

provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement (5 U.S.C. 808(2)). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of July 16, 2003. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**.

The EPA's compliance with these Executive Orders and statutes to the underlying rule is discussed in the January 21, 2003, **Federal Register** notice containing the Allowance System for Controlling HCFC Production, Import and Export final rule (68 FR 2820).

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Reporting and recordkeeping requirements.

Dated: July 7, 2003.

Jeffrey R. Holmstead,

Assistant Administrator for the Office of Air and Radiation.

■ For the reasons stated in the preamble, 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

■ 2. In § 82.4 paragraph (n) introductory text is amended by revising the reference “(t)(2) and (t)(3)” to read “(n)(2) and (n)(3)” and revising the reference “(t)(1)(i) through (iii)” to read “(n)(1)(i) through (iii).”

■ 3. In § 82.4(n)(4), revise the reference “(t)(3)” to read “(n)(3)” and the reference “(t)(1)” to read “(n)(1).”

[FR Doc. 03–18000 Filed 7–15–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0219; FRL–7313–6]

Cymoxanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cymoxanil in or on hop, dried cones; lettuce, head; imported lychee; vegetable, cucurbit, group 9; and vegetable, fruiting, group 8. The Interregional Research Project Number 4 (IR-4), the Taipai Economic and Cultural Representative Office, and E.I du Pont Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. EPA is also deleting the time-limited tolerance for hop, dried cones established in connection with use of the pesticide under section 18 emergency exemptions and the tolerance for imported tomato. These tolerances are no longer needed since this rule establishes tolerances in support of the U.S. registration for hops and tomato.

DATES: This regulation is effective July 16, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0219, must be received on or before September 15, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)

- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification ID number OPP–2003–0219. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. Electronic access. You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00>Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public

docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

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.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in rodents (rat)	Maternal NOAEL = 25 mg/kg/day Maternal LOAEL = 75 mg/kg/day, based upon reduced body weight, body weight change and food consumption Developmental NOAEL = 10 mg/kg/day Developmental LOAEL = 25 mg/kg/day, based upon significant increase in overall malformations, and generalized dose-related delay in skeletal ossification; at 75 and 150 mg/kg/day significant decrease in fetal body weights; at 150 mg/kg/day increased early resorptions resulting in reduced litter size.
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL 32 mg/kg/day Maternal LOAEL was not established Developmental NOAEL = 4 mg/kg/day Developmental LOAEL = 8 mg/kg/day, based upon an increase in skeletal anomalies of the cervical and thoracic vertebrae and ribs; at 32 mg/kg/day, cleft palate was also observed.
870.3800	2-Generation reproduction and fertility effects (rat)	Systemic toxicity NOAEL = 6.5 males and 7.9 females mg/kg/day Systemic toxicity LOAEL = 32.1 males and 40.6 females mg/kg/day, based on reduced pre-mating body weight, body weight gain, and food consumption for P males; and decreased gestation and lactation body weight for F1 females Reproductive toxicity NOAEL 97.9 mg/kg/day for males and 130 mg/kg/day for females. Reproductive toxicity LOAEL was not established Offspring toxicity NOAEL = 6.5 males and 7.9 females mg/kg/day Offspring toxicity LOAEL = 32.1 female and 40.6 females mg/kg/day, based upon decreased F1 pup viability on postnatal days 0–4 and on a significant reduction in F2b pup weight.
870.4100	Chronic toxicity (dog)	Systemic toxicity NOAEL = 3.0/3.1 mg/kg/day for males/ and females Systemic toxicity LOAEL = 5.7 mg/kg/day (HDT in males), based upon depressed weight gains through week 12 and changes in the hematology and blood chemistry in males LOAEL was not established for females.
870.4300	Combined chronic toxicity/ carcinogenicity rodents (rat)	Systemic toxicity NOAEL = 4.08 mg/kg/day for males and 5.36 mg/kg/day for females Systemic toxicity LOAEL = 30.3 mg/kg/day for males and 38.4 mg/kg/day for females, based upon decreased body weight, body weight gain, and food efficiency, increased incidence of elongate spermatid degeneration and increased aggressiveness and/or hyperactivity in males and increased incidence of non-neoplastic lesions of the lungs, liver, sciatic nerve and retinal atrophy in females No evidence of carcinogenicity.
870.4200	Carcinogenicity mice	Systemic toxicity NOAEL = 4.19 mg/kg/day for males and 5.83 mg/kg/day for females, lowest dose tested (LDT) Systemic toxicity LOAEL = 42 mg/kg/day for males and 58.1 mg/kg/day for females HDT, based upon increased frequency of sperm cyst/cystic dilatation, tubular dilatation and lymphoid aggregates in males and hyperplastic gastropathy in females No evidence of carcinogenicity.
870.5100	Gene mutation	Cytotoxicity in all strains was seen at 750 µg/plate -S9 and 1,000 µg/plate +S9. The positive controls induced the expected mutagenic responses in the appropriate tester strain. There was, however, no evidence that the test material induced a mutagenic effect under any test condition.
870.5300	<i>In vitro</i> mammalian cell gene mutation assay (CHO)	Severe cytotoxicity was seen at 750 µg/mL -S9 and 1,000 µg/mL +S9. The positive controls induced the expected mutagenic responses. There was, however, no evidence that the test material was mutagenic at the Hypoxanthine Guanine Phophoribosyl Transferase locus at any dose under any assay condition.
870.6200	Subchronic neurotoxicity screening battery (rat)	No effects on the functional observation battery, or motor activity were observed. No treatment-related gross or microscopic findings in the nervous system or skeletal muscles of the male and female rats were observed The neurotoxicity NOAEL 3,000 ppm (224 mg/kg/day in males and 333 mg/kg/day in females; HDT). Neurotoxicity LOAEL was not established.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.6300	Developmental neurotoxicity (rat)	Maternal toxicity NOAEL = 50 mg/kg/day Maternal toxicity LOAEL = 100 mg/kg/day, based on slight decrease body weight, body weight gains (17%) and food consumption. Offspring NOAEL = 50 mg/kg/day Offspring LOAEL = 100 mg/kg/day, based on decreased pup survival, decreased pup weight and body weight gain during early lactation (less than 6%), increases in morphometric measurements (anterior/posterior cerebrum for males, cerebellar height for females) at PND 79–83, and decreased retention in the water maze task for adult females (latency 158% of control levels) seen at the LOAEL of 100 mg/kg/day.
870.7485	Metabolism and pharmacokinetics (rat)	Cymoxanil was readily absorbed and 86 to 94% of the administered dose was excreted in 96 hours. The majority of the administered dose was recovered in the urine (64 - 57%) with smaller amounts excreted in the feces (16 - 24%) and carcass (<1%). There were no sex-related differences in the absorption, distribution and metabolism of cymoxanil. In urine about 37 - 55% of the dose was free and/or conjugated [¹⁴ C]glycine and 2 cyano-2-methoxyiminoacetic acid (IN-W3595; about 7 to 33% of the dose). Intact cymoxanil was not isolated in urine. In feces intact ¹⁴ C cymoxanil (<1%) and IN W3595 was detected, but the majority of radioactivity was ¹⁴ C glycine (about 9 - 13%). Based on the data, the metabolic pathway involves hydrolysis of cymoxanil to IN W3595, which is then degraded to glycine, which in turn is incorporated into natural constituents or further metabolized.

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern. However, the the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF).

Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic population adjusted dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the lever of concern. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the lever of concern.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure

will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a “point of departure” is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for cymoxanil used for human risk assessment is shown in the following Table 2.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYMOXANIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = 4 mg/kg/day UF = 100 aRfD = 0.04 mg/kg/day	FQPA SF = 1X aPAD = aRfD FQPA SF = 0.04 mg/kg/day	Developmental toxicity study - rabbit Developmental LOAEL = 8 mg/kg/day based on increased skeletal anomalies of the cervical and thoracic vertebrae (hemivertebrae) and ribs; at 32 mg/kg/day, cleft palate was also observed.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYMOXANIL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NA	NA	An effect attributable to a single exposure was not observed in the oral toxicity studies, including the developmental toxicity studies in rats and rabbits. Therefore, an aRfD was not established for this population.
Chronic dietary (all populations)	NOAEL = 4 mg/kg/day UF = 100 cRfD = 0.04 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD FQPA SF = 0.04 mg/kg/day	Combined chronic toxicity/carcinogenicity study - rat Systemic LOAEL = 30.3 mg/kg/day based on decreases in body weight, body weight gain, reduced food efficiency and histopathological lesions in the eyes and testes of males.
Short-term dermal (1 to 30 days) (Residential)	Oral study NOAEL = 4 mg/kg/day (Dermal absorption rate = 2.5%)	LOC for MOE = 100 (Residential)	Developmental toxicity study - rabbit Developmental LOAEL = 8 mg/kg/day based on increased skeletal anomalies of the cervical and thoracic vertebrae (hemivertebrae) and ribs; at 32 mg/kg/day, cleft palate was also observed.
Intermediate-term dermal (1 to 6 months) (Residential)	Oral study NOAEL = 4 mg/kg/day (Dermal absorption rate = 2.5%)	LOC for MOE = 100 (Residential)	Developmental toxicity study - rabbit Developmental LOAEL = 8 mg/kg/day based on increased skeletal anomalies of the cervical and thoracic vertebrae (hemivertebrae) and ribs; at 32 mg/kg/day, cleft palate was also observed.
Long-term dermal (>6 months) (Residential)	Oral study NOAEL = 4 mg/kg/day (Dermal absorption rate = 2.5% when appropriate)	LOC for MOE = 100 (Residential)	Combined chronic toxicity/carcinogenicity study - rat Systemic LOAEL = 30.3 mg/kg/day based on decreases in body weight, body weight gain, reduced food efficiency and histopathological lesions in the eyes and testes of males.
Short-term inhalation (1 to 30 days) (Residential)	Oral study NOAEL = 4 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental toxicity study - rabbit Developmental LOAEL = 8 mg/kg/day based on increased skeletal anomalies of the cervical and thoracic vertebrae and ribs; at 32 mg/kg/day, cleft palate was also observed.
Intermediate-term inhalation (1 to 6 months) (Residential)	Oral study NOAEL = 4 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental toxicity study - rabbit Developmental LOAEL = 8 mg/kg/day based on increased skeletal anomalies of the cervical and thoracic vertebrae and ribs; at 32 mg/kg/day, cleft palate was also observed.
Long-term inhalation (> 6 months) (Residential)	Oral study NOAEL = 4 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Combined chronic toxicity/carcinogenicity study - rat Systemic LOAEL = 30.3 mg/kg/day based on decreases in body weight, body weight gain, reduced food efficiency and histopathological lesions in the eyes and testes of males.
Cancer (oral, dermal, inhalation)	NA	NA	Classification: not likely human carcinogen Q1* = none.

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. Dietary exposure from food and feed uses. Tolerances have been established (40 CFR 180.503) for the

residues of cymoxanil, in or on a variety of raw agricultural commodities. A permanent tolerance of 0.05 ppm for residues of cymoxanil per se in/on

potatoes has been established under 40 CFR 180.503(a). A time-limited tolerance of 1 ppm for residues of cymoxanil per se in/on hops, dried has

also been established under 40 CFR 180.503(b) in connection with EPA's granting of a section 18 emergency exemption. The time-limited tolerance for hops, dried cone was set to expire December 31, 2003. Tolerances for residues of cymoxanil per se in/on imported grapes and tomatoes at 0.1 ppm are established under 40 CFR 180.503(e). Risk assessments were conducted by EPA to assess dietary exposures from cymoxanil in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Data base (FCDI DEEM™) which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996, and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute dietary exposure analyses assumed tolerance level residues, 100% crop treated and DEEM™ (ver. 7.76) default processing factors for all registered/proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessments EPA used the DEEM™ software with the FCID which incorporates food consumption data as reported by respondents in the USDA 1994–1996, and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analyses assumed tolerance level residues, 100% CT, and DEEM™ (ver. 7.76) default processing factors for all registered/proposed commodities.

iii. *Cancer.* In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July 1999), the Agency classified cymoxanil as a "not likely" human carcinogen. Therefore, a cancer dietary exposure analysis was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cymoxanil in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates

are made by reliance on simulation or modeling taking into account data on the physical characteristics of cymoxanil.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENECC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENECC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENECC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to cymoxanil they are further discussed in the aggregate risk sections in Unit II.E.

Cymoxanil appears to be mobile in soils. However, the rapid dissipation of cymoxanil in the environment precludes the possibility of extensive leaching. No detections of cymoxanil were observed below the 0–15 cm soil depth at any of the test sites. Though the degradates of cymoxanil are mobile, the aerobic soil metabolism study showed that the degradates are short-lived. Cymoxanil and its degradates should not pose a threat to ground water. Therefore, ground water EEC values were not included in the risk assessment.

Based on the GENECC model the EECs of cymoxanil for surface water are estimated to be 4.13 parts per billion (ppb) for acute exposures and 0.19 ppb for chronic exposure.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cymoxanil is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether cymoxanil has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cymoxanil and any other substances and cymoxanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cymoxanil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose

level that poses no appreciable risk to humans.

2. Prenatal and postnatal sensitivity. There is an indication of increased susceptibility (qualitative and quantitative) of rats and rabbits to *in utero* exposure to cymoxanil. In the rat developmental toxicity study, decreased fetal body weights and skeletal malformations were observed at 25 mg/kg/day LOAEL, which is below the maternal toxicity of 75 mg/kg/day LOAEL. In the rabbit developmental study increased skeletal malformations were observed at 8 mg/kg/day LOAEL, also below the maternal NOAEL of 32 mg/kg/day. In the 2-generation reproduction study there was an indication of increased qualitative susceptibility in the offspring, since there was decreased pup viability at a maternally toxic dose.

3. Conclusion. There is a complete toxicity data base for cymoxanil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X. The FQPA factor is reduced to 1X because in the developmental and postnatal studies (including a developmental neurotoxicity study in rats) the effects are well characterized and conservative NOAELs were established for all developmental and offspring effects. In addition, the doses selected for risk assessment are lower than the NOAELs from these studies and are protective of any potential prenatal and post-natal effects. Therefore, there are low levels of concern and no residual uncertainties for prenatal and postnatal toxicity.

In response to the notice of filing of July 6, 2001, WWF urged EPA to apply the full 10X FQPA safety factor to cymoxanil. According to WWF the data for cymoxanil is inadequate to address potential endocrine disruption and there is evidence of increased susceptibility in the prenatal developmental rabbit study. WWF claimed the multigeneration reproduction study in rats is inadequate because it was conducted before the 1996 guideline changes which added additional endpoints responsive to estrogenic and/or androgenic endocrine disruption. In addition, WWF noted that inferences about endocrine disruption based on current guidelines are still not fully adequate to evaluate endocrine disruption. In particular, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) recommended the inclusion of more endpoints relevant to thyroid disruption and measurement of estradiol, testosterone,

luteinizing hormone, follicle stimulating hormone, T4 and thyroid stimulating hormone levels in multigeneration studies. WWF further argued for the inclusion of certain adrenal hormones such as ACTH and corticosterone (the primary glucocorticoid in rodents) to fully address the endocrine disruption issue. In addition, WWF believes that there is an increased developmental susceptibility to rabbits fetuses. WWF questioned the conclusions reached by the Office of Pesticide Programs' Hazard Identification Assessment Review Committee (HIARC) Jan 20, 1998 that there is no sensitivity in fetuses compared to maternal animals. Developmental malformations were observed at 8 mg/kg/day, which is below the maternal NOAEL of 16 mg/kg/day. These results were discounted due to uncertainties regarding the source of the parental rabbits. In another rabbit study, developmental malformations were observed at the same dose (8 mg/kg/day) as in the previous study, however, HIARC did not consider this to show increased susceptibility because the effects were observed at 8 mg/kg/day, which is also a maternal toxic dose.

On June 18, 2002, HIARC reviewed the WWF comments and concluded that possible endocrine-related effects on testicular and/or epididymal tissues are fully characterized and well defined in mouse, subchronic and chronic rat and dog studies with clear NOAELs. Further, in the reproduction toxicity study in rats, testicular effects were seen, however, these effects did not affect any measured reproductive parameters, indicating no adverse effects on reproduction. Additional measurements recommended by EDSTAC and WWF are unlikely to provide any significant additional information for cymoxanil since NOAELs are clearly defined for the testicular and/or epididymal effects and there are no indications of endocrine disruption in other organs e.g., thyroid (thyroid weight changes and hyperplasia), adrenal toxicity.

Prior to receipt of WWF letter, the HIARC on August 21, 2001, reevaluated the toxicology data base and modified certain study reviews resulting in the selection of new endpoints. The reevaluations resulted in the qualitative and quantitative evidence of increased susceptibility to rabbit fetuses (as suggested by WWF) and rat fetuses. In addition, reevaluation of rat reproduction toxicity study resulted in the qualitative increased susceptibility to offspring. A conservative NOAEL from the rabbit developmental study was used for establishing the aRfD. Nonetheless, it was concluded that

reliable data supported applying no additional safety factor since endpoints chosen for risk assessments adequately protect infants and children with regard to the prenatal and/or postnatal toxicity that has been identified.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to cymoxanil will occupy <71% of the aPAD for females 13 to 49 years old. This is the only

population for which an acute toxicological endpoint has been determined. In addition, there is potential for acute dietary exposure to cymoxanil in drinking water derived from surface water. After calculating

DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYMOXANIL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–49 years old)	0.04	<71	4.13	350

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cymoxanil from food will utilize 13% of the cPAD for the U.S. population, and all population subgroups. Adults 20–49 years old and

females 13–49 years old were the most highly exposed subpopulations. There are no residential uses for cymoxanil that result in chronic residential exposure. In addition, there is potential for chronic dietary exposure to cymoxanil in drinking water derived

from surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYMOXANIL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.04	<13	0.19	1,200

5. *Aggregate cancer risk for U.S. population.* In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999), the Agency classified cymoxanil as a “not likely” human carcinogen. Cymoxanil is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to cymoxanil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Cymoxanil was shown to be recoverable using Protocol D of FDA's Pesticide Analytical Manual I methodology. The residue of concern in plants was previously determined to be parent only. In addition, Method AMR 3060–94 Revision 2, a High Performance Liquid Chromatography Ultraviolet (HPLC/UV) method, should be adequate for lychee tolerance enforcement purposes.

B. International Residue Limits

There are no CODEX, Canadian or Mexican Maximum Residue Levels established for cymoxanil on hops, lychee, or cucurbit vegetables. The U.S. tolerance for fruiting vegetables is

compatible with Codex. Therefore, no compatibility problems exist for the tolerances established by this rule.

V. Conclusion

Therefore, the tolerance is established for residues of cymoxanil, [2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino) acetamide], in or 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 lychee at 1.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new

section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0219 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 15, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in

40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. #104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0219, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp_docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045,

entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the

relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.503 is amended by adding alphabetically the following commodities and a footnote to the table in paragraph (a) and removing paragraph (e) to read as follows:

§ 180.503 Cymoxanil, tolerance for residues.

(a) * * *

Commodity	Parts per million
Grape ¹	0.1
Hop, dried cones	1.0

Commodity	Parts per million
Lettuce, head	4.0
Lychee ¹	1.0
* * * * *	*
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.2

¹There are no U.S. registrations for grape and lychee.

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[FR Doc. 03-17731 Filed 7-15-03; 8:45 am]

BILLING CODE 6560-50-S

DATES: Effective August 15, 2003.

FOR FURTHER INFORMATION CONTACT:

Shannon Lipp, Attorney, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418-7400.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s Twenty-Fifth Order on Reconsideration and Report and Order (Order) in CC Docket No. 96-45 released on May 21, 2003. This Order was also released with a companion Further Notice of Proposed Rulemaking. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, SW., Washington, DC 20554.

I. Introduction

1. In this Order, we address the requests of several petitioners to reconsider portions of the *Twelfth Report and Order and Further Notice of Proposed Rulemaking*, 65 FR 47941, August 4, 2003, adopting rules to provide additional, targeted universal service support to low-income consumers on tribal lands and establishing a framework for the resolution of Eligible Telecommunications Carrier (ETC) designations under section 214(e)(6) of the Communications Act of 1934, as amended (the Act). The advancement of universal service on tribal lands remains a major policy goal of this Commission. Through our on-going dialogue with the tribes, as most recently exemplified by the Commission’s launch of the Indian Telecommunications Initiatives in Phoenix, Arizona on September 19, 2002, the Commission continues in its efforts to promote telecommunications subscribership within American Indian and Alaskan Native tribal communities.

2. We affirm that the framework adopted by the Commission for resolution of ETC designations on tribal lands provides a reasonable means to facilitate the expeditious resolution of such requests, while balancing the respective federal, state, and tribal interests. We also conclude that the definition of “reservation” for purposes of the universal service programs remains the same as that adopted in the *Twelfth Report and Order and Further Notice of Proposed Rulemaking* despite the Bureau of Indian Affairs’ (BIA) subsequent modification of that definition for purposes of its direct assistance programs. We address several requests for reconsideration relating to the rule amendments to the universal service low-income programs adopted in the *Twelfth Report and Order and*