

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. Population	1,200	100	33	3.1	8,000
Children 1–2 years old	430	100	33	3.1	1,900

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).

Azoxystrobin is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food

and water and intermediate-term exposures for azoxystrobin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 420 for children 1–2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In

addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of azoxystrobin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Children 1–2 years old	420	100	33	3.1	1,600

5. Aggregate cancer risk for U.S.

population. There is no evidence for mutagenicity or carcinogenicity. Azoxystrobin has been classified as “not likely to be carcinogenic in humans” by EPA; therefore, azoxystrobin is not expected to pose a carcinogenic risk.

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 azoxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methodology is available for enforcement of these tolerances. The gas chromatography/nitrogen phosphorous detector (GC/NPD) method (RAM 243/04) has undergone a method validation by the EPA analytical laboratory. EPA comments have been incorporated and the revised method (designated RAM 243) will be submitted to FDA for inclusion in PAM, Volume II as an enforcement method.

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.

B. International Residue Limits

No Codex, Canadian, or Mexican Maximum Residue Levels (MRLs) have been established for residues of azoxystrobin. Therefore, no tolerance discrepancies exist between countries for this chemical.

V. Conclusion

Therefore, the tolerances are established for combined residues of azoxystrobin, methyl (E)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]- ∞ -(methoxymethylene)-benzeneacetate, and its Z isomer, methyl (Z)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]- ∞ -(methoxymethylene)-benzeneacetate, in or on artichoke, globe at 4.0 ppm; asparagus at 0.04 ppm; brassica, head and stem, subgroup 5A at 3.0 ppm; herb subgroup 19A, dried, except chive at 260 ppm; and herb subgroup 19A, fresh, except chive at 50 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–2003–0196 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 August 18, 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