

8. PP 2E6402 proposed establishment of a tolerance for spinach at 0.2 ppm.

9. PP 1E6234 proposed establishment of a tolerance for carambola (starfruit) at 1.0 ppm.

The residue chemistry data submitted in support of PP 6E4630 (leaf petioles subgroup) and PP 1E6234 (carambola) were determined by EPA to be insufficient to support the proposed tolerances. PP 1E6234 was subsequently withdrawn by the Taipei Economic and Cultural Representative Office. The requested tolerance for the leaf petioles subgroup (PP 6E4630) cannot be established until adequate residue chemistry data are submitted and reviewed.

Based on EPA's review, the remaining petitions described in Unit II were revised by the petitioners (FMC Corporation and IR-4) to propose tolerances for residues of bifenthrin in or on almond, hulls at 2.0 ppm; banana at 0.1 ppm; fruit, citrus, group at 0.05 ppm; herb subgroup at 0.05 ppm; pear at 0.5 ppm; nut, tree, group at 0.05 ppm; spinach at 0.2 ppm; tomato at 0.15 ppm; and food/feed products in food/feed handling establishments at 0.05 ppm. The revisions were requested for the following reasons:

EPA determined that the tolerance for pear should be set at 0.5 ppm, not 1.0 ppm as the petitioner originally proposed, based on the results of submitted field residue data, showing a maximum residue of 0.38 ppm. EPA determined that the tolerance for food/feed products in food/feed handling establishments should be set at 0.05 ppm, the limit of quantitation (LOQ) of the analytical method, rather than 0.01 ppm, the limit of detection (LOD), as the petitioner originally proposed. It is Agency policy to use the LOQ for setting tolerances when detectable residues are not found in the residue trials. No other

changes to the originally proposed tolerance levels were requested; however, EPA did request minor changes in commodity terms to reflect current nomenclature practices.

Although EPA requested changes to the initial petitions, the nature of the changes is not considered significant. Therefore, EPA is issuing this as a final action.

EPA is also deleting time-limited tolerances established for residues of bifenthrin in or on citrus, dried pulp, at 0.3 ppm, citrus oil at 0.3 ppm and citrus, whole fruit, at 0.05 ppm in connection with section 18 emergency exemptions granted by EPA. With the establishment of the citrus fruit group tolerance (PP 1F6266), these tolerances are no longer needed.

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 bifenthrin in or on almond, hulls at 2.0 ppm; banana at 0.1 ppm; fruit, citrus, group 10 at 0.05 ppm; herb subgroup 19A at 0.05 ppm; pear at 0.5 ppm; nut, tree, group 14 at 0.05 ppm; spinach at 0.2 ppm; tomato at 0.15 ppm; and food/feed products in food/feed handling establishments at 0.05 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 bifenthrin 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 Number	Study Type	Results
870.3100	90-Day Oral Toxicity - Rat (1984)	NOAEL = 3.8 mg/kg/day (males); 4.3 mg/kg/day (females) LOAEL = 7.5 mg/kg/day (males), 8.5 mg/kg/day (females), based on increased incidence of tumors. Classification: Acceptable-Guideline
870.3150	90-Day Oral Toxicity - Dog (1984)	NOAEL = 2.21 mg/kg/day (males and females) LOAEL = 4.42 mg/kg/day (males and females) based on increased incidence of tremors. Classification: Acceptable-Guideline
870.3700	Developmental Toxicity (Gavage; corn oil vehicle) - Rat (1983)	Maternal Toxicity NOAEL = 0.88 mg/kg/day LOAEL = 1.77 mg/kg/day based on tremors during gestation. Developmental Toxicity NOAEL = not determined (fetuses not examined) LOAEL = not determined (fetuses not examined) Classification: Acceptable-Guideline