42187

FROM: CMA 3-07-1997 12:30 PAGE 1/1 Via Electronic FAX

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CHEMICAL MANUFACTURERS ASSOCIATION

Facsimile Transmission

TO

Name ..... Charles Auer
Company ..... Director, Chemical Control Division, EPA
Location ..... Washington, D.C. 20460

Fax Number..... 912022608168
Voice Number.. 202-260-3749

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From

Name ..... Christine Tripp
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Message *or* comment ...

Re: Series 870:Health Effects Testing Guidelines

As requested, the participants on the conference call of today (11:00-11:40 a.m.) with CMA members and staff were:

Jim Quance (Exxon Chem), Chair, Chemicals Testing Task Group
John Bankston (Aristeohl, Chair, CCTG/HAP Work Group
Steve Russell, CMA, Office of General Counsel
Christine Tripp, CMA, Regulatory Affairs

Thanks again for taking the time to clarify and discuss some issues related to the above.

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Date and time of transmission: Fri 03-07-97 12:29PM
Number of pages: 0 1 (Including this cover page)

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Report to the Record: Phone conversation between Charles Auer and a group of CMA and company officials (known hereafter as "CMA" in this report; see attached listing of CMA participants) concerning the "Series 870 guidelines" and the HAPs rule; March 7, 1997, 11 :00-11:40 a.m.

Q: CMA asked about how the §870 test guidelines would be handled in the HAPs rule: would there be an additional opportunity for comment beyond that in the SAP process.

A: I responded that EPA would be providing a 30-day comment period (currently this would start at the end of March) on the final versions of eleven guidelines relevant to the HAPs rule. Final decisions as to the specific means for making the guidelines available for comment have not been made but that regardless a 30-day comment period would be provided. To the extent that CMA had questions regarding the other $870 guidelines, I noted that these other guidelines did not relate to the HAPs rule as such and that my division had not been involved in the development of the guidelines. Public comment on the $870 guidelines had been handled via the OPPTS guidelines harmonization process as described in the June 20, 1996 notice (61 FR 3 1522) cited on page 33 187 of the HAPs proposed rule and that guideline comments were considered at a November meeting of the FIFRA Science Advisory Panel (SAP). I indicated that to my knowledge this comment window had closed. To the extent that CMA had comments on the $870 guidelines, I encouraged them to send a letter to EPA, e.g., to the individuals named in the June notice or, as appropriate, to the Assistant Administrator.

Q: CMA asked about the status of the ECAs submitted to EPA; what is my guidance on the question of HAPs rule comments on these ECA-proposed chemicals (i.e., would any HAPs rule issues relating to these chemicals be resolved such that comments might not need to be submitted).

A: I responded that EPA planned to get out its response on the ECAs in the same timeframe as our release of the guidelines for comment. I noted that while I had hoped to complete decisions on the ECAs in a timeframe to allow for greater progress in developing the ECAs, this was not possible for several reasons, including the fact that the proposals contained testing packages which in some cases went beyond pharmacokinetics testing. I cited my recent letter to the MIBK panel which noted that, despite the submission of the ECA proposal, companies should be prepared to respond to all relevant issues concerning MIBK under the proposed rule. I also called attention to the statement in my letter indicating that EPA was considering the ECA proposal on MIBK; I also noted that the EPA review was proceeding even though the ECA proposal did not include pharmacokinetics testing. Given that the final disposition of the ECAs on any of the HAPs chemicals was not known at this time, I indicated that this point concerning the need to consider submitter comments on all aspects of the, proposed rule was applicable to other chemicals in the HAPs rule for which ECA proposals had been submitted (i.e., companies should consider submitting comments on the HAPs rule as proposed, regardless of the specifics of any ECA proposals).

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Q: CMA asked how EPA might handle ECA-relevant portions of the test rule in promulgating the rule. The suggestion was made that EPA could promulgate those portions of the rule which were

not affected by ECA proposals and that, in cases where ECA negotiations were successful, the relevant portions of the rule could be held open pending the completion of the ECA testing, CMA also suggested that EPA begin ECA negotiations very quickly after we have released our responses to the-industry ECA proposals; it was suggested that this could occur in April if the EPA respopnses come out at the end of March.

A: I declined to discuss EPA's possible approach to the issue raised or the suggestion offered, and suggested that this would be an appropriate area for comment by the industry. I noted EPA's interest in proceeding quickly with the ECA process and saw the next several months as offering potential opportunities for the ECA negotiations to occur (e.g., while EPA's contractor was organizing the comments). I did not rule out starting ECA negotiations in April but noted that the companies would be finalizing comments during this period. I noted further that key Agency participants in the ECA discussions were in EPA's Office of Research and Development which, as a practical matter, could limit my ability to arrange for their participation.

Q.: CMA brought up the question of meeting with companies regarding specific chemicals and encouraged that such meetings be held ifpossible. It was noted that this point was being made with an awareness of my recent letter declining to meet with industry to discuss carbonyl sulfide.

A: I noted that EPA declined to meet concerning carbonyl sufide because the issues of interest to the companies were judged to be best dealt with via the notice and comment route.

Prepared by Charles M. Auer, Director, CCD/OPPT

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