of

spiroxamine in raisin, and no tolerance is needed for grape juice.

ii. *Hops.* IR-4 has received a request from Washington State for the use of spiroxamine on hops. To support this request, three fields trials were performed in the states of Washington, Oregon and Idaho. In each trial, four foliar applications of KWG 4168 300 CS spaced 8–14 days apart were applied to mature hops, and collected 12–14 days following the last application. Spiroxamine residue levels ranged from 1.9 to 10.9 ppm.

iii. *Banana.* Twelve field trials were conducted in commercial banana plantations of the major production areas of Latin and South America to compare the quantity of residues of spiroxamine in/on bananas following foliar applications. In 11 trials, duplicate composite samples of bananas were collected at a 0–day PHI from each of two side-by-side or super-imposed plots in which the racemes (bunches) were bagged or unbagged. In one trial, duplicate composite samples of bananas were collected at a 0–, 7–, 14–, and 21–day PHI from each of the plots containing bagged and unbagged bananas. The highest total residue value of spiroxamine in unwashed, bagged, whole bananas was 0.46 ppm at a 0–day PHI. The highest total residue value of spiroxamine in unwashed, unbagged, whole bananas was 2.44 ppm at a 0–day PHI. The total spiroxamine residues in whole bananas appeared to decline with time.

B. Toxicological Profile

1. *Acute toxicity*—i. *KWG 4168 (spiroxamine) Technical.* The acute oral LD₅₀ in male rats was 595 milligrams/kilogram (mg/kg) and in female rats was >500 but <560 mg/kg. The acute dermal LD₅₀ in rats was >1,600 and 1,068 mg/kg for males and females, respectively. The 4–hour inhalation LC₅₀ in rats was 2.772 and 1.982 milligrams/liter (mg/L) for males and females, respectively. Irritation studies in rabbits revealed spiroxamine was severely irritating to the skin while not irritating to the eye. Spiroxamine exhibited a skin-sensitizing potential in guinea pigs in both the Magnusson/Kligman maximization test and the Buehler patch test.

ii. *Prosper 300.* The acute oral LD₅₀ in rats was >2,036 and >2,028 mg/kg for males and females, respectively. The acute dermal LD₅₀ in rats was >5,000 mg/kg for males and females. The 4–hour inhalation LC₅₀ in rats was >2.730 mg/L for both sexes. In an eye irritation study in rabbits, minimal irritation to the iris and conjunctiva was observed with all irritation, resolving by 72 hours