

involving anti-androgenic chemicals. Significant work on this issue has been done. Although EPA in 2000 thought this issue could be resolved relatively quickly, that has not proven correct. Since 2000 EPA has completed a significant amount of work, some of which is currently ongoing. The Agency has completed an updated review of literature data for vinclozolin, and is currently examining in-house data for other chemicals, both those whose major toxic effects are related to androgen hormones, and those which have other major effects, but which still may be appropriate for inclusion in a cumulative risk assessment for androgen-related toxicity. Additional review of literature data for these chemicals is still required. The Office of Pesticide Programs (OPP) has also consulted with researchers in EPA's Office of Research and Development (ORD) who are conducting work for OPP in two areas. First, ORD is conducting experiments to determine whether the androgen-related toxicity of compounds whose effects are caused by different molecular mechanisms are additive, synergistic, or neither. Secondly, ORD is doing both experimental work and mathematical modeling to support a Physiologically Based Pharmacokinetic (PBPK) model for anti-androgenic compounds to support a cumulative risk assessment. Much of the work being done in ORD has been completed, although some remains ongoing. These data are important in assuring that the cumulative risk assessment for these chemicals is scientifically sound.

With regard to the presence of vinclozolin metabolites in drinking water, on February 14, 2001 the Agency issued a data call-in notice to BASF Corporation. The data call-in notice required the submission of a small prospective ground water monitoring study and a surface water monitoring study. These studies are required to be submitted by March 7, 2005 and March 8, 2004, respectively. The studies require that data be collected on vinclozolin and major degradation products. Additionally, on December 20, 2000, the Agency issued a data-call-in notice to BASF for an aerobic soil metabolism study and a soil column leaching/adsorption/desorption study to gain additional data on the persistence, biodegradation, and migration of vinclozolin in soil profile. These studies have been submitted to the Agency and are under review.

Finally, Earthjustice alleges that EPA admitted to many other data gaps in publishing the Notice of Filing (NOF) pertaining to these tolerances. The language cited by NRDC, however, is

merely the boilerplate added by EPA to all NOFs to indicate that EPA has not yet finished its review of the petition at the time the NOF is published.

In response to Earthjustice's assertion that the Agency should fully describe the cancellation status of vinclozolin uses, EPA would note that the NOF for this tolerance action was prepared by the petitioner, BASF Corporation, as the statute requires. In this rulemaking document, EPA has fully and accurately described the status of the 2000 cancellation order and the agreement regarding NRDC's withdrawal of its objections to the 2000 tolerance action.

## V. Conclusion

Therefore, the tolerances are established for combined residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety, in or on succulent beans at 2.0 ppm; canola at 1.0 ppm; eggs, milk, and the meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm. The tolerance for succulent beans will expire on September 30, 2005, and the canola, eggs, milk, meat and meat-by-product tolerances will expire on November 30, 2008.

## 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), 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-2003-0311 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 December 1, 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.