

**ENVIRONMENTAL PROTECTION AGENCY**

[OPPTS-42134C; FRL-4873-9]

**Notice of Opportunity to Participate in Negotiations for Neurotoxicity Testing**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice invites interested parties and manufacturers and processors of seven substances subject to the Multi-Substance Rule for the Testing of Neurotoxicity at 40 CFR 799.5050 who wish to participate in or monitor consent agreement negotiations pursuant to 40 CFR 790.22(b) to contact the EPA in writing. This notice also announces a public meeting to negotiate Enforceable Consent Agreements (ECAs). The seven substances for which testing will be negotiated are acetone (CAS No. 67-64-1), technical grade *n*-amyl acetate (CAS No. 628-63-7), *n*-butyl acetate (CAS No. 123-86-4), ethyl acetate (CAS No. 141-78-6), isobutyl alcohol (CAS No. 78-83-1), methyl isobutyl ketone (CAS No. 108-10-1), and tetrahydrofuran (CAS No. 109-99-9). These seven substances along with 1-butanol (CAS No. 71-36-3), diethyl ether (CAS No. 60-29-7), and 2-ethoxyethanol (CAS No. 110-80-5) were the subject of a final test rule promulgated under section 4 of the Toxic Substances Control Act ("TSCA") on July 27, 1993 (58 FR 40262). The final test rule requires manufacturers and processors of the 10 substances to conduct testing for neurotoxicity. On October 8, 1993, the Chemical Manufacturers Association (CMA) and the manufacturers and processors of these substances filed suit seeking review of the rule in the 5th Circuit Court of Appeals. Elsewhere in this Federal Register, EPA has issued an administrative stay and proposed to revoke the final test rule as part of a settlement agreement reached with the manufacturers of these chemicals, who have agreed to perform certain neurotoxicity and pharmacokinetics testing of the group of seven substances mentioned above, subject to execution of ECAs containing these studies. The settlement agreement signed by EPA and industry in April 1994 will be the starting point for the ECA negotiations (Ref. 3). EPA does not anticipate entering into an ECA for 1-butanol, diethyl ether, or 2-ethoxyethanol.

**DATES:** A meeting to negotiate ECAs for neurotoxicity testing of the seven substances will be held at the Environmental Protection Agency on

July 28, 1994. For a person to be designated an "interested party" to these negotiations, written notice must be received by EPA on or before July 27, 1994. EPA will provide an agenda to all "interested parties" and contact them if the meeting date changes.

**ADDRESSES:** The public meeting will be held at the Environmental Protection Agency, Room 1605, Northeast Mall, 401 M St., SW., Washington, DC. Submit written requests to be designated an interested party to TSCA Docket Receipts (7407), Rm NE B607, Office of Prevention, Pesticides, and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Submission should bear the document control number OPPTS-42134C. The public version of the administrative record supporting this action, with any confidential business information deleted, is available for inspection in Room NE B607 at the above address from 12 noon to 4:00 p.m. Monday through Friday, except legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Catherine Roman, Chemical Control Division, (7405); Office of Pollution Prevention and Toxics, 401 M St., SW., Washington, DC 20460, (202) 260-8155.

**SUPPLEMENTARY INFORMATION:** The manufacturers of 7 of the 10 chemicals subject to the final test rule have agreed, subject to certain conditions set forth in the settlement agreement (Ref. 3), to conduct a set of neurotoxicity and pharmacokinetics testing under enforceable consent agreements ("ECA"). If ECA negotiations are successful, EPA believes that the previously issued final test rule would no longer be needed. EPA believes that, under a negotiated ECA, neurotoxicity and pharmacokinetics testing would be conducted and results made publicly available more quickly, and EPA resources used more effectively, than if EPA continued to litigate the merits of the final test rule. This Notice will allow all interested parties an opportunity to indicate their interest in participating in the negotiations of ECAs.

**I. Background**

On July 27, 1993 (58 FR 40262) EPA issued a test rule under TSCA section 4 that required manufacturers and processors of ten substances to conduct testing for neurotoxicity (Ref. 1). The required testing was the same for all 10 substances and included acute and subchronic functional observational battery and motor activity, and subchronic neuropathology and schedule-controlled operant behavior. These 10 substances are listed below:

Chemical name	CAS No.
acetone	67-64-1
<i>n</i> -amyl acetate, technical grade	628-63-7
1-butanol	71-36-3
<i>n</i> -butyl acetate	123-86-4
diethyl ether	60-29-7
2-ethoxyethanol	110-80-5
ethyl acetate	141-78-6
isobutyl alcohol	78-83-1
methyl isobutyl ketone	108-10-1
tetrahydrofuran	109-99-9

The manufacturers of these substances petitioned for review of the final rule under TSCA section 19 in the Fifth Circuit Court of Appeals (Ref. 2). Subsequent to the filing of this challenge to the rule, EPA, the Chemical Manufacturers Association ("CMA"), and authorized representatives of all parties challenging the rule, entered into settlement negotiations to resolve the lawsuit.

As a result of these settlement discussions, CMA and the other parties to the lawsuit have agreed, subject to certain conditions set forth in the settlement agreement (Ref. 3), to conduct neurotoxicity and pharmacokinetics testing of 7 chemical substances under negotiated ECAs, to be implemented by an order issued by EPA under TSCA section 4. Testing on two of the chemicals subject to the final rule, *n*-butyl acetate and isobutyl alcohol, is already underway. It is CMA's stated intent that such testing continue on schedule during the pendency of this proceeding (Ref. 3).

In turn, EPA has agreed to propose to revoke the final test rule. The proposed revocation is published elsewhere in this Federal Register, and contains a more detailed explanation of EPA's decision with regard to the anticipated testing program. EPA is aware that the settlement agreement contemplates a reduced set of testing on fewer chemicals than the testing regimen required by the final rule. However, EPA believes that the settlement agreement is in the public interest as it will allow testing to proceed on an expedited basis, without the uncertainties of protracted litigation. EPA notes that although CMA's lawsuit has been dismissed without prejudice by the 5th Circuit Court of Appeals, in response to a joint motion for a stay, it can be reinstated by either party upon filing of a letter with the court (Ref. 4).

**II. Testing Program**

The settlement agreement contemplates a testing program which would retain the full set of tests for three chemicals (*n*-butyl acetate, ethyl acetate, and isobutyl acetate), reduce the

number of tests for four chemicals (acetone, *n*-amyl acetate, methyl isobutyl ketone, and tetrahydrofuran), and eliminate testing of three chemicals (1-butanol, diethyl ether, and 2-ethoxyethanol). It is anticipated, however, that the pharmacokinetics/metabolism test of *n*-butyl acetate may indicate that the separate testing of 1-butanol may not be necessary, and because of this, 1-butanol manufacturers have agreed to share in the cost of *n*-butyl acetate testing. The evaluation of the pharmacokinetics and metabolic fate of butyl acetate will be performed in a study of its *in vivo* hydrolysis to 1-butanol. If the conversion of butyl acetate to 1-butanol is sufficiently rapid and complete, EPA may determine that the neurotoxic effects of 1-butanol can be predicted from the results of butyl acetate testing. If this is not the case, EPA may consider reproposing separate testing of 1-butanol. EPA believes that this testing would represent a reasonable compromise which could avoid protracted litigation while still developing relevant data necessary to determine the neurotoxicity of these chemical substances.

### III. Solicitation of Interested Parties

EPA utilizes its procedures at 40 CFR part 790, subpart B, to develop enforceable consent agreements (ECA), implemented through orders issued under TSCA section 4, to require health and environmental effects testing of chemical substances in cooperation with test sponsors. EPA believes testing will be achieved more quickly, and EPA resources used more effectively, under an ECA, compared with continued

litigation on the merits of the final Multi-Substance Rule for the Testing of Neurotoxicity.

EPA is soliciting interested parties for participation in or monitoring of ECA negotiations to implement the settlement agreement in this case. Written notice of interest in being designated an "interested party" to the ECA negotiations must be received by July 27, 1994. Such notice should be sent to the address listed above in the ADDRESSES section of this notice.

The ECA negotiations will be limited to the seven chemicals outlined in the settlement agreement. The testing program described in Appendix A of the settlement agreement (Ref. 3) will be offered for consideration during the initial session of the ECA negotiations. Persons wishing to comment on EPA's decision to revoke all testing requirements for 1-butanol (CAS No. 71-36-3), diethyl ether (CAS No. 60-29-7), and 2-ethoxyethanol (CAS No. 110-80-5), and EPA's intention to propose a SNUR for 2-EE, should file these comments with EPA in response to EPA's proposed revocation of the final rule, which is published elsewhere in this Federal Register. These three chemicals will not be considered as part of the ECA negotiations.

### IV. Rulemaking Record

EPA has established a record for this notice under docket no. OPPTS-42134C. This record contains the information EPA considered in reaching the settlement agreement and the following information:

#### A. Supporting Documentation

(1) Federal Register notices pertaining to this notice consisting of:

(a) Notice of proposed multi-substance rule for the testing of neurotoxicity (56 FR 9105, March 4, 1991).

(b) Notice of final multi-substance rule for the testing of neurotoxicity (58 FR 40262, July 27, 1994).

#### B. References

(1) Final multi-substance rule for the testing of neurotoxicity (58 FR 40262, July 27, 1994).

(2) Chemical Manufacturers Association (CMA). Petition for Review. Filed with United States Court of Appeals for the Fifth Circuit. (October 8, 1993).

(3) United States Court of Appeals for the Fifth Circuit. Settlement Agreement between Environmental Protection Agency (USEPA) and petitioners. No. 93-5381. (April 28, 1994).

(4) United States Court of Appeals for the Fifth Circuit. Dismissal of petitioners appeal against EPA. No. 93-5381. (May 13, 1994).

The public record for this rulemaking is available for inspection in the TSCA Nonconfidential Information Center (also known as the TSCA Public Docket Office), Rm. NE B607, 401 M St., SW., Washington, DC from 12 noon to 4:00 p.m., Monday through Friday, except legal holidays.

Authority: 15 U.S.C. 2603

Dated: June 10, 1994.

Charles M. Auer,  
Director, Chemical Control Division, Office  
of Pollution Prevention and Toxics.

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