

determined that a cumulative risk assessment is not necessary.

## VII. Determination of Safety for U.S. Population

Based on the conformance to the criteria used to identify a low risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of 1,3 benzene dicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with 1,3-benzene dicarboxylic acid, 1,4-benzene dicarboxylic acid, dimethyl 1,4-benzene dicarboxylate and 1,2-ethanediol.

## VIII. Determination of Safety for Infants and Children

FFDCA 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 unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of 1,3 benzene dicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with 1,3-benzene dicarboxylic acid, 1,4-benzene dicarboxylic acid, dimethyl 1,4-benzene dicarboxylate and 1,2-ethanediol, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

## IX. Other Considerations

### A. Endocrine Disruptors

There is no available evidence that 1,3 benzene dicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with 1,3-benzene dicarboxylic acid, 1,4-benzene dicarboxylic acid, dimethyl 1,4-benzene dicarboxylate and 1,2-ethanediol is an endocrine disruptor.

### B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### C. International Tolerances

The Agency is not aware of any country requiring a tolerance for 1,3 benzene dicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with 1,3-benzene dicarboxylic acid, 1,4-benzene dicarboxylic acid, dimethyl 1,4-benzene dicarboxylate and 1,2-ethanediol nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

## X. Conclusion

Accordingly, EPA finds that exempting residues of 1,3 benzene dicarboxylic acid, 5-sulfo-, 1,3-dimethyl ester, sodium salt, polymer with 1,3-benzene dicarboxylic acid, 1,4-benzene dicarboxylic acid, dimethyl 1,4-benzene dicarboxylate and 1,2-ethanediol from the requirement of a tolerance will be safe.

## XI. 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-2003-0037 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 May 6, 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 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](mailto: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 XI.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-2003-0037, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,