

TABLE 1.—REQUIRED TESTING, TEST STANDARD, AND REPORTING REQUIREMENTS FOR EDC—Continued

Testing Segment	Required testing	Test standard	Deadline for final report ¹ (Months)
	Reproductive toxicity route-to-route extrapolation of dose-response (oral data to inhalation, including Tier II Testing and extant studies reported by Alumot <i>et al.</i> (1976), Rao <i>et al.</i> (1980), and Lane <i>et al.</i> (1982)).	ECA Appendix C.4 and C.6.	52

¹ Number of months after the effective date of the Order that incorporates this ECA when the final report is due. In addition, every 6 months from the effective date of the Order until the end of the ECA testing program, interim reports describing the status of all testing to be performed under this ECA must be submitted by the Companies to EPA.

C. What are the Uses for the Test Data for EDC?

EPA would use the data obtained from testing to implement several provisions of section 112 of the Clean Air Act (CAA), including the determination of residual risk, the estimation of the risks associated with accidental releases of chemicals, and other HAP risk assessments. EPA will also use the data from this ECA to fulfill part of the Tier I Testing portion of the Voluntary Children's Chemical Evaluation Program (VCCEP). (For more information about VCCEP, see: <http://www.epa.gov/chemrtk/vccep/>.) In addition, the data will be used by other Federal agencies (e.g., the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC)) in assessing chemical risks and in taking appropriate actions within their programs (see the proposed HAPs test rule at 61 FR 33178, 33179, June 26, 1996).

D. Does the ECA for EDC Meet all the Testing Requirements for EDC that were Contained in the Proposed Test Rule?

In the proposed HAPs test rule, as amended, EPA proposed testing of EDC for acute, subchronic, developmental, and reproductive effects and neurotoxicity by the inhalation route of exposure. The ECA alternative testing program for EDC requires inhalation testing for acute toxicity and acute neurotoxicity, and oral drinking water testing for subchronic neurotoxicity and reproductive effects toxicity. The ECA requires the development of PK/MECH data to support computational PBPK modeling to inform quantitative route-to-route extrapolations of dose-response (oral to inhalation) for the endpoints of subchronic toxicity, subchronic neurotoxicity, and reproductive effects toxicity as described in the ECA.

During discussions to develop this ECA, EPA concluded that the

developmental toxicity studies reported by Rao *et al.* (1980; Ref. 11), in rabbits, and Payan *et al.* (1995; Ref. 13), in rats, adequately fulfill the HAPs rulemaking testing requirement for developmental toxicity testing for EDC and, therefore, the ECA does not require, and the final HAPs test rule will not require this testing. In addition, the ECA does not require, and the final HAPs test rule will not require, macrophage function testing (a component of EPA's acute toxicity test guideline 40 CFR 799.9135) because EPA considers existing data by Sherwood *et al.* (1987; Ref. 14) adequate to fulfill this aspect of the acute testing need. Furthermore, the Tier I HAPs Testing endpoints (acute toxicity and acute neurotoxicity) will not be included in the final HAPs test rule because the route of testing to be conducted under this ECA is identical to that specified in the HAPs rulemaking. Finally, depending on the outcome of EPA's Program Review, the Agency anticipates that the balance of the testing for EDC that was contained in the proposed HAPs test rule, as amended, will also not be included in the final HAPs test rule because the Companies will conduct equivalent testing as Tier II Testing and Extrapolation Reporting under this ECA alternative testing program for EDC. Therefore, EPA anticipates the fulfilling of all of the health effects testing requirements, identified in the HAPs proposed rule, as amended, by implementing the ECA and Order.

The issuance of the ECA and Order constitutes final EPA action for purposes of 5 U.S.C. 704.

E. What if EPA Should Require Additional Health Effects Testing on EDC?

If EPA decides in the future that it requires additional health effects data on EDC, the Agency will initiate a separate action.

IV. Other Impacts of the ECA for EDC

The issuance of the ECA and Order under TSCA section 4 subjects the Companies that signed the ECA to

export notification requirements under TSCA section 12(b)(1), as set forth at 40 CFR part 707, subpart D, if they export or intend to export EDC.

In the 12(b) proposal published in the **Federal Register** of December 23, 1997 (62 FR 67038) (FRL-5762-8), EPA proposed to amend 40 CFR 799.5000 by adding EDC to the list of chemicals subject to testing consent orders. The listing of a chemical substance at 40 CFR 799.5000 serves as notification to all persons who export or intend to export the chemical substance that:

1. The chemical substance is the subject of an ECA and Order.
2. EPA's export notification regulations at 40 CFR part 707, subpart D, apply to those exporters who have signed the ECA, as well as those exporters who have not signed the ECA (40 CFR 799.19).

When a final rule based on the proposed rule is published in the **Federal Register**, all persons who export or who intend to export EDC will be subject to export notification requirements.

V. Paperwork Reduction Act

The ECA and Order announced in this notice do not contain any information collection requirements that require additional approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements related to test rules and ECAs issued under TSCA section 4 have already been approved by OMB under OMB control number 2070-0033 (EPA ICR No. 1139). The one-time public burden for this collection of information is estimated to be approximately 3,364 hours total (Ref. 15). Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; complete and review the collection of information; and transmit or otherwise disclose the information. An agency