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[OPTS-42019A; TSH-FRL 2429-8]

Toxic and Hazardous Substances Control; Acetonitrile; Decision To Adopt Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA, in response to the Interagency Testing Committee's (ITC) designation of acetonitrile for priority testing consideration under the Toxic Substances Control Act (TSCA), published in the Federal Register of December 29, 1982, a Negotiated Testing Agreement which announced a preliminary decision not to require health effects testing of acetonitrile based on the Agency's analysis of existing data and preliminary acceptance of a testing program submitted by acetonitrile manufacturers.

On the basis of the Agency's review and comments received, EPA has concluded that the testing program sponsored by the manufacturers will more expeditiously provide the needed test data than would initiating rulemaking under Section 4(a) of TSCA. Therefore, EPA will not initiate rulemaking to require health effects testing of acetonitrile at this time.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington D.C. 20460. Toll Free: (800-424-9065), in Washington, D.C. (554-1404), outside the USA (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

EPA issued a notice, published in the Federal Register of June 1, 1979 which announced ITC's designation of acetonitrile for priority testing consideration under section 4(e) of TSCA. The ITC recommended that acetonitrile be considered for health effects testing. The ITC's recommendation was based on: (1) Large production volume; (2) the potential for human exposure to occur in the workplace; and (3) the lack of adequate data on carcinogenicity, mutagenicity, teratogenicity, other chronic effects and epidemiology.

In a December 29, 1982, Federal Register notice (47 FR 58020) the Agency responded to the ITC as required under section 4(e) of TSCA by describing a Negotiated Testing Agreement developed by the EPA, E. I. Dupont de Nemours and Company, Inc., Monsanto Chemical Intermediates Company, and the Vistron Corporation and announcing

its preliminary decision not to initiate rulemaking under section 4(a) of TSCA requiring health effects testing for acetonitrile. This decision was based on the Agency's analysis of the existing data and its preliminary acceptance of the program submitted by the above named acetonitrile manufacturers which, in the Agency's view, appeared likely to provide adequate test data more expeditiously than a test rule.

The acetonitrile manufacturers' program was included in the public record (docket number OPTS-42019). The Agency requested comments on the December 29, 1982, Federal Register notice (47 FR 58020) which described the acetonitrile manufacturers' program and the Agency's rationale for not proposing to require testing by rule.

II. EPA's Response to Public Comments

The Agency received comments from the Natural Resources Defense Council (NRDC), E. I. Dupont de Nemours and Company, Inc., Monsanto Chemical Intermediates Company, and the Vistron Corporation. EPA's responses to them are summarized below.

NRDC made a generic criticism of EPA's policy of accepting negotiated testing agreements in lieu of rulemaking to require testing under section 4(a) of TSCA. It argued that the "plain language" of TSCA mandates that testing of section 4(e) chemicals must be accomplished by rule. In addition, NRDC contended that negotiated testing had many procedural and legal deficiencies, noting particularly the lack of enforceability of negotiated testing agreements and failure of the agreements to trigger other statutory provisions as would be triggered by a TSCA section 4(a) rule. NRDC made no chemical specific comments about the Agency's testing rationale or the proposed acetonitrile testing program.

EPA has previously addressed NRDC's general concern about negotiated testing in a January 5, 1982, Federal Register notice (47 FR 335) which described the negotiated testing program for alkyl phthalates. A more detailed analysis of NRDC's arguments was prepared for inclusion in the public record of that action (docket number OPTS-42005). As was indicated in that notice, EPA believes that neither TSCA nor its legislative history support NRDC's contention that Congress established rules as the exclusive means for accomplishing testing. EPA believes that negotiated testing is consistent with the statutory purpose that adequate data on chemicals be developed expeditiously by the involved companies.

EPA agrees that negotiated testing is not legally enforceable; but, as the Agency has previously indicated in the January 5, 1982, Federal Register notice (47 FR 335), there are compelling practical reasons why it expects that involved companies will follow their agreements in the vast majority of cases. Furthermore, the Agency disagrees with NRDC's contention that if EPA is forced to develop a rule because of failure of a negotiated program, the entire program will take substantially longer than if EPA had initially pursued rulemaking. Rather, EPA believes that it could conduct an expedited rulemaking which in many cases would not substantially lengthen the entire process.

NRDC is correct in asserting that acceptance of a negotiated testing program will not trigger certain other statutory provisions that would be initiated if the Agency proposed, and then promulgated, a testing rule for particular substances. However, EPA believes that NRDC has considerably exaggerated the practical impact of this difference. Although a negotiated testing program does not trigger the obligation of a manufacturer of a new substance subject to a section 4 rule to submit test data under section 5(b)(1) and to delay manufacturing until that is done, that particular requirement only relates to EPA actions under section 4 concerning categories of chemical substances. It is not applicable to acetonitrile, an individual chemical substance currently in production.

In addition, contrary to NRDC's claim, EPA has the same authority to disclose health and safety data generated from negotiated testing as it would if the testing were conducted under a rule. Section 14(b)(1)(A)(i) concerns data from any health and safety study on a chemical in "commercial distribution" (which should include virtually all chemicals designated by the ITC) and makes no distinction based upon how the Agency receives the data.

EPA's position that negotiated testing is a legally sufficient alternative to section 4 rulemaking was examined by the General Accounting Office (GAO) during 1982. The GAO concluded that "neither section 4(a) nor 4(e) compels the promulgation of a test rule proceeding where adequate test data may be developed pursuant to voluntary testing agreements. GAO further concludes that since voluntary agreements are consistent with significant purposes of section 4, implied authority exists for EPA to negotiate such agreements." (GAO, 1982, EPA Implementation of Selected Aspects of the Toxic Substances Control Act.

General Accounting Office, December 7, 1982. GAO/RCED-83-62 p. 15).

Based on the above, EPA continues to believe that, where appropriate testing is being undertaken, negotiated testing agreements are an appropriate alternative to expensive, time-consuming rulemaking under section 4 of TSCA.

In their comments, the acetonitrile manufacturers clarified two important issues addressed in the December 29, 1982, Federal Register notice (47 FR 58020). The Agency reviewed their comments and its response is provided below.

1. *Use of TSCA section 11.* The acetonitrile manufacturers commented that they did not agree in their test program "to permit laboratory audit inspections in accordance with the procedures outlined in TSCA section 11, at the request of authorized representatives of the EPA." Section 11 of TSCA provides EPA with the authority to perform quality assurance audits to ensure that testing is being conducted in accordance with Good Laboratory Practice Standards. The Agency informed the acetonitrile manufacturers that adherence to the procedures outlined in section 11 is not negotiable. As a result, the acetonitrile manufacturers agreed to adhere to the procedures outlined in section 11 of TSCA.

2. *Use of Good Laboratory Practice Standards.* The acetonitrile manufacturers commented that they did not agree in their test program "that all raw data, documentation and reports generated as a result of studies will be retained as specified in the proposed TSCA Good Laboratory Practice Standards (May 9, 1979, Federal Register notice, 44 FR 27334) and made available during an inspection or submitted to EPA if requested by EPA or its authorized representative."

The Agency acknowledges the inconsistency in this statement in the December 29, 1982, Federal Register notice (47 FR 58020) with the language concerning Good Laboratory Practice Standards cited in other Federal Register notices of Negotiated Testing Agreements (Chlorobenzotrifluoride (November 8, 1982 Federal Register notice, 44 FR 50555); Methyl Isobutyl Ketone and Methyl Ethyl Ketone (December 29, 1982, Federal Register notice, 47 FR 58025) Antimony Metal, Antimony Trioxide, and Antimony Sulfide (January 6, 1983, Federal Register notice, 48 FR 717); Acrylamide (January 6, 1983, Federal Register notice, 48 FR 725); and Isophorone (January 6, 1983 Federal Register notice, 48 FR 727)). In order to resolve this inconsistency the

Agency amends the December 29, 1982, Federal Register notice (47 FR 58020) with the following language: "In conducting the mutagenicity and teratology studies, industry has agreed to adhere to Good Laboratory Practice Standards issued by the Food and Drug Administration in the December 22, 1978, Federal Register (43 FR 59986). In addition, industry has agreed that all raw data, documentation records, protocols, specimens, and reports generated as a result of the studies will be retained for at least 10 years from the date of the program's acceptance by EPA and will be made available on inspection or submitted to EPA if requested by EPA or its authorized representative." Documentation records are to include correspondence and other documents relating to the interpretation and evaluation of data. EPA sees no practical difference between the language contained in the December 29, 1982, Federal Register (47 FR 58020) and the above language. The substitution of language is being made to insure that the factual statement of what was agreed to it totally correct.

III. Testing

1. *Study Plans.* In a notice of a Negotiated Testing Agreement which appeared in the December 29, 1982, Federal Register (47 FR 58020), the Agency described the acetonitrile manufacturers' proposed program. The final study plans for this program have been submitted and are in the public record (docket number OPTS-42019). The final study plans include:

- a. A CHO/HGPRT *in vitro* mammalian cell mutation assay to be started in mid-1983 and for which a final report will be submitted by early 1984.
- b. An embryo-fetal toxicity and teratogenicity study in New Zealand White Rabbits to be initiated in mid-1983 and for which a final report will be submitted by early 1984.

2. *Conclusions.* EPA has reviewed the study plans and has concluded that:

- a. The CHO/HGPRT *in vitro* mammalian cell mutation assay will provide sufficient data to complete the first tier battery of mutagenicity data that the Agency would have normally required under a section 4(a) test rule.
- b. The teratogenicity study, in conjunction with existing data on acetonitrile's effects, can be expected to provide sufficient data to determine the embryo-fetal toxicity and the teratogenic potential of acetonitrile. This study will provide the Agency with teratogenicity data for a second mammalian species, which the Organization for Economic Cooperation

and Development and TSCA test guidelines recommend.

IV. Public Record

EPA has established a public record for this decision not to pursue testing under section 4 (docket number (OPTS-42019A)). This record includes:

(1) Federal Register notice containing the ITC report adding acetonitrile to the priority list.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays in the OPTS Reading Room, E-107, 401 M Street, SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: October 27, 1983.

William D. Ruckelshaus,
Administrator.

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[OPTS-59137; BH-FRL 2464-3]

Toxic Substances Control,
Premanufacture Exemption
Applications; Certain Chemicals

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: EPA may upon application exempt any person from the premanufacturing notification requirements of section 5(a) or (b) of the Toxic Substances Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt, are discussed in EPA's revised statement of interim policy published in the Federal Register of November 7, 1980 (45 FR 74378). This notice, issued under section 5(h)(6) of TSCA, announces receipt of five applications for exemptions, provides a summary, and requests comments on the