

weight gain and food consumption at 150 mg/kg/day. Maternal toxicity at 75 mg/kg/day is a conservative call based on decreased food consumption. The susceptibility assumption is based on effects at the high dose.

In a development toxicity study with rabbits there is no evidence of increased susceptibility since there was no evidence of developmental toxicity at the highest dose tested in the presence of maternal toxicity. In the two generation reproductive toxicity study in rats, there is no evidence of increased susceptibility of offspring.

3. *Conclusion.* The Agency determined that the FQPA safety factor of 10x for protection of infants and children be reduced to 3x since:

i. The toxicity data base is complete for an FQPA assessment;

ii. No increase in susceptibility was seen in the rabbit developmental study or in the 2-generation reproduction in rats;

iii. A developmental neurotoxicity study is not required for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane; and

iv. The exposure data are understood and the food exposure assessment will not underestimate the residues resulting from the use of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane.

E. Aggregate Risks and Determination of Safety

1. *Aggregate risks.* The Agency has concluded that exposure to 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane from food imported corn commodities will utilize less than 1% of the aPAD and cPAD for all population groups.

The cancer risk estimates from aggregate exposure to 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane in food has also been assessed. For the U.S. population, the cancer dietary risk from food is 6.5×10^{-7} which is below the Agency's concern for excess lifetime cancer risk.

There are no uses for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane that will result in drinking water or residential exposure.

2. *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 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement method (gas chromatography method using electron

capture detection) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460-0001; telephone number; (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian or Mexican limits for residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane in corn.

V. Conclusion

Therefore, import tolerances are established for residues of 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane, in or on corn commodities at 0.005 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 the 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-2002-0245 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 March 31, 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. 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