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MEMORANDUM FOR THE HAP TASK FORCE

Re: Proposed HAP Test Rule

Background

On June 26, a proposed test rule containing testing requirements for 21 hazardous air pollutants (HAPs) was published by EPA. 61 Fed. Reg. 33178. A copy of the proposal is attached. EPA solicits proposals for enforceable consent agreements (ECAs) to conduct pharmacokinetic conversions of available oral data to inhalation exposure, and asks that such proposals be submitted by October 24, 1996. Comments on the proposed test rule itself must be submitted by December 23, 1996. EPA will hold a public meeting before the close of the comment period, and, if requested before November 25, will hold two such public meetings.

The HAP Task Force has a particular interest in the testing requirements proposed for four HAPs. For ethylene dichloride (EDC), EPA is proposing developmental, reproductive, and neurotoxicity studies, as well as tests of acute and subchronic toxicity, at a total estimated cost of \$2,007,325. For 1,1,2-trichloroethane, EPA proposes to require, in addition to the five studies required for EDC, a carcinogenicity bioassay and studies of immunotoxicity and *in vivo* cytogenetics. The total estimated costs for these studies is \$3,837,900. For vinylidene chloride (VDC), EPA proposes to require a neurotoxicity study and a test of acute toxicity, at a total estimated cost of \$708,700. Significantly, EPA is withdrawing a cancer bioassay, along with distribution, metabolism, and excretion studies originally proposed for VDC in 1986. EPA has concluded that an additional bioassay would add little to its understanding of the oncogenic potential of VDC, in light of the numerous cancer bioassays of VDC that have already been conducted. Chloroethane was dropped from the proposed test rule.

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Each of the test rule studies would be required to be conducted in accordance with proposed testing guidelines published by the Office of Prevention, Pesticides and Toxic Substances, or an EPA-approved equivalent protocol. A notice of availability of these proposed test guidelines was published on June 20 and is attached. Comments on the proposed guidelines are due by August 19, 1996. The proposed test rule itself contains specific additional requirements, in particular modifications to the acute test guidelines to evaluate pulmonary and respiratory sensory irritation, and to the subchronic test guidelines to require additional respiratory tract histopathology and bronchoalveolar lavage. These additional requirements, the animal species to be used, and the route, duration, and frequency of exposure are provided, for each study, in Table 1.

EPA proposes to exempt manufacturers and processors that produce a listed HAP only as an impurity from the test rule. Persons who manufacture the substances as byproducts would, however, be subject to the test requirements. EPA's regulations define "byproduct" as a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

For each of the listed HAPs, EPA is required under the Toxic Substances Control Act to find, and has determined, (A) that the manufacture, distribution, processing, use, or disposal of such substance may present an unreasonable risk of injury to health or the environment, or (B) that the substance is or will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure to such substance. The basis for these findings for each HAP is outlined in a table in the preamble. If one or the other of these findings is made, and EPA determines that test data are necessary to determine the effects of a substance on health or the environment, it may require testing to develop such data.

Action Items

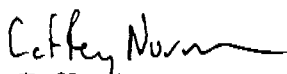
The six-month deadline provided for comments on the proposal is generous. Nevertheless, the HAP Task Force must begin immediately to review the proposed testing guidelines and evaluate available data on the substances of interest. If you have not already done so, you should obtain the proposed testing guidelines. Assignments to review existing data on the three HAPs of interest should be made, with a view toward

identifying oral or gavage studies that would provide the basis for pharmacokinetic modeling to obtain comparable inhalation exposures. We also need to line up contractor support, assuming the Task Force will wish to submit some ECA proposals. I propose that a conference call or meeting be scheduled before July 19 to get this work underway.

Longer term, we need to assess whether EPA has a solid basis for its findings of substantial production and substantial human exposure. We also need to develop arguments for opposing particular test requirements proposed by EPA that the Task Force believes are unwarranted scientifically. If desired, we can also advise as to the likelihood of success of a challenge to the imposition of testing requirements on persons who manufacture the HAPs as byproducts.

In addition, EPA specifically requests comment on alternative approaches to incorporating the proposed testing guidelines in the final test rule. The Task Force will presumably wish to support use of equivalent protocols, and may wish to object to the somewhat burdensome procedures outlined by EPA for use of equivalent protocols. The Task Force may also decide to join other groups in more generic comments attacking the overall burdens imposed by the required testing and advocating more targeted screening approaches. We will need to develop our position well in advance of the comment deadline of December 23.

We or the Manager will be in touch shortly to schedule a conference call or meeting.


W. Caffey Norman, III

Attachments