

and has also cleared this chemical for direct addition to food for human consumption without limits. Decanoic acid is also permitted for use in food as a lubricant, binder and as a defoaming agent as a component in the manufacture of other food-grade components, without limits, provided it meets the criteria as set forth in 21 CFR 172.860.

4. Evidence of adverse reactions to decanoic acid in dietary toxicity testing was observed only at doses that were at or above limit doses.

5. The estimated exposures to decanoic acid and other fatty acids from direct or indirect addition to food as well as sanitizer uses are well below the doses administered in animal studies that are required to elicit an adverse effect. For example, adverse effects in toxicity testing could only be achieved by doses in the range of several grams of decanoic acid per kilogram of body weight per day. A worst case dietary exposure for the sanitizer use estimated exposure for a 70 kg adult of 1.6 µg/kg/day, and for a 15kg child of 7.5 µg/kg/day.

Accordingly, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to pelargonic acid.

## VIII. Other Considerations

### A. Analytical Method(s)

Because an exemption from the requirement of a tolerance without numerical limitation for residues in food is being granted for decanoic acid, an enforcement analytical method is not needed. However, an analytical method is available in cases of gross misuse. The analytical method is being made available to anyone interested in pesticide enforcement when requested, from Norm Cook, Antimicrobials Division (7510C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, D.C. 20460. Office location and telephone number: 1921 Jefferson Davis Highway, 3rd Floor, Arlington, VA 22202, (703) 308-8253.

### B. International Tolerances

No codex maximum residue levels have been established for decanoic acid.

## IX. Conclusion

An exemption from the requirement of a tolerance is established for residues of decanoic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of decanoic

acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of decanoic acid up to 170 ppm per application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants. The sanitizer is applied by immersion, coarse spray, or circulation technique as appropriate to the equipment. The solution, once applied is allowed to drain and dry and there is no potable water rinse.

## X. 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-2002-0272 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 April 21, 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 VI.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-2002-0272, to: Public Information