

and submitted to the FDA for inclusion in the Pesticide Analytical Manual (PAM) Vol. II. In addition, an analytical method (HPLC-fluorescence) for the enforcement of tolerances for residues of emamectin and its metabolites in/on ruminant commodities has been submitted to EPA for review. The ruminant method has been validated by an independent laboratory but EPA validation is required as a condition of registration.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican maximum residue limits on emamectin or its metabolites.

C. Conditions

The following studies must be submitted as conditions for product registrations related to these tolerances: A storage stability study for cotton seed, gin byproducts, and processed commodities which reflect the storage intervals and conditions of the submitted field trial and processing studies; additional storage stability studies to support 19 month storage intervals for bell pepper and tomatoes; a new tomato processing study with tomatoes treated at an exaggerated rate (up to 5x the maximum proposed seasonal application rate); three additional spinach field trials conducted in Regions X, VI, and II (one study each) based on OPPTS Guidelines 860.1500; and a 28-day inhalation study using the CF-1 mouse. In addition, a successful method validation by EPA is required for the high performance liquid chromatography-fluorescence method submitted for residues in ruminant commodities; the registrant is required to make any necessary modifications resulting from the EPA method review.

V. Conclusion

Therefore, the tolerance is established for combined residues of emamectin, (a mixture of a minimum of 90% 4"-epi-methylamino-4"-deoxyavermectin B_{1a} and maximum of 10% 4"-epi-methylamino-4"-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4"-deoxy-4"-epi-amino-avermectin B_{1a} and 4"-deoxy-4"-epi-amino-avermectin B_{1b}; 4"-deoxy-4"-epi-amino avermectin B_{1a} (AB_{1a}); 4"-deoxy-4"-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4"-deoxy-4"-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}), in or on *Brassica* leafy vegetables (crop group 5) at 0.05 ppm; turnip greens at 0.05 ppm; cotton, undelinted seed at 0.025 ppm; cotton gin byproduct at 0.05 ppm; leafy vegetables (except *Brassica*) (crop group

4) at 0.10 ppm; fruiting vegetables (crop group 8) at 0.02 ppm; and tomato paste at 0.15 ppm. In addition, tolerances are established for indirect or inadvertent combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in or on milk and fat of cattle, goats, hogs, horses, and sheep at 0.003 ppm; meat byproducts, except liver, of cattle, goats, hogs, horses, and sheep at 0.005 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.020 ppm; and meat of cattle, goat, hogs, horses, and sheep at 0.002 ppm. Note that the tolerance expression in 40 CFR 180.505 is being changed from emamectin benzoate to emamectin since the enforcement method, Method 244-92-3, Revision 1, analyzes residues of emamectin MAB₁ isomers (not emamectin benzoate), 8,9-ZMA, AB_{1a}, MFB_{1a}, and FAB_{1a} in/on crops.

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-2003-0220 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 8, 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, 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