



CHEMICAL MANUFACTURERS ASSOCIATION

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R&S 020071

November 28, 1994

Charles M. Auer
Director
Chemical Control Division
Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

11/28/94

Christopher T. DeRosa, Ph.D.
Director
Division of Toxicology
Agency for Toxic Substances and
Disease Registry
1600 Clifton Rd.
Atlanta, GA 30333

Dear Mr. Auer and Dr. DeRosa:

I am writing this letter on behalf of the Chemical Manufacturers Association Vinyl Chloride Panel to express our intent to work with the Agency for Toxic Substances and Disease Registry to develop a voluntary testing program that will satisfy the two data needs for vinyl chloride identified by ATSDR and referred to EPA. The Panel also would like to discuss with EPA the rationale for a neurotoxicity study and how to address EPA's concerns. The Panel represents all U.S. manufacturers of vinyl chloride.

ATSDR identified final priority data needs for 38 priority hazardous substances, including studies of the reproductive and development toxicity of vinyl chloride by the inhalation route. 57 Fed. Reg. 54150 (Nov. 16, 1992). More recently, ATSDR solicited voluntary research proposals to meet the identified data needs, and indicated that it had referred the two data needs described above to the EPA for addition to its master list, the first step in test rule development under Section 4 of the Toxic Substances Control Act. 59 Fed. Reg. 11434 (March 10, 1994).

EPA now has issued a notice inviting manufacturers and processors of nine of the chemicals referred by ATSDR to negotiate enforceable consent agreements with EPA for testing to fill those data needs. 59 Fed. Reg. 49934 (Sept. 30, 1994) (the "solicitation notice"). In certain cases, EPA has included testing to satisfy requests from its own program offices or from other agencies that are additional to the data needs referred to it by ATSDR. For vinyl chloride, EPA has added an inhalation neurotoxicity study to the data needs referred to it by ATSDR.



On November 18, our counsel, Mr. Caffey Norman, received from you a policy statement concerning the respective roles of ATSDR and EPA with regard to voluntary testing for four of the chemicals that are the subject of the solicitation notice, including vinyl chloride. This statement has been quite helpful to us in responding to the solicitation notice.

To begin our negotiations with ATSDR and EPA to develop a voluntary testing program, we propose a meeting between scientists from our member companies and ATSDR scientific staff in the first half of December to discuss the design of a two-generation reproductive study by an inhalation route. In light of the existing two-species inhalation developmental toxicity study, and other available data concerning the developmental toxicity of vinyl chloride, we would like to discuss how this study and other available data might be enhanced to include measures of developmental toxicity as an alternative to the two-species developmental toxicity study referred to EPA. Once we have reached agreement on the testing program, the Panel would propose to move forward with ATSDR to negotiate and execute, by May 31, 1995, a memorandum of understanding to address these data needs for vinyl chloride.

We understand that, should EPA decide that our voluntary research agreement with ATSDR will not address all the testing needs for vinyl chloride identified in the solicitation notice, EPA may proceed to negotiate an ECA or propose a test rule to meet such unaddressed testing needs. According to the policy statement, EPA will proceed with development of an ECA or test rule for vinyl chloride if an MOU between the Panel and ATSDR has not been executed by May 31, 1995.

If possible, the Panel would prefer that any voluntary testing program it develops addresses the data needs for vinyl chloride that have been identified by EPA as well as the two studies proposed by ATSDR. As the rationale for a neurotoxicity data need is not identified in the solicitation notice, we propose that scientists from our member companies also meet with EPA scientific staff to discuss EPA's concerns and how the neurotoxicity data need identified by EPA might be addressed.

According to the policy statement, ATSDR will within 30 days notify EPA of the terms of any voluntary testing agreement it might enter into with the Panel on vinyl chloride, and EPA will then decide whether the agreement addresses all the testing needs identified in the solicitation notice. We are not at this time in a position to judge whether EPA would decide that our voluntary research agreement with ATSDR will address all the testing needs for vinyl chloride identified in its solicitation notice. As described above, it will be necessary in this regard to have further discussions with EPA and ATSDR scientific staff and to see how our voluntary testing program develops. Accordingly, we request that the time for submission of a proposal to EPA to conduct testing of vinyl chloride under an ECA for any testing needs identified in the solicitation notice but not included under a voluntary research agreement with ATSDR be extended until June 30, 1995.

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I will call you in the next several days to determine your response regarding the negotiations with ATSDR and EPA on a voluntary testing program for vinyl chloride and to discuss meeting schedules. If you have any questions or need additional information, please call me at (202) 887-1192.

Sincerely,



Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel

cc: Brian P. Riedel, Esq.
W. Caffey Norman, Esq.
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