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II. Background and Statutory Findings

In the **Federal Register** of July 6, 2001 (66 FR 130) (FRL-6784-9) and February 28, 2003 (68 FR 9660) (FRL-7288-9), EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (1E6224) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390; PP 1E6233 from the Taipai Economic and Cultural Representative Office, 4301 Connecticut Ave., NW Suite 420, Washington, DC 20008; and PP 0F6072 from E.I. duPont de Nemours and Company, DuPont Agricultural Products, Barley Mill Plaza, Wilmington, DE 19880-0038. Those notices included summaries of the petitions prepared by E.I. duPont de Nemours and Company, DuPont Agricultural Products, the registrant. The petitions requested that 40 CFR 180.503 be amended by establishing tolerances for residues of the fungicide cymoxanil, [2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide], in or on hop at 1.0 part per million (ppm) (PP 1E6224); lettuce, head at 4.0 ppm (PP 6F6072); imported lychee at 1.0 ppm (PP 1E6233); vegetable, cucurbit, group at 0.05 ppm (PP 0F6072); and vegetable, fruiting, group at 0.2 ppm (PP 0F6072).

The World Wildlife Fund (WWF) submitted comments on August 7, 2001

in response to the notice of filing for hops and lychee. WWF urged EPA to apply the full 10X FQPA safety factor to cymoxanil "because completed studies for this fungicide are inadequate to detect endocrine disruption and the endocrine disruptor data gap is of critical importance when determining a reasonable certainty of no harm to embryos, fetus, infants and children." In addition, WWF stated that there may be evidence of increased developmental susceptibility for cymoxanil. EPA reviewed the comments submitted by WWF and has addressed them in Unit III. D. of this document.

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 November 26, 1997 (62 FR 62961) (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 residues of cymoxanil on hop, dried cones at 1.0 ppm; lettuce, head at 4.0 ppm; vegetable, cucurbit, group 9 at 0.05 ppm; vegetable, fruiting, group 8 at 0.2 ppm; and imported lychee at 1.0 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 cymoxanil 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 (rat)	Systemic toxicity NOAEL = 47.6 milligrams/kilogram/day (mg/kg/day) in males and 59.9 mg/kg/day in females Systemic toxicity LOAEL = 102 mg/kg/day in males and 137 mg/kg/day in females, based on decreases in body weights, body weight gains and food efficiency in the females, and body weight decreases and testicular and epididymal changes in males.
870.3150	90-Day oral toxicity in non-rodents (dog)	Systemic toxicity NOAEL not established Systemic toxicity LOAEL = 3 mg/kg/day, based on decreased body weights (13%) and food consumption in females.
870.3200	21/28-Day dermal toxicity (rat)	Systemic and dermal toxicity NOAEL = 1,000 mg/kg/day, highest dose tested (HDT) Systemic and dermal toxicity LOAEL was not established.