

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT-2003-0010. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566-0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

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II. Background

A. What is EDC?

EDC is used as a chemical intermediate principally in the production of vinyl chloride, but also vinylidene chloride, 1,1,1-trichloroethane, trichloroethylene, tetrachloroethylene, aziridines, and ethylene diamines. It is also used as a solvent. An estimated 77,111 workers are exposed to EDC (Ref. 1). The Chemical Abstract Service Registry Number (CAS No.) for EDC is 107-06-2.

B. Why Does EPA Need Health Effects Data on EDC?

EPA proposed health effects testing under TSCA section 4(a) for a number of hazardous air pollutants ("HAPs" or "HAP chemicals"), including EDC (61 FR 33178, June 26, 1996) (FRL-4869-1), as amended at 62 FR 67466, December 24, 1997 (FRL-5742-2) and 63 FR 19694, April 21, 1998 (FRL-5780-6). In the original HAPs proposal, the Agency made preliminary findings for EDC (61 FR 33178, 33190, 33191; and Ref. 1) that:

1. EDC may present an unreasonable risk of injury to health.

2. EDC is or will be produced in substantial quantities, and there is or may be substantial human exposures to the chemical.

3. There are insufficient data to determine or predict the effects of activities on human health involving EDC.

4. Testing is necessary to develop health effects data for EDC.

The HAPs rule, as amended, proposed testing of EDC for acute toxicity, subchronic toxicity, developmental toxicity, reproductive effects toxicity, and neurotoxicity (61 FR 33178, 33198, June 26, 1996; 62 FR 67466, 67483, December 24, 1997).

III. ECA Development and Conclusion

A. How is EPA Going to Obtain Health Effects Testing on EDC?

In the proposed HAPs test rule, as amended, EPA invited the submission of proposals regarding the performance of pharmacokinetics studies that would permit extrapolation from oral data to predict risk from inhalation exposure. Such proposals could provide the scientific basis for alternative testing to the testing proposed and form the basis for developing needed HAPs data via ECAs (61 FR 33178, 33189, June 26, 1996; 62 FR 67466, 67474, December 24, 1997). EPA uses ECAs to accomplish testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing (40 CFR 790.1(c)).

The procedures for ECA development are described at 40 CFR 790.22(b).

In response to EPA's request for proposals for ECAs, the HAP Task Force submitted a proposal for alternative testing that included physiologically-based pharmacokinetics (PBPK) studies and computational modeling to inform route-to-route extrapolations of dose-response for EDC on November 22, 1996 (Ref. 2). EPA responded to this proposal on June 26, 1997 (Ref. 3), indicating that the HAP Task Force alternative

approach offered sufficient merit to proceed with discussions for developing an ECA for EDC. Consequently, EPA issued a document which was published in the **Federal Register** of December 19, 1997 (62 FR 66626) (FRL-5763-1), soliciting interested parties to monitor or participate in these discussions.

EPA held a public meeting to develop an ECA for EDC on January 12, 1998. Representatives of the Companies and other interested parties attended this meeting. The participants reached consensus on the general scope of the testing to be required under the ECA. Following the public meeting, the HAP Task Force submitted (March 19, 1999) a revised proposal for a testing program (Ref. 4). On February 13, 2001, EPA responded to the HAP Task Force with comments on the revised proposal and by initiating a draft ECA for consideration by the HAP Task Force (Ref. 5). A final version of the ECA was later circulated to the HAP Task Force for signature, and returned to EPA for signature. On February 3, 2003, EPA received the ECA signed by the Companies. On May 13, 2003, EPA signed the ECA and accompanying Order (Ref. 6).

B. What Testing Does the ECA for EDC Require?

The EDC ECA alternative testing program has four segments as follows: Tier I HAPs Testing, Tier I Program Review Testing, EPA Program Review, and Tier II Testing. This is described in Table 1 in this unit and includes the following testing, reporting, and review activities:

1. *Tier I HAPs Testing.* This testing consists of endpoint testing, conducted by inhalation exposure, that EPA deemed necessary to meet certain data needs identified in the proposed HAPs test rule, as amended, and includes acute toxicity with bronchoalveolar lavage (BAL) and histopathology, and acute neurotoxicity testing. These tests will be conducted under a combined protocol as described in Appendix D.1 of the ECA.

2. *Tier I Program Review Testing.* Under this segment of the EDC ECA alternative testing program, the Companies will conduct studies to extend the computational dosimetry model of D'Souza *et al.* (1987; 1988; Refs. 7 and 8) in order to apply the model to the specific health effects endpoints for EDC listed in the ECA, validate the model, and verify the model's ability to perform quantitative route-to-route extrapolations of dose-response. In addition, the Companies will sponsor development of