

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 combined residues of emamectin, (a mixture of a minimum of 90% 4"-epi-methylamino-4"-deoxyavermectin B_{1a} and maximum of 10% 4"-epi-methylamino-4"-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b}

component of the parent (8,9-ZMA), or 4"-deoxy-4"-epi-amino-avermectin B_{1a} and 4"-deoxy-4"-epi-amino-avermectin B_{1b}; 4"-deoxy-4"-epi-amino-avermectin B_{1a} (AB_{1a}); 4"-deoxy-4"-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4"-deoxy-4"-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}), in or on *Brassica* leafy vegetables (crop group 5) at 0.05 ppm; turnip greens at 0.05 ppm; cotton, undelinted seed at 0.025 ppm; cotton gin byproduct at 0.05 ppm; leafy vegetables (except *Brassica*) (crop group 4) at 0.10 ppm; fruiting vegetables (crop group 8) at 0.02 ppm; and tomato paste at 0.15 ppm. In addition, tolerances are established for indirect or inadvertent combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in or on milk and fat of cattle, goats, hogs, horses, and sheep at 0.003 ppm; meat byproducts, except liver, of cattle, goats, hogs, horses, and sheep at

0.005 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.020 ppm; and meat of cattle, goat, hogs, horses, and sheep at 0.002 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 emamectin 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	Subchronic-Feeding-Rat MK-0243	Systemic Toxicity NOAEL=2.5 mg/kg/day. Systemic Toxicity LOAEL=5 mg/kg/day based on tremors, hindlimb splaying, urogenital staining, histological changes in brain and spinal cord, sciatic and optic nerves and skeletal muscles in males, emaciation, reduced body weight and reduced food consumption in both sexes.
870.3150	Subchronic-Feeding-Dog MK-0243	Systemic Toxicity NOAEL=0.25 mg/kg. Systemic Toxicity LOAEL=0.50 mg/kg based on microscopic pathological signs of neurotoxicity consisting of skeletal muscle atrophy and white matter multifocal degeneration in the brains of both sexes and white matter multifocal degeneration in the spinal cords of males.
870.3200	21-Day Dermal Toxicity-Rat	No Study Available.
870.3700	Developmental Toxicity-Rat MK-0243	Maternal Toxicity NOAEL=2 mg/kg/day. Maternal Toxicity LOAEL=4 mg/kg/day based on a significant trend towards decreased body weight gain during the dosing period. Developmental Toxicity NOAEL=4 mg/kg/day. Developmental Toxicity LOAEL=8 mg/kg/day based on altered growth and an increased incidence of supernumerary rib.
870.3700	Developmental Toxicity-Rabbit MK-0243	Maternal Toxicity NOAEL=3 mg/kg/day. Maternal Toxicity LOAEL=6 mg/kg/day based on a significant trend towards decreased body weight gain during dosing period and increased clinical signs (mydriasis and decreased pupillary reaction). Developmental Toxicity NOAEL=6 mg/kg/day. Developmental Toxicity LOAEL=Not Determined.
870.3800	Reproductive Toxicity-Rat MK-0244	Systemic Toxicity NOAEL=0.6 mg/kg/day. Systemic Toxicity LOAEL=1.8 mg/kg/day based on decreased body weight gain and histopathological changes (neuronal degeneration in the brain and spinal cord) in both sexes and generations. Reproductive Toxicity NOAEL=0.6 mg/kg/day. Reproductive Toxicity LOAEL=1.8 mg/kg/day based on decreased fecundity and fertility indices and clinical signs (tremors and hind limb extension) in offspring of both generations.