

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FAMOXADONE—Continued

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children 1–2 years old	0.0014	76%	0.47	0.23	3.4
Children 3–5 years old	0.0014	68%	0.47	0.23	4.5

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background-exposure level). Famoxadone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background-exposure level). Famoxadone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Famoxadone is classified as "not likely to be carcinogenic to humans." As such, no cancer risk is expected.

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, including infants and children, from aggregate exposure to famoxadone residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Famoxadone was screened through multi-residue methods listed in the Pesticide Analytical Manual Volume I (PAM Vol. I), Third Edition (January 1994), using Protocols C to E. Protocols A and B were not used because famoxadone does not have an n-methyl carbamate structure (Protocol A), nor is it an acid or phenol (Protocol B). Protocol C showed good analytical response using the electron-capture detector (ECD) and nitrogen-phosphorus detector (NPD). Good recoveries were obtained for the analysis of wine, grapes, and tomatoes (92–138%) using Protocol D. Food commodities can be analyzed for famoxadone residues using the appropriate extraction method with the mixed ether elution system, resulting in recovery values of 92 to 108%.

The multi-residue methods testing appears to be scientifically acceptable and has been sent to the FDA for further evaluation. Preliminary analysis suggests that Protocol D may be appropriate for analysis of famoxadone in plant matrices and has the potential to be the primary enforcement method.

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

No CODEX maximum residue limits currently exist for famoxadone: Maximum Residue Levels (MRLs) have been established for potatoes in the Netherlands at 0.02 ppm and for grapes in Germany at 2.0 ppm.

#### V. Conclusion

Therefore, tolerances are established for residues of famoxadone (3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione) in or on vegetables, fruiting, group 8 (except tomato) at 4.0 ppm; tomato at 1 ppm; vegetables cucurbit, group 9 at 0.30 ppm; lettuce, head at 10.0 ppm; potato at 0.02 ppm grape at 2.50 ppm (import only); raisin at 4.0 ppm (import only); fat of cattle, horses, goats, sheep at 0.02 ppm; liver of cattle, horses, goats, sheep at 0.05 ppm; and milk, fat (reflecting negligible residues in whole milk) at 0.060 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–2003–0130 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 2, 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 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