

cattle, goat, hog, horse, and sheep at 0.02 ppm and milk at 0.02 ppm. There were no comments received on these petitions.

EPA has received objections to tolerances it established for residues of bifenthrin on a variety of food commodities in a final rule published in the **Federal Register** of February 1, 2002 (67 FR 4913) (FRL-6818-3). The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has initiated a public comment period on them in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL-7167-7), which ended on October 16, 2002. Although that proceeding remains ongoing, prior to acting on this current tolerance action, EPA reviewed the bifenthrin-specific objections raised by NRDC and has addressed them at relevant points throughout this preamble.

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 tolerances for combined residues of bifenthrin and

diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenthrin) on almond, hulls at 15 ppm; nut, tree, group 14 at 0.20 ppm; okra at 2.0 ppm; peppermint, tops at 25 ppm; pistachio at 0.20 ppm; spearmint, tops at 25 ppm; vegetable, cucurbit, group 9 at 0.75 ppm; and vegetable, fruiting, group 8 at 2.0 ppm, and combined residues of bifenthrin; diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenthrin); 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (expressed as 1,1'-biphenyl, 4-ol) in meat and meat byproducts of cattle, goat, hog, horse, and sheep at 0.02 ppm and milk at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

#### 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 No.	Study	Results
870.3100	90-Day oral toxicity rodents—rat	NOAEL = 13.8 mg/kg/day in males, 3.2 mg/kg/day in females. LOAEL = 27.7 mg/kg/day in males, 16.3 mg/kg/day in females based on decreased body weight gain in both sexes, decreased liver weight in males, increased spleen weight in females, and histopathology in liver in both sexes, and histopathological changes in the spleen and adrenal cortex in males.
870.3150	90-Day oral toxicity non-rodents—dog	NOAEL = 0.9 mg/kg/day in males, 1.3 mg/kg/day in females. LOAEL = 10.4 mg/kg/day in males, 10.7 mg/kg/day in females based on changes in hematological parameters in both sexes, increased bilirubin in the urine in males, increased absolute and relative liver weight in females and liver histopathologic effects in both sexes.
870.3200	21-Day dermal toxicity—rat	NOAEL = 80 mg/kg/day in males and females. LOAEL = 400 mg/kg/day in males and females based on decreased body weight in females, decreased food consumption in both sexes, increased urinary ketones, increased urinary protein, increased urinary specific gravity, and decreased urinary volume in both sexes, and increased incidence of extramedullary hematopoiesis in the spleen in both sexes.
870.3700	Prenatal developmental in rodents—rat	Maternal NOAEL = 10 mg/kg/day. LOAEL = 100 mg/kg/day based on increased clinical signs, and decreased body weight, body weight gain, and food consumption. Developmental NOAEL = 500 mg/kg/day. LOAEL = not established