

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 boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) on: Vegetable, root, subgroup 1A, except sugar beet/garden beet/radish/turnip, at 1.0 ppm; vegetable, tuberous and corm, subgroup 1C, at 0.05 ppm; vegetable, bulb, group 3, at 3.0 ppm; lettuce, head at 6.5 ppm; lettuce, leaf at 11.0 ppm; vegetable, Brassica leafy, head and stem, subgroup 5A, at 3.0 ppm; vegetable, Brassica leafy, leafy greens, subgroup 5B, at 18.0 ppm; vegetable, legume, edible-podded, subgroup 6A, at 1.6 ppm; vegetable, legume, succulent shelled pea and bean, subgroup 6B, except cowpea, at 0.6 ppm; vegetable, legume, dried shell pea and bean (except soybean), subgroup 6C, except cowpea, field pea, and grain lupin at 2.5 ppm; vegetable, fruiting, group 8, at 1.2 ppm; vegetable, cucurbit, group 9, except cucumber, at 1.6 ppm; cucumber at 0.20 ppm; fruit, stone, group 12, at 1.7 ppm; berries, group 13, at 3.5 ppm; nut, tree, group 14, at 0.70 ppm; almond, hulls at 3.0 ppm; pistachio at 0.70 ppm; grape at 3.5 ppm; grape, raisin at 8.5 ppm; strawberry at 1.2 ppm; peanut at 0.05 ppm; peanut, meal at 0.15 ppm; peanut, refined oil at 0.15 ppm; canola, seed at 3.5 ppm; canola, refined oil at 5.0 ppm; sunflower, seed at 0.60 ppm; peppermint, tops at 30.0 ppm and spearmint, tops at 30.0 ppm.

The Agency also included in this risk assessment dietary exposure (at the anticipated tolerance level) from

another pesticide petition (2F6434) for boscalid use on pome fruit and hops. However, the Agency is not establishing tolerances for these commodities at this time, because the residue chemistry review for these commodities is not complete and in fact is not scheduled until the Office of Pesticide Program FY-2004 Workplan.

In addition, also 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 boscalid from indirect or inadvertent residues (from rotational crop use), 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) on: Beet, garden, roots at 1.0 ppm; radish, roots at 1.0 ppm; turnip, roots at 1.0 ppm; beet, sugar, roots at 1.0 ppm; vegetable, root and tuber, leaves, group 2 at 1.0 ppm; vegetable, leafy, group 4, except lettuce at 1.0 ppm; vegetable, legume foliage, group 7, forage at 1.5 ppm; vegetable, legume, foliage, group 7, hay at 2.0 ppm; vegetable, legume, foliage group 7, vines at 0.05 ppm; grain, cereal, group 15, at 0.20 ppm; rice, hulls at 0.50 ppm; grain, cereal, forage, fodder, and straw, group 16, fodder at 1.5 ppm; grain, cereal, forage, fodder, and straw, group 16, forage at 2.0 ppm; grain, cereal, forage, fodder, and straw, group 16, straw at 3.0 ppm; grass, forage, fodder, and hay, group 17, forage at 2.0 ppm; grass, forage, fodder, and hay, group 17, hay at 8.0 ppm; grass, forage, fodder, and hay, group 17, straw at 0.30 ppm; grass, forage, fodder, and hay, group 17, seed screenings at 0.20 ppm; animal feed, nongrass, group 18, forage at 1.0 ppm animal feed, nongrass, group 18, hay at 2.0 ppm; animal feed, nongrass, group 18 seed at 0.05 ppm; cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 0.30 ppm; soybean, seed, 0.10 ppm; soybean, hulls at 0.20 ppm; cowpea, seed at 0.1 ppm; lupin, grain, grain, at 0.1 ppm; pea,

field, seed at 0.1 ppm and flax seed at 3.5 ppm.

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 the fungicide 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) and metabolites M510F01 2-chloro-N-(4'-chloro-5-hydroxy-biphenyl-2-yl) nicotinamide and M510F02 glucuronic acid conjugate of M510F01 in or on milk at 0.10 ppm, cattle, meat at 0.10 ppm, cattle, fat at 0.30 ppm, cattle, meat byproducts at 0.35 ppm, egg at 0.02 ppm, poultry, meat at 0.05 ppm, poultry, fat at 0.05 ppm, poultry, meat byproducts at 0.10 ppm, goat, meat at 0.10 ppm, goat, fat at 0.30 ppm, goat, meat byproducts at 0.35 ppm, hog, meat at 0.05 ppm, hog, fat at 0.10 ppm, hog, meat byproducts at 0.35 ppm, horse, meat at 0.10 ppm, horse, fat at 0.30 ppm, horse, meat byproducts at 0.35 ppm, sheep, meat at 0.10 ppm, sheep, fat at 0.30 ppm, and sheep, meat byproducts at 0.35 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 boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) 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	90-Day oral toxicity rodents(rats)	NOAEL = 34/159 milligram/kilogram/day (mg/kg/day) Male/Female. LOAEL = 137/395 mg/kg/day M/F based on [M = increases in absolute and relative thyroid weights and increased incidence of thyroid hyperplasia as well as follicular epithelial hypertrophy; F = increases in absolute and relative thyroid weights.]