



CHEMICAL MANUFACTURERS ASSOCIATION

Vinyl Chloride Panel
Health Committee
Fax
November 21, 1994

TO: James Barter PPG 412/434-2137
Ed Beeler GEON 216/447-6459
Ron Gilbert Westlake 713/963-1540
Mark Gruenwald Borden 614/431-6611
James Knaak OxyChem 716/286-3141
Patrick Logue Georgia Gulf 504/687-0294
Dave Penney Vista 512/331-2387
David Pun Formosa 201/716-7283
Jonathan Ramlow Dow 517/636-1875

FROM: Has Shah *H. Shah**And: DAN KIRACOW
CAPT. NORMAN*

RE: CONFERENCE CALL ANNOUNCEMENT

This is to confirm that the conference call to discuss the enclosed agenda items is scheduled for Tuesday, November 22, 1994 at 11:30 a.m., EST. Please review the enclosed information prior to the call. Jonathan Ramlow will discuss item two. If you have any questions, please call me at (202) 887-1192. Thanks.

PAGES: 12 (including cover)

SENDER: Kim Reed

PHONE: (202) 887-1191



CHEMICAL MANUFACTURERS ASSOCIATION

Vinyl Chloride Panel

Health Committee

Tentative Agenda

Conference Call

DATE: November 22, 1994
TIME: 11:30 a.m., EST

- ✓ 1.0 Discussion of Response to ATSDR/EPA Request for Proposal
- ✓ 2.0 Discussion of a (Proposal) from Carlo Tamburo Regarding a Brain Cancer Case Control Study #100M
- ✓ 3.0 Update on Revised Proposal from Kenneth Mundt for Update of Vinyl Chloride Epidemiology Study #335M
Blank out remaining proposal content.
- ✓ 4.0 Financial Discussion
- 5.0 Set Date for Next Meeting > After Randle

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

Subject to Approval

Letter to EPA
ATSDR will be
refined.
2-3 companies
have 2004
proposal.
↓
Timeline
to AFO
↓
Review in
BFG unit
↓
Mott & Co.
in 1/95?

11/21/94 DRAFT

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

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

Re: Data Needs for Vinyl Chloride

Dear Dr. DeRosa and Mr. Auer:

In 1992, the Agency for Toxic Substances and Disease Registry (ATSDR) identified final priority data needs for 38 priority hazardous substances, including studies of the reproductive and developmental 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 Environmental Protection Agency (EPA) for addition to its master testing 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 has now issued a notice inviting manufacturers and processors of nine of the chemicals referred by ATSDR to negotiate enforceable consent agreements (ECAs) with EPA for testing to fill those data needs. 59 Fed. Reg. 499934 (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 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.

BFG 00136

- 2 -

The Vinyl Chloride Panel represents the U.S. producers of vinyl chloride. On their behalf, I am writing to express our intent to work with ATSDR to develop a voluntary testing program that would satisfy the two data needs for vinyl chloride it identified and referred to EPA. In this regard, 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 an inhalation multigeneration reproductive toxicity study and to discuss, as an alternative to the two-species developmental toxicity study referred to EPA, a one-species inhalation developmental study that could be compared to data from the inhalation developmental study on vinyl chloride already in the scientific literature. 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 (MOU) 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 address the data needs for vinyl chloride that have been identified by EPA as well as the two studies proposed by ATSDR. We believe that it may be possible to design the reproductive toxicity study in such a way that it includes measures of neurotoxicity. Accordingly, we propose that scientists from our member companies meet with EPA scientific staff at or shortly after the meeting with ATSDR scientific staff proposed above, to discuss the rationale for the neurotoxicity data need identified by EPA and how it 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

BFG 00137

- 3 -

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.

We look forward to working with you. Please do not hesitate to call if you wish to discuss any of the points in this letter.

Sincerely,

Hesmukh Shah
Manager

cc: Brian P. Riedel, Esq.
W. Caffey Norman, Esq.
EPA Docket OPPTS-42052P; FRL-4756-5

BFG 00138



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

NOV 18 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

W. Caffey Norman, Esq.
Patton, Boggs & Blow, L.L.P.
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,

A handwritten signature in cursive script, reading "Chris DeRosa".

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

A handwritten signature in cursive script, reading "Charles M. Auer".

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

Enclosure



Recycled/Recyclable
Printed with Soy-based ink on paper that
contains at least 60% recycled fiber

BFG 00139

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.

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

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.

Received Time Nov. 18. 4:24PM

Print Time

Nov. 18. 4:26PM

BFG 00142