



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 18 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

W. Caffey Norman, Esq.
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2550 M Street, N.W.
Washington, D.C. 20037

Dear Mr. Norman:

In the interest of coordinating the processes and clarifying several issues associated with the voluntary research program of the Agency for Toxic Substances and Disease Registry (ATSDR) and the Enforceable Consent Agreement (ECA)/test rule program of the Environmental Protection Agency (EPA), we have developed and plan to follow the approach outlined in the enclosed policy statement.

As the policy indicates, the testing proposals under the ATSDR voluntary testing research program or under EPA's ECA program must address all testing needs identified in the solicitation notice of September 30, 1994 or EPA intends to proceed with a test rule to meet these needs. The chemical endpoints identified for testing in the solicitation notice are the product of a considerable amount of coordination among EPA programs and Federal Agencies.

ATSDR and EPA strongly encourage submission of testing proposals under either program and look forward to working with you.

Sincerely,

Dr. Christopher DeRosa
Director, Division of Toxicology
Agency for Toxic Substances and
Disease Registry

Charles M. Auer
Director, Chemical Control Division
Environmental Protection Agency

Enclosure

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Development and Finalization of Agreements under
the Voluntary Research Program of the Agency for
Toxic Substances and Disease Registry (ATSDR) versus
Development and Submittal to the Environmental Protection Agency
(EPA) of Proposals for Enforceable Consent Agreements (ECAs)
in Response to EPA's 9/30/94 Notice of Solicitation

Section 104(i) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) provides that ATSDR will develop a substance-specific research program to fill data needs identified for chemicals that are most commonly found at Superfund sites and that are posing the most significant potential threat to human health. Under CERCLA, section 104(i)(5)(D), Congress contemplates that authorities under the Toxic Substances Control Act (TSCA) would be utilized to collect needed health effects data.

In October, 1992, ATSDR referred 38 chemicals to EPA for testing under TSCA authorities. See Notice, Status of the Superfund Substance-Specific Applied Research Program, Federal Register, March 10, 1994 (59 FR 11434-11435). As required under CERCLA, section 104(i), ATSDR's substance-specific research program was coordinated with testing programs under TSCA/Federal Insecticide, Fungicide, Rodenticide Act and with the National Toxicology Program. Such coordination was required "to avoid duplication of effort" and to assure that the chemicals are tested "thoroughly at the earliest practicable date." ATSDR also considered the recommendations of the Interagency Testing Committee established under TSCA, section 4(e) on the types of research to be done, as required under CERCLA. In addition, EPA considered and coordinated the data needs of its program offices and other Federal Agencies on these chemicals. Thus, the resulting list of chemicals and endpoints identified by EPA for testing under TSCA is the product of considerable coordination and represents the current federal testing priorities for these chemicals.

On September 30, 1994, EPA published a notice in the Federal Register (59 FR 49934) soliciting testing proposals from manufacturers and processors that wish to participate in negotiations for an ECA on chemicals which ATSDR referred to EPA for testing under TSCA. These chemicals are vinyl chloride, benzene, trichloroethylene, tetrachloroethylene, hydrogen cyanide, sodium cyanide, toluene, methylene chloride, and chloroethane.

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EPA understands that ATSDR is anticipating concluding voluntary agreements for testing of certain chemicals listed in the solicitation. ATSDR and EPA agree that the scope of each agency's testing program should be clearly defined. Accordingly, ATSDR and EPA have developed the following approach to meeting the identified testing priorities for the chemicals on the solicitation list:

Application. This policy applies to development of testing proposals on methylene chloride, trichloroethylene, tetrachloroethylene, and vinyl chloride. Testing proposals for the other chemicals on the solicitation list will fall under the auspices of EPA's testing program and will be governed by the procedures set forth in the solicitation notice.

Methylene Chloride. The Halogenated Solvents Industry Alliance, Inc. (HSIA) has submitted a voluntary research proposal to ATSDR on methylene chloride and, as of this date, is revising the proposal to meet ATSDR's concerns. If HSIA concludes a Memorandum of Understanding (MOU) with ATSDR for voluntary testing of methylene chloride by December 30, 1994, ATSDR will within 30 days notify EPA of the specific testing included in the voluntary agreement. In considering whether to remove methylene chloride from the solicitation list EPA will consider whether the ATSDR voluntary research agreement addresses all testing needs identified in the solicitation notice. Pursuant to the process described in the solicitation notice, HSIA may submit a proposal to conduct testing of methylene chloride under an ECA for testing needs identified in the solicitation notice but not included under the voluntary research plan. HSIA may request a reasonable extension for such submission. If HSIA and ATSDR do not conclude a MOU on methylene chloride by December 30, 1994, EPA will proceed with development of an ECA or, if an acceptable response to the solicitation notice has not been received, with a test rule.

Trichloroethylene, Tetrachloroethylene, and Vinyl Chloride. In order to participate in ATSDR's voluntary research program for trichloroethylene, tetrachloroethylene, or vinyl chloride, a party must submit, by November 29, 1994, a "statement of intent" to enter into a MOU with ATSDR for voluntary testing of trichloroethylene, tetrachloroethylene, or vinyl chloride. If a party and ATSDR conclude a MOU for voluntary testing of trichloroethylene, tetrachloroethylene, or vinyl chloride by May 31, 1995, ATSDR will within 30 days notify EPA of the specific testing included in the voluntary agreement. In considering whether to remove trichloroethylene, tetrachloroethylene, or vinyl chloride from the solicitation list EPA will consider whether the ATSDR research proposal addresses all testing needs identified in the solicitation notice. Pursuant to the process described in the solicitation notice, a party may submit a testing proposal to conduct testing of trichloroethylene, tetrachloroethylene, or vinyl chloride under an ECA for testing needs identified in the solicitation notice but not included

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under the voluntary research plan. A party may request a reasonable extension for such submission. If a party does not submit a "statement of intent" by November 29, 1994, or does not enter into a MOU with ATSDR by May 31, 1995, EPA will proceed with development of an ECA or, if an acceptable response to the solicitation notice has not been received, with a test rule.

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Received Time Nov. 18. 4:24PM

Print Time

Nov. 18. 4:26PM

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PAGE.12