

toxicity and conducting cumulative risk assessments. For most pesticides, although, the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

In consideration of potential cumulative effects of etoxazole and other substances that may have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by etoxazole would be cumulative with those of other chemical compounds. Thus, only the potential risks of etoxazole have been considered in this assessment of aggregate exposure and effects.

Valent will submit information for EPA to consider concerning potential cumulative effects of etoxazole consistent with the schedule established by EPA at 62 *Federal Register* 42020 (Aug. 4, 1997) and other subsequent EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population.*—i. *Acute risk.* The potential acute exposure from food to the U.S. population and various non-child/infant population subgroups are estimated to be 0.06 to 0.13 % of the proposed aPAD. Exposure to potential acute residues in drinking water is expected to be negligible, as acute DWLOC's are substantially higher than modeled acute DWEC's. Based on this assessment, Valent concludes that there is a reasonable certainty that no harm to the U.S. population or any population subgroup will result from acute exposure to etoxazole.

ii. *Chronic risk.* The potential chronic exposure from food to the U.S. population and various non-child/infant population subgroups are estimated to be 0.7% to 1.9% of the proposed cPAD. Chronic exposure to potential residues in drinking water is also expected to be negligible, as chronic DWLOC's are substantially higher than modeled chronic DWEC's. Based on this assessment, Valent concludes that there is a reasonable certainty that no harm to the U.S. population or any population subgroup will result from chronic exposure to etoxazole.

2. *Infants and children.*—i. *Safety Factor for Infants and Children.* In assessing the potential for additional sensitivity of infants and children to residues of etoxazole, FFDCA section

408 provides that EPA shall apply an additional margin of safety, up to ten-fold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children. The toxicological data base for evaluating prenatal and postnatal toxicity for etoxazole is complete with respect to current data requirements. There are no special prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 2-generation reproductive toxicity study in rats. Valent has concluded that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed for etoxazole to be further protective of infants and children.

ii. *Acute risk.* The potential acute exposure from food to infants and children are estimated to be 0.16 to 0.50 % of the proposed aPAD. Exposure to potential acute residues in drinking water is expected to be negligible, as acute DWLOC's are substantially higher than modeled acute DWEC's. Based on this assessment, Valent concludes that there is a reasonable certainty that no harm to infants and children will result from acute exposure to etoxazole.

iii. *Chronic risk.* The potential chronic exposure from food to infants and children are estimated to be 2.1 to 5.7% of the proposed cPAD. Chronic exposure to potential residues in drinking water is expected to be negligible, as chronic DWLOC's are substantially higher than modeled DWEC's. Based on this assessment, Valent concludes that there is a reasonable certainty that no harm to infants and children will result from chronic exposure to etoxazole.

3. *Safety determination summary.* Aggregate acute or chronic dietary exposure to various sub-populations of children and adults demonstrate acceptable risk. Acute and chronic dietary exposures to etoxazole occupy considerably less than 100% of the appropriate PAD. EPA generally has no concern for exposures below 100% of the acute and chronic PAD's because these represent levels at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Chronic and acute dietary risk to children from etoxazole should not be of concern. Further, etoxazole has only agricultural uses and no other uses, such as indoor pest control, homeowner or turf, that could lead to unique, enhanced exposures to vulnerable sub-groups of the population. Valent concludes that there

is a reasonable certainty that no harm will result to the U.S. population or to any sub-group of the U.S. population, including infants and children, from aggregate chronic or aggregate acute exposures to etoxazole residues resulting from proposed uses.

F. International Tolerances

Etoxazole has not been evaluated by the JMPR and there are no Codex Maximum Residue Limits (MRL) for etoxazole. MRL values have been established to allow the following uses of etoxazole in the following countries: Turkey, Israel, South Africa, Japan, France, Taiwan, and Korea. The use pattern and MRL's are similar to those proposed for the U.S.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7543-8]

Proposed CERCLA Section 122(h) Administrative Agreement for Recovery of Response Costs for the Amenia Town Landfill Superfund Site, Town of Amenia, Dutchess County, NY

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency ("EPA"), Region II, of a proposed administrative agreement pursuant to Section 122(h) of CERCLA, 42 U.S.C. 9622(h), for recovery of response costs concerning the Amenia Town Landfill Superfund Site ("Site") located in the Town of Amenia, Dutchess County, New York. The settlement requires the settling parties, Town of Amenia, New York; Ashland, Inc.; BP America Inc.; Curtiss-Wright Corporation; International Business Machines Corporation; Alastair B. Martin; Estate of Edith Martin; Metal Improvement Company, Inc.; Town of Sharon, Connecticut; Syngenta Crop Protection, Inc.; TBG Services, Inc.; Unisys Corporation; and Weyerhaeuser Company to pay \$361,873.17 in reimbursement of EPA's response costs at the Site. The settlement includes a covenant not to sue the settling parties pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a), in exchange for their

payments. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region II, 290 Broadway, New York, New York 10007-1866.

DATES: Comments must be submitted on or before September 12, 2003.

ADDRESSES: The proposed settlement is available for public inspection at EPA Region II offices at 290 Broadway, New York, New York 10007-1866. Comments should reference the Amenia Town Landfill Superfund Site located in the Town of Amenia, Dutchess County, New York, Index No. CERCLA-02-2003-2029. To request a copy of the proposed settlement agreement, please contact the individual identified below.

FOR FURTHER INFORMATION CONTACT: George A. Shanahan, Assistant Regional Counsel, New York/Caribbean Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007-1866. Telephone: 212-637-3171.

Dated: July 31, 2003.

George Pavlou, Director,

*Emergency and Remedial Response Division,
U.S. Environmental Protection Agency,
Region 2.*

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7543-4]

Notice of Approval of Submission to Prohibit Mixing Zones for Bioaccumulative Chemicals of Concern Pursuant to Section 118 of the Clean Water Act and the Water Quality Guidance for the Great Lakes System for the State of New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given of approval of the submission by the State of New York to prohibit mixing zones for bioaccumulative chemicals of concern (BCCs) in the Great Lakes System pursuant to section 118(c) of the Clean Water Act and the Water Quality

Guidance for the Great Lakes System, as amended.

DATES: EPA's approval is effective on August 13, 2003.

FOR FURTHER INFORMATION CONTACT: Wayne Jackson, U.S. EPA, Region 2, 290 Broadway, New York, NY, or telephone him at (212) 637-3807. Copies of materials considered by EPA in its decision are available for review by appointment at U.S. EPA Region 2, 290 Broadway, New York, NY. Appointments may be made by calling Mr. Jackson.

SUPPLEMENTARY INFORMATION: On March 23, 1995, EPA published the Final Water Quality Guidance for the Great Lakes System (Guidance). See 60 FR 15366. The 1995 Guidance established minimum water quality standards, antidegradation policies, and implementation procedures for the waters of the Great Lakes System in the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania and Wisconsin. Specifically, the 1995 Guidance specified numeric criteria for selected pollutants to protect aquatic life, wildlife and human health within the Great Lakes System and provided methodologies to derive numeric criteria for additional pollutants discharged to these waters. The 1995 Guidance also contained minimum implementation procedures and an antidegradation policy.

The 1995 Guidance, which was codified at 40 CFR part 132, required the Great Lakes States to adopt and submit to EPA for approval water quality criteria, methodologies, policies and procedures that are consistent with the Guidance. 40 CFR 132.4 & 132.5. EPA is required to approve of the State's submission within 90 days or notify the State that EPA has determined that all or part of the submission is inconsistent with the Clean Water Act (CWA) or the Guidance and identify any necessary changes to obtain EPA approval. If the State fails to make the necessary changes within 90 days after the notification, EPA must publish a notice in the **Federal Register** identifying the approved and disapproved elements of the submission and a final rule identifying the provisions of part 132 that shall apply for discharges within the State.

Soon after being published, the Guidance was challenged in the U.S. Court of Appeals for the District of Columbia Circuit. On June 6, 1997, the Court issued a decision upholding virtually all of the provisions contained in the 1995 Guidance (*American Iron and Steel Institute, et al. v. EPA*, 115

F.3d 979 (D.C. Cir. 1997)); however, the Court vacated the provisions of the Guidance that would have eliminated mixing zones for BCCs (115 F.3d at 985). The Court held that EPA had "failed to address whether the measure is cost-justified," and remanded the provision to EPA for an opportunity to address this issue (115 F.3d at 997). In response to the Court's remand, EPA reexamined the factual record, including its cost analyses, and published the Proposal to Amend the Final Water Quality Guidance for the Great Lakes System to Prohibit Mixing Zones for Bioaccumulative Chemicals of Concern in the **Federal Register** on October 4, 1999 (64 FR 53632). EPA received numerous comments, data, and information from commenters in response to the proposal.

After reviewing and analyzing the information in the rulemaking record, including those comments, on November 13, 2000, EPA published the final rule amending the Final Water Quality Guidance for the Great Lakes System to Prohibit Mixing Zones for Bioaccumulative Chemicals of Concern, to be codified in Appendix F, Procedure 3.C of 40 CFR part 132. As amended, the Guidance requires that States adopt mixing zone provisions that prohibit mixing zones for new discharges of BCCs effective immediately upon adoption of the provision by the State, and to prohibit mixing zones for existing discharges of BCCs after November 15, 2010, except where a mixing zone is determined by the State to be necessary to support water conservation measures and overall load reductions of BCCs or where a mixing zone is determined by the State to be necessary for technical or economic reasons. Under the amended Guidance, States were given two years to adopt and submit revised water quality standards conforming with the amended Guidance.

New York's regulations banning for mixing zones for BCCs are found at 6NYCRR Part 750 State Pollutant Discharge Elimination System (SPDES) Permits, Subparts 750-1.11(a)(5)(i) and 750-1.11(a)(5)(ii), "Application of standards, limitations and other requirements." They were adopted on February 11, 2003, and the revisions were filed with the New York State Department of State on April 11, 2003, and became effective on May 11, 2003. In accordance with Section 303(c)(2)(A) of the Clean Water Act (CWA) and 40 CFR 131.20(c), the New York State Department of Environmental Conservation (NYSDEC) forwarded the amended regulation to the U.S. Environmental Protection Agency (EPA)