

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 issues(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