

**ENVIRONMENTAL PROTECTION
AGENCY**
40 CFR Part 799

[OPPTS-42134D; FRL-4874-4]

Rin 2070-AC27

**Stay of Final Multi-substance Rule for
the Testing of Neurotoxicity**

 AGENCY: Environmental Protection
Agency (EPA).

ACTION: Administrative Stay.

SUMMARY: This document announces EPA's decision to stay the Multi-Substance Rule for the Testing of Neurotoxicity at 40 CFR 799.5050, promulgated under section 4 of the Toxic Substances Control Act ("TSCA"), pending final action on a proposed revocation of the final test rule, which is published elsewhere in this Federal Register. The final test rule was published on July 27, 1993 (58 FR 40262), and requires manufacturers and processors of 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. EPA is announcing a stay of this rule as part of a settlement agreement reached with the manufacturers of these chemicals, who have agreed to perform certain neurotoxicity and pharmacokinetics testing on 7 of the 10 chemicals subject to the final test rule, subject to execution of enforceable consent agreements ("ECA") containing these studies.

DATES: This stay is effective June 27, 1994.

ADDRESSES: A public version of the administrative record supporting this action, with any confidential business information deleted, is available for inspection at the TSCA Public Docket Office (7407), Rm. NE B607, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, 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: This document announces EPA's decision to stay the Multi-Substance Rule for the Testing of Neurotoxicity at 40 CFR 799.5050, promulgated under section 4

of the Toxic Substances Control Act ("TSCA"), pending final action on a proposed revocation of the final test rule, which is published elsewhere in this Federal Register. 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. It is anticipated that the following seven substances would be tested pursuant to ECAs: 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). Testing is currently underway for *n*-butyl acetate and isobutyl alcohol. EPA does not anticipate entering into an ECA for 1-butanol (CAS No. 71-36-3), diethyl ether (CAS No. 60-29-7), and 2-ethoxyethanol (CAS No. 110-80-5), three other substances for which testing is required under the final test rule.

Elsewhere in this Federal Register, EPA is soliciting interested parties for participation in or monitoring of ECA negotiations. The settlement agreement signed by EPA and the parties to the lawsuit in April 1994 will be the starting point for the ECA negotiations (Ref. 3).

I. Background

On July 27, 1993 (58 FR 40262) EPA issued a test rule under TSCA section 4 that required manufacturers and processors of 10 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 seven 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. 21).

II. Testing Program

The testing program required for all 10 substances by the final test rule includes the following tests conducted according to the designated TSCA test guidelines:

Test	TSCA guideline
Functional observational battery, acute and subchronic	\$ 798.6050
Motor activity, acute and subchronic	\$ 798.6200
Neuropathology, subchronic	\$ 798.6400
Schedule-controlled operant behavior (SCOB), subchronic	\$ 798.6500

The test rule requires the submission of interim status reports every 6 months until the completion of testing, as well as final reports and data once testing is complete.

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. Stay of Final Test Rule

EPA is issuing this administrative stay of the final test rule pursuant to 5 U.S.C. 705, which authorizes an agency to postpone the effective date or any deadlines imposed by administrative action taken by the agency when "justice so requires," pending judicial review. See also Rule 18 of the Federal Rules of Appellate Procedure authorizing issuance of administrative stays pending review. (The need for and proper scope of neurotoxicity testing of the 10 chemical substances subject to the final test rule is at issue in litigation challenging the final rule. Although the suit has been dismissed, it can be reinstated by either party upon filing of

a letter with the Fifth Circuit Court of Appeals (Ref. 21.) EPA believes that issuance of a stay of the deadlines for submission of interim and final reports, and final submissions of test data, is necessary pending resolution of all outstanding issues. In particular, EPA believes that should ECAs be concluded, and testing conducted under orders incorporating such ECAs, the final rule itself would be moot. Consequently, EPA finds issuance of this stay is in the interests of justice.

Although EPA does not regard this administrative stay as a rule, were it to be viewed as a rule, to the extent good cause (pursuant to 5 U.S.C. 553(b)) is needed to justify EPA's immediately effective stay of all deadlines in the final rule, EPA believes that there is good cause for issuing it without prior notice and opportunity for comment and for making it immediately effective. EPA believes that the impending deadlines for submission of interim status reports under a rule that, pending public comment, may be rescinded, the ongoing testing that is being conducted even pending the final outcome of negotiations for ECAs, EPA's solicitation of interested parties to monitor or participate in ECA negotiations, and EPA's solicitation of comment on all other aspects of today's action, provide such good cause.

IV. Rulemaking Record

EPA has established a record for this stay under docket no. OPPTS-42134D. 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 stay consisting of:

(a) Notice of proposed multi-substance rule for the testing of neurotoxicity (58 FR 9105, March 4, 1991).

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

(2) Communications consisting of:

(a) Written letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

B. References

(1) Final multi-substance rule for the testing of neurotoxicity (58 FR 40262, July 27, 1993).

(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. 93-5391. (May 12, 1994).

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

V. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis and review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule: (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this order, EPA has determined that this stay would not be "significant".

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. EPA is certifying that a stay of this test rule would not have a significant impact on a substantial number of small businesses.

C. Paperwork Reduction Act

There are no information collection requirements associated with this administrative stay covered under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 799

Chemicals, Chemical export, Environmental protection, Hazardous substances, Health effects, Laboratories,

**Reporting and recordkeeping
requirements, Testing.**

Dated: June 18, 1994.

Lynn R. Goldman,
*Assistant Administrator for Prevention,
Pesticides and Toxic Substances.*

Therefore, 40 CFR, chapter I,
subchapter R, part 799 is amended as
follows:

PART 799—[AMENDED]

1. The authority citation for part 799
would continue to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

§799.5050 [Stayed]

2. By staying §799.5050 until further
notice.

[FR Doc. 94-15567 Filed 6-24-94; 8:45 am]

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