

IRON AND STEEL INDUSTRY—Continued

Petition No.	Facility
0460.....	MOOG Automotive.
0471.....	H. H. Robertson Co.
0491.....	CWM.
0507.....	Teledyne Monarch Rubber.
0523.....	All-Brite.
0524.....	International Galvanizing Co.
0605.....	Foatrink.
0624.....	Dresser Industries.
0628.....	Florida Wire & Cable.
0644.....	Wiremill Inc.
0648.....	American Recovery Co.
0651.....	Maytag.
0659.....	Chem Met Services.
0688.....	Carborundum.
0660.....	Al Chem-Tron, Inc.
0139.....	Resource Recycle Tech/Industrial.

The Agency requests that all comments be submitted to the RCRA Docket Clerk on or before February 21, 1984.

Dated: December 21, 1983.

Jack McGraw,
Acting Assistant Administrator for Solid Waste.

[FR Doc. 84-18 Filed 1-3-84; 8:45 am]

BILLING CODE 6580-60-M

40 CFR Part 799

[OPTS-42026A; FRL 2742-3]

Propylene Oxide; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In the First Report of the Interagency Testing Committee (ITC), the ITC designated the category of alkyl epoxides for priority consideration for epidemiological studies and testing for carcinogenicity, mutagenicity, teratogenicity, other chronic effects, and environmental fate. This notice addresses one member of the alkyl epoxides category, propylene oxide. Other members of the category will be addressed in other Federal Register notices.

Under section 4(a) of the Toxic Substances Control Act (TSCA), EPA today is proposing that manufacturers and processors of propylene oxide test this chemical for teratogenicity. EPA is not proposing epidemiological studies or testing for carcinogenicity, mutagenicity, other chronic effects, or environmental fate at this time.

DATES: Submit written comments on or before March 5, 1984. Make requests to submit oral comments by February 21, 1984. If requests are made to submit oral comments, EPA will hold a public meeting on March 19, 1984 on this rule in Washington, D.C. For further

information on arranging to speak at the meeting see Unit X of this preamble.

ADDRESS: Submit written comments in triplicate identified by the document control number (OPTS-42028A) to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), 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).

I. Introduction

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*) established in Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated the alkyl epoxides category for priority consideration in its First Report, submitted to EPA in October 1977, and published in the Federal Register of October 12, 1977 (42 FR 55028). The category, as defined by the ITC, includes all non-cyclic aliphatic hydrocarbons with one or more epoxide functional groups. The ITC recommended that the alkyl epoxides category be considered for the following testing: carcinogenicity, mutagenicity, teratogenicity, other chronic effects and environmental fate; it also recommended epidemiological studies. This notice serves as EPA's response to the recommendations of the ITC for one member of the alkyl epoxide category, propylene oxide.

Under section 4(a) of TSCA, the Administrator shall by rule require testing of a chemical substance or mixture to develop appropriate test data if the Agency finds that:

(A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B) (i) a chemical substance or mixture will be produced in substantial quantities and (i) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (ii) there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

In making section 4(a)(1)(A) findings, EPA considers both exposure and toxicity information to make the finding that the chemical may present an unreasonable risk. For the first finding under section 4(a)(1)(B), EPA considers only production, exposure and release information to determine if there is substantial production and significant or substantial exposure or substantial release. For the second finding under both sections 4(a)(1)(A) and 4(a)(1)(B), EPA examines toxicity and fate studies to determine if existing information is adequate to reasonably determine or predict the effects of human exposure to or environmental release of the chemical. In making the third finding that testing is necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's approach to determining when these findings are appropriately made is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) finding is discussed in 45 FR 48528 and the section 4(a)(1)(B) finding is discussed in 46 FR 30300.

In evaluating the ITC's testing recommendations for propylene oxide, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of propylene oxide under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); unpublished health and safety studies submitted by manufacturers and processors of propylene oxide under the TSCA section

(4) Health and Safety Data Reporting Rule (40 CFR Part 716); and other published and unpublished data available to the Agency.

II. Proposed Rule

On the basis of its evaluation, as described in this proposed rule and the technical support document, EPA is proposing teratogenicity testing for propylene oxide on the authority of sections 4(a)(1)(A) and 4(a)(1)(B) of TSCA.

A. Profile

Propylene oxide (CAS No. 75-56-9) is a colorless liquid that has an ether-like odor and is extremely flammable. It has a boiling point of 34.23°C (Ref. 1) and a density of 0.859 g/ml at 0°C (Ref. 1). Its solubility in water is 405,000 ppm at 20°C (Ref. 1).

In 1980, domestic production of propylene oxide totaled 1.77 billion pounds. Propylene oxide is currently produced by two firms—Dow and ARCO Chemical Companies—at four sites in the United States. Dow uses the chlorohydrin process at its propylene oxide plants; ARCO uses the peroxidation process. Each process accounts for about 50 percent of total U.S. capacity. Propylene oxide's major use is as a chemical intermediate. It is also used as a stabilizer in dichloromethane. In 1977, there were 32 processors of propylene oxide (Ref. 2). For a more detailed discussion of production, uses and exposure of propylene oxide, see the propylene oxide support document available from the TSCA Assistance Office.

B. Findings

EPA is basing its proposed testing on the authority of sections 4(a)(1)(A) and 4(a)(1)(B) of TSCA.

1. The 4(a)(1)(A) findings for teratogenic effects are as follows:

a. EPA finds that the manufacture, processing, and use of propylene oxide may present an unreasonable risk of injury to human health due to teratogenic effects because (a) available animal studies suggest that propylene oxide has a teratogenic potential and (b) in excess of 40,000 individuals are potentially exposed to propylene oxide as a result of its manufacture, processing, and use.

b. EPA also finds that there are insufficient animal and human data to reasonably determine or predict the teratogenic effects of propylene oxide. The finding of "may present an unreasonable risk" of teratogenic effects is based on a NIOSH inhalation teratology study (Ref. 3). Rats and rabbits were exposed to a single

concentration of 300 ppm propylene oxide. Neither developmental toxicity nor maternal toxicity was observed in rabbits exposed to 300 ppm. However, developmental and maternal toxicity were observed among female rats and their pups exposed to 300 ppm propylene oxide. A no-effect level for developmental toxicity in the rat could not be determined and one can not determine if the developmental toxicity observed in the study can be attributed entirely to maternal toxicity.

c. EPA finds that additional teratogenicity testing of propylene oxide is necessary to develop additional data to evaluate reasonably the teratogenic risks posed by exposure to propylene oxide.

2. The 4(a)(1)(B) findings for teratogenic effects are as follows:

a. There are substantial amounts of propylene oxide produced in or imported into the United States each year. The annual U.S. production volume of propylene oxide is estimated to be approximately 1.8 billion pounds, with another 90 million pounds imported into the United States each year.

b. Estimates indicate that over 40,000 people may be exposed to propylene oxide each year via manufacturing, processing, and use activities.

c. EPA finds that there are insufficient data from the NIOSH teratology study (Ref. 3) from which to reasonably determine or predict the teratogenic effect from exposure to propylene oxide, and that additional testing of propylene oxide for teratogenicity is necessary to develop such data.

On the basis of these findings, the Agency is proposing a teratogenicity test in rats on propylene oxide.

The Agency is not proposing the other tests which the ITC recommended at this time. Data from several recently completed oncogenicity studies should be sufficient to make a reasonable determination of the carcinogenicity of propylene oxide. A decision for additional mutagenicity testing on propylene oxide will be postponed until the results of a number of mutagenicity tests in progress on ethylene oxide are analyzed by the Agency (ethylene oxide, a member of the alkyl epoxides category, consistently has shown greater activity in mutagenesis assays and has tested positive in more mutagenesis assays than propylene oxide). EPA believes that the data from ongoing mutagenicity testing on ethylene oxide, along with available mutagenicity data on propylene oxide, should be used to determine what, if any, further mutagenicity testing on propylene oxide may be appropriate. Inhalation mutagenicity testing in progress on

ethylene oxide includes: (1) Alkylation in *Drosophila* sperm cells; (2) alkylation in mouse sperm cells; (3) mouse specific locus test; (4) biochemical specific locus test in mice; and (5) heritable translocation test in mice. After the data from the ongoing ethylene oxide mutagenicity testing and existing propylene oxide mutagenicity data are analyzed by the Agency, the Agency will consider: (1) whether a mouse specific locus test or other additional mutagenicity testing on propylene oxide is necessary or (2) whether ethylene oxide mutagenicity data will provide a sufficient basis for mutagenicity risk assessment for propylene oxide without further testing of propylene oxide for this effect. In making its analysis, EPA will take into account available data on other effects that may provide sufficient basis for regulation. The Agency is interested in public comment on the various aspects of assessing mutagenicity testing needs for propylene oxide. Because Dow and ARCO are performing reproductive and neurotoxic effects testing, EPA is not proposing testing for these two effects at this time. Data from these studies should be sufficient to make a reasonable determination of the reproductive and neurotoxic effects (including behavioral changes) of propylene oxide. EPA is not proposing an epidemiological study at this time. When the Agency has evaluated the results of all the oncogenicity studies on propylene oxide, it will determine whether an epidemiological study is necessary. In addition, EPA has concluded that available data are sufficient to reasonably predict the environmental fate of propylene oxide.

The analysis on which the above findings are based is presented in the propylene oxide support document, which is available from the TSCA Assistance Office.

C. Test Substance

EPA is proposing that propylene oxide of at least 99.0 percent purity be used as the test substance. Such a grade is readily available commercially.

D. Persons Required to Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Administrator makes section 4(a) findings (manufacturing, processing, distribution in commerce, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are

required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal. Because EPA has found that manufacture, processing, and use of propylene oxide give rise to exposures that may lead to an unreasonable risk, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process this chemical at any time from the effective date of this test rule to the end of the reimbursement period, be subject to the rule. The end of the reimbursement period ordinarily will be 5 years after the submission of the last final report required under the final test rule. As discussed in Unit II. F, EPA expects that manufacturers will conduct testing and that processors will ordinarily be exempted from testing.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from that requirement.

E. Approach to Adoption of Test Rules

1. General process. On March 26, 1982, EPA announced a new approach to adoption of test rules (47 FR 13102). EPA intends to promulgate a general procedural rule in 40 CFR Part 770 which will contain the procedural requirements of this new approach. However, since that procedural rule is not in effect, this proposed rule contains specific procedures for adoption of this test rule. If the general rule is promulgated before this proposed rule becomes final, the propylene oxide rule will be modified to comport with the general procedural provisions.

Under the new approach, test rule development will be a two-phase process. In phase I, EPA will propose that specific testing be required for the chemical. This phase of the rulemaking will allow the public to comment on the decision to require testing and the specific tests required. Phase II begins after promulgation of the phase I rule. In phase II, EPA will receive proposed study plans for the specific tests adopted in the phase I rule. EPA will propose those study plans for public comment. After comment, the Agency will adopt the study plans, as proposed or modified, as specific test standards

for the tests required by the phase I rule. Persons who submit the study plans will be obligated to perform the tests in accordance with the test standards adopted.

2. Letter of intent to test or exemption application. The proposed rule would require manufacturers and processors of propylene oxide to perform certain tests. Once the rule is in effect (February 3, 1984) each current manufacturer would have 30 days to submit, for each required test, either a letter of intent to perform the test or an application for exemption. Each manufacturer who submitted a letter of intent to perform a specific test would be obligated, first, to submit, within 90 days of the effective date, a proposed study plan for the test and, ultimately, to perform the test.

If manufacturers of propylene oxide performed all the required tests, processors of propylene oxide would not be required to test or to submit exemption applications. EPA would automatically grant them exemptions from the requirements of the rule.

If no manufacturer of propylene oxide submitted a letter of intent to perform a particular test within the 30-day period, EPA would publish a notice in the Federal Register to notify all processors of propylene oxide. The notice would state that EPA had not received letters of intent to perform certain tests and that current processors would have 30 days to submit, for each test remaining, either a letter of intent to perform the test or an exemption application for that test. Each processor who submitted a letter of intent to perform a specific test would be obligated, first, to submit, within 90 days of the publication of the Federal Register notice, a proposed study plan for the test and, ultimately, to perform the test.

If no manufacturer or processor submitted a letter of intent to perform a particular test, EPA would notify all manufacturers and processors, by letter or through the Federal Register, that all exemption applications would be denied and that all manufacturers and processors would be in violation of the rule until a proposed study plan is submitted for the test.

Any person not manufacturing propylene oxide at the time the rule goes into effect, who later begins manufacturing, would be required to submit a letter of intent to test or an exemption application for each required test by the day the person begins manufacture. If EPA has published a notice in the Federal Register telling processors to submit letters of intent or exemption applications for certain tests, any person not processing propylene

oxide at the time the Federal Register notice is published who later begins processing would be required to submit a letter of intent to test or an exemption application for each test specified in the Federal Register notice by the day the person begins processing.

3. Submission and adoption of study plans. Any manufacturer of propylene oxide who submitted a letter of intent to perform a test would have to submit, within 90 days after the effective date of the rule, a proposed study plan for that test. In the event manufacturers do not submit letters of intent for all the required tests, any processor who submits a letter of intent to perform a specific test would have to submit, within 90 days of the publication of the Federal Register notice discussed in Unit II. E., a proposed study-plan for that test. Paragraph (e) of the rule describes the contents of a proposed study plan.

EPA proposed generic test methodology requirements (generic test standards) which were published in the Federal Register of May 9, 1979 (44 FR 27334), July 26, 1979 (44 FR 44054), and November 21, 1980 (45 FR 77332). In response to concerns about the rigidity of generic test methodology requirements, EPA has changed its approach for providing test standards for TSCA section 4 test rules. It has issued generic test methodology guidelines to replace the previously proposed generic test methodology requirements. The TSCA guidelines have been published by the National Technical Information Service (NTIS) for health effects (PB 82-232984), environmental effects (PB 82-232992), and chemical fate (PB 82-233008). Good Laboratory Practice (GLP) standards for development of data on health effects of chemical substances under TSCA were proposed in the Federal Register of May 9, 1979 (44 FR 27334) and July 26, 1979 (44 FR 44054). GLP standards for development of data on physical and chemical properties, persistence, and ecological effects of chemical substances under TSCA were proposed in the Federal Register of November 21, 1980 (45 FR 77353). These GLP standards will be promulgated as generic requirements. The final GLP Standards will apply to the propylene oxide rule.

For guidance in preparing study plans, EPA recommends that test sponsors consult the TSCA Test Guidelines and the TSCA GLP Standards as referenced in Unit II. E.; the Organization for Economic Cooperation and Development's (OECD) Guidelines, as adopted by the OECD Council on May 12, 1981; or the FIFRA Pesticide Assessment Guidelines (PB 83-153916),

published by the National Technical Information Service (see the Federal Register of November 24, 1982 (47 FR 53192), for a list of these guidelines).

Failure to submit a study plan would be a violation of the rule.

EPA would review the proposed study plans. If they are incomplete, the manufacturer or processor would be notified of the deficiency and would have 15 days to provide appropriate information to make the plan complete. If the information is not provided in 15 days, the manufacturer or processor would be in violation of the rule. In addition, EPA would return to the appropriate stage of the process and require manufacturers or processors, as appropriate, to submit letters of intent, exemption application, and study plans.

If the proposed study plan is complete, EPA will propose the study plan for public comment. In particular, the comment would focus on whether the study plan will ensure that data from the test will be reliable and adequate. There would be a 45-day comment period and the opportunity to present views orally upon request. After considering the public comment, EPA would adopt the study plan as proposed, or as modified in response to comment, as the test standard for the required test.

The person who submitted the proposed study plan would be required to perform the test according to that standard. Failure to perform the test would be a violation of the rule.

F. Exemptions

EPA's proposed policy on application for exemptions from section 4 testing requirements was published in the Federal Register of July 18, 1980 (45 FR 48512). EPA intends to promulgate its final procedures for exemptions in 40 CFR Part 770. The exemption procedures described in Unit II. F. and included in the proposed rule language are consistent with EPA's current thinking on exemption procedures. If the general rule is promulgated before this proposal becomes final, the propylene oxide rule will be modified to comport with the general procedural provisions.

Any manufacturer or processor of propylene oxide would be able to apply for an exemption. Any person who has applied for an exemption would not be in violation of the rule until such time as EPA denies the application.

If manufacturers perform all the required testing, processors would be granted exemptions automatically without having to file applications.

When EPA has received a proposed study plan for a test and has adopted the plan as the test standard, EPA would conditionally grant all exemption

applications for that test. If the test sponsor later fails to perform the test, EPA would notify all persons who had submitted exemption applications for that test, that the exemptions would be denied unless within 30 days a manufacturer or processor notified EPA of its intent to perform the test in accordance with the adopted test standards.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for propylene oxide. As noted in Unit II. C., EPA is interested in evaluating the effects attributable to propylene oxide itself and has specified a relatively pure substance for testing.

G. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with the final EPA Good Laboratory Practice (GLP) Standards which will appear in 40 CFR Part 792. EPA has reviewed public comments on the proposed GLP Standards and will soon publish final GLP standards. The final GLP standards will apply to this rule.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. These deadlines will be established in the phase II rulemaking in which study plans are approved.

TSCA section 14(b)(1)(A)(ii) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

H. Enforcement Provisions

Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to (1) establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA. The Agency considers that failure to comply with any aspect of a section 4 rule or the submission of invalid data would be a violation of section 15 of TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held

before or after their distribution in commerce. . . ." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory audits/inspections will be periodically conducted in accordance with the authority and procedures outlined in TSCA section 11 by authorized representatives of the EPA for the purpose of determining compliance with this rule. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to EPA Good Laboratory Practice Standards and the test standards adopted in the phase II rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(F) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they had never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to \$25,000 per day for each violation. Each day of operation in violation may constitute a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to \$25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 18. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

Dow Chemical Company, which is conducting reproductive effects and neurotoxic effects testing on propylene oxide, has agreed to adhere to the proposed TSCA Good Laboratory Practice Standards issued by the Agency and published in the Federal Register of May 9, 1979 (44 FR 27334) and Nov. 21, 1980 (45 FR 77332) and has agreed to permit laboratory audits/inspections in accordance with the procedures outlined in TSCA section 11, at the request of authorized representatives of the EPA for the purpose of determining compliance with this agreement. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the raw data, and that the studies are being conducted with adequate quality assurance procedures.

In addition, Dow has agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of a study will be retained as specified in the proposed TSCA Good Laboratory Practice Standards published by the Agency and made available during an inspection or submitted to EPA if requested by EPA or its authorized representative.

Dow has agreed that TSCA section 14(b)(1)(A)(ii) governs Agency disclosure of all test data submitted for these tests.

Dow Chemical Company began the reproductive effects test and neurotoxicity test in March, 1983. The final reports on the 2-generation reproductive test and neurotoxicity test will be submitted in June 1985. Should industry fail to make a good faith effort to adhere to this schedule, EPA may require this testing by rule.

I. Issues

1. EPA considers it appropriate to postpone proposing additional mutagenicity testing on propylene oxide until the results of the ongoing mutagenicity testing on ethylene oxide are submitted to and analyzed by the Agency. Ethylene oxide is a member of the alkyl epoxides category. It has

consistently shown greater activity in mutagenicity assays and has tested positive in more mutagenicity assays than propylene oxide. Inhalation mutagenicity testing in progress on ethylene oxide includes: (1) Mouse specific locus test; (2) biochemical specific locus test in mice; (3) heritable translocation test in mice; (4) sperm alkylation in mice; and (5) sperm alkylation in *Drosophila*. EPA believes that the data from ongoing mutagenicity testing on ethylene oxide along with available mutagenicity data on propylene oxide, should be considered in determining what, if any, further mutagenicity testing on propylene oxide may be appropriate.

After the data from the ongoing ethylene oxide mutagenicity testing and existing propylene oxide mutagenicity data are analyzed by the Agency, the Agency will consider: (1) Whether a mouse specific locus test or other additional mutagenicity testing on propylene oxide is necessary or (2) whether ethylene oxide mutagenicity data will provide a sufficient basis for mutagenicity risk assessment for propylene oxide without further testing of propylene oxide for this effect. In making its analysis, EPA will take into account available data on other effects that may provide sufficient basis for regulation. The Agency is interested in public comment on the various aspects of assessing mutagenicity testing needs for propylene oxide.

2. Propylene oxide has been found to be oncogenic. (See pages 22-23 of the propylene oxide support document, which is available from the TSCA Assistance Office.) Will control of propylene oxide for its established oncogenicity be sufficient to provide adequate protection against other possible health effects of concern?

III. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis; this analysis consists of evaluating each chemical, or chemical group, on four principal market characteristics: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis for propylene oxide, along with a consideration of the cost of the required tests, indicated no significant adverse economic impact exists; therefore, Level II analysis was not needed.

Total teratogenicity testing costs for the proposed rule for propylene oxide are estimated to range from \$18,000 to \$54,000. The annualized cost range is

\$4,700 to \$14,000 per year based upon the requirement for a teratogenic health effects test.

The potential for adverse economic effects due to this test rule is small. Each of the market characteristics evaluated indicates that the potential for adverse economic impact is low. Furthermore, the additional product costs imposed by the required tests would at most be 0.0007 cents per pound, or between 0.0006 and 0.002 percent of the current price per pound (46.5 cents). This suggests that the economic impact would be minimal.

For a more complete and thorough discussion of the methodology used to conduct the economic analysis of this test rule see *Economic Impact Analysis for Test Rule on Propylene Oxide*. A copy of this document is available in the public record for this rulemaking, docket number (OPTS-42028A).

IV. Availability of Test Facilities and Personnel

Section 4(b)(1) requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs negotiated with industry in place of rulemaking. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service (NTIS), Springfield, Virginia (Publication No. 82-140773).

The conclusions reached in the laboratory availability study were: (1) The chemical testing industry's anticipation of increased testing requirements has prompted the rapid expansion of testing facilities in recent years; (2) currently, excess capacity exists in all major testing areas, and surveyed laboratories indicated they could perform about 20 percent more testing; (3) measurable industry concentration exists, but it is not enough to restrict market entry or control key resources; and (4) currently, capital and professional manpower are the most constraining resources on industry expansion of testing facilities. Capital is understandably a cyclical constraint. The constraint imposed by a shortage of professional personnel can be long-term because of the lengthy period required for professional preparation; however, current personnel numbers appear adequate relative to present testing levels.

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing required in this proposed rule.

V. Environmental Impact Statement

EPA is not required to prepare Environmental Impact Statements (EIS) under the National Environmental Policy Act (NEPA), 41 U.S.C. 4321, for test rules. EPA has determined that voluntary preparation of an EIS is not appropriate for regulations issued under section 4 of TSCA. See the preamble to the Agency's rules for compliance with NEPA published in the Federal Register of November 6, 1979 (44 FR 64174).

VI. Guidelines and Study Plans

The following guidelines and/or study plans cited in this proposed test rulemaking are available from the: National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650).

NTIS Publication No.	Title	Price
PB 82-232984	Health Effects Test Guidelines	\$40.00
PB 82-233008	Environmental Effects Test Guidelines	40.00
PB 82-233008	Chemical Fate Test Guidelines	40.00
PB 82-140773	Chemical Testing Industry: Profile of Toxicological Testing	16.00
PB 83-153916	Pesticide Assessment Guidelines	11.50

VII. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. According to section 1, definition (b) "Major rule" means any regulation that is likely to result in: (1) Annual effect on the economy of \$100 million or more; (2) A major increase in costs of prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets." This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the actual annual cost of all the testing proposed for propylene oxide is \$4,700-14,000, or less than \$54,000 over the testing and reimbursement period. Second, because the cost of the required testing will be distributed over a large production volume, the rule will have only very minor effects on users' prices (less than 0.002 percent) for this chemical, even if all test costs were

passed on. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic effects of any type as a result of this rule.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments received from OMB are included in the Public Record for this rulemaking.

VIII. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small business for the following reasons:

1. There are no small manufacturers of this chemical.
2. Small processors will not perform testing themselves, or participate in the organization of the testing efforts.
3. Small processors will experience only very minor costs in securing exemption from testing requirements.
4. Small processors are unlikely to be affected by reimbursement requirements and any testing costs passed on to small processors through price increases will be small.

IX. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* the information provisions in test rules are subject to the OMB review and are not effective until OMB approves them. OMB is currently reviewing information requirements under section 4 test rules. A notice concerning the results of that review will be published in the Federal Register.

X. Public Meetings

If persons indicate to EPA that they wish to present comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting on March 19, 1984 in Washington, D.C. This meeting is scheduled after the deadline for submission of written comments, so that issues raised in the written comments can be discussed by EPA and the public commenters. Information on the exact time and place of the meeting will be available from the TSCA Assistance Office. Toll Free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the U.S.A.: (Operator-202-554-1404).

Persons who wish to attend or present comments at the meeting should call the TSCA Assistance Office by February 21, 1984. While the meeting will be open to the public, active participation will be limited to those persons who have arranged to present comments and to designated EPA participants. Attendees should call the TSCA Assistance Office before making travel plans because the meeting will not be held if members of the public do not indicate they wish to make oral comments.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

XI. References

- (1) Winholz, M., editor. *The Merck Index*, 9th Ed. Rathway, NJ. Merck and Co., p. 1017. (1976).
- (2) SRI, "A Study of Industrial Data on Candidate Chemicals for Testing." Prepared by SRI International, Menlo Park, CA. for the Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. Contract No. 68-4109 (PB 274-264). (1977).
- (3) Hackett, P.L., Brown, M.G., Buschbom, R.L., Clark, M.L., Miller, R.A., Musie, R.L., Rowe, S.E., Schirmer, R.E., and Sikov, M.R., "Teratogenic Study of Ethylene and Propylene Oxide and n-Butyl Acetate." Prepared for the National Institute for Occupational Safety and Health under contract 2311104277 (NIOSH Contract No. 210-80-0013). (1982).

XII. Rulemaking Record

EPA has established a public record for this rulemaking, docket number [OPTS-42028A]. This record includes the basic information considered by the Agency in developing this proposal, and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received.

The Record includes the following information:

- (1) Federal Register notices pertaining to this rule consisting of:
 - (a) Notice of proposed rule on propylene oxide
 - (b) Notice containing the ITC addition of the alkyl epoxides category to the Priority List [42 FR 550926]
 - (c) Notices relating to EPA's health effects test guidelines and TSCA Good Laboratory Practice Standards [44 FR 27334 and 44 FR 44054]
 - (d) Notice of proposed rule on exemption policy and procedures

- (e) Notice of final rule on reimbursement policy and procedures
- (2) Support Documents: consisting of:
- (a) Propylene oxide support document
 - (b) Economic analysis support document
 - (3) Minutes of informal meetings
 - (4) Communications before proposal consisting of:
 - (a) Written public and intra-agency or interagency memoranda and comments
 - (b) Summaries of telephone conversations
 - (c) Summaries of meetings
 - (d) Reports—published and unpublished factual materials, including contractors' reports.

Confidential business information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Room, Rm. E-107, 401 M St. SW., Washington, D.C., from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

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

List of Subjects in 40 CFR Part 799

Testing, Environmental Protection Agency, Environmental protection, Hazardous materials, Chemicals.

Dated: December 23, 1983.

Alvin L. Alm,
Acting Administrator.

PART 799—[AMENDED]

Therefore, it is proposed that a new § 799.3450 be added to Subpart B of proposed Part 799 to read as follows:

§ 799.3450 Propylene Oxide.

(a) *Identification of test substance.* (1) Propylene oxide (CAS No. 75-56-9) shall be tested in accordance with this part.

(2) Propylene oxide of at least 99.0 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.*

(1) All persons who manufacture or process propylene oxide from the effective date of this section February 3, 1984 to the end of the reimbursement period shall submit letters of intent to test, exemption applications, and study plans and shall conduct tests and submit data as specified in paragraphs (c), (d), (e), (h), (i), and (j) of this section.

(2) Any person subject to the requirements of this section may apply to EPA for an exemption from study plan submission and testing requirements. Any such application shall be in accordance with paragraph (h) of this section.

(c) *Submission of notice of intent to test or exemption application.* (1) No

later than 30 days after the effective date of this section, each person manufacturing propylene oxide as of the effective date of this section must, for each test required by paragraph (i) of this section, either notify EPA by letter of its intent to perform the test or submit an application for an exemption from the study plan submission and testing requirements for the test.

(2) If, by the date specified in paragraph (c)(1) of this section, no manufacturer of propylene oxide has notified EPA of its intent to perform testing for a test required by paragraph (i) of this section, EPA will publish a notice in the Federal Register of this fact specifying the test for which no notice of intent has been submitted. No later than 30 days after publication of such a notice, each person processing propylene oxide as of the [effective date of this rule] must, for each test specified in the Federal Register notice, either notify EPA by letter of its intent to perform the test or submit an application for an exemption from the study plan submission and testing requirements for the test.

(3) Any person not manufacturing propylene oxide as of the effective date of this section who, before the end of the reimbursement period, manufactures propylene oxide must comply with the requirements of paragraphs (c)(1) and (d)(1) of this section. For purposes of this paragraph (c)(3), the manufacturer must submit the notice of intent to test or exemption application required by paragraph (c)(1) of this section by the date manufacture begins and must submit any proposed study plan required by paragraph (d)(1) of this section within 60 days of the date manufacture begins.

(4) If a Federal Register notice has been published under paragraph (c)(2) or (d)(4) of this section, any person not processing propylene oxide as of the effective date of this section who, before the end of the reimbursement period, processes propylene oxide must comply with the requirements of paragraphs (c)(2) and (d)(2) of this section. For purposes of this paragraph, the processor must submit the notice of intent to test or exemption application required by paragraph (c)(2) of this section by the date processing begins and must submit any proposed study plan required by paragraph (d)(2) of this section within 60 days of the date processing begins.

(5) Any manufacturer or processor of propylene oxide, which has notified EPA under paragraphs (c) (1), (2), (3), or (4) of this section of its intent to perform testing for a test required by paragraph (i) of this section, must submit a

proposed study plan for the test as required in paragraph (d) of this section and must perform that test in accordance with the test standards in paragraph (j) of this section.

(d) *Submission of proposed study plans.* (1) Manufacturers of propylene oxide which notify EPA under paragraph (c)(1) of this section that they intend to perform a test must submit a proposed study plan for the test in accordance with paragraph (e) of this section no later than 90 days after the effective date of this section. Manufacturers may jointly submit a single proposed study plan if they plan to sponsor or perform the test jointly. Any manufacturer which, having notified EPA of its intent to perform a test, fails to submit a proposed study plan for that test will have been in violation of this section as if no letter of intent to perform the test had been submitted.

(2) Processors of propylene oxide which notify EPA under paragraph (c) (2) of this section that they intend to perform a test must submit a proposed study plan for the test in accordance with paragraph (e) of this section no later than 90 days after the publication of the notice specified in paragraph (c) (2) of this section. Processors may jointly submit a single proposed study plan if they plan to sponsor or perform the test jointly. Any processor which, having notified EPA of its intent to perform a test, fails to submit a proposed study plan for that test will have been in violation of this section as if no letter of intent to perform the test had been submitted.

(3) If EPA determines in accordance with paragraph (f)(1)(i) of this section that a proposed study plan is incomplete and the manufacturer or processor has not, after notice from EPA, submitted appropriate information to make the study plan complete within 15 days, the manufacturer or processor will have been in violation of this section as if no letter of intent to perform the test had been submitted.

(4) If either: (i) By the date specified in paragraph (d)(1) of this section a manufacturer of propylene oxide, which notified EPA of its intent to perform a test, has failed to submit a proposed study plan for that test, or

(ii) A proposed study plan submitted under paragraph (d)(1) of this section has been found to be incomplete under paragraph (f)(1)(i) of this section and the manufacturer has not submitted appropriate information to make the study plan complete within 15 days, EPA will publish a notice in the Federal Register of this fact specifying the test.

The requirements of paragraphs (c)(2) and (d)(2) of this section for processors to submit letters of intent to perform testing, applications for exemption, and proposed study plans will apply.

(5) If either: (i) By the date specified in paragraph (c)(2) of this section no processor of propylene oxide has notified EPA of its intent to perform testing for any test identified in a Federal Register notice published under paragraphs (c)(2) or (d)(4) of this section, or

(ii) By the date specified in paragraph (d)(2) of this section any processor of propylene oxide, which notified EPA of its intent to perform a test, has failed to submit a proposed study plan for that test, or

(iii) A proposed study plan submitted under paragraph (d)(2) of this section has been found to be incomplete under paragraph (f)(1)(i) of this section and the processor has not submitted appropriate information to make the study plan complete within 15 days, all applications for exemption from the requirements to submit study plans and to perform tests for the specific test involved will automatically be denied. EPA will notify each manufacturer and processor of propylene oxide, which applied for an exemption for the specific test involved, of this automatic denial either by letter or by notice in the Federal Register.

Each manufacturer or processor of propylene oxide for whom an exemption application has been automatically denied will be in violation of this section 30 days from the time that it receives the notice letter or that the notice is published in the Federal Register, whichever comes first. The violation will continue until a manufacturer or processor of propylene oxide submits a proposed study plan for each test involved.

(6) Any manufacturer or processor of propylene oxide may submit a proposed study plan for any test required by this section at any time regardless of whether the manufacturer or processor previously submitted an application for exemption from testing for that test.

(e) *Content of study plans.* (1) All study plans are required to contain the following information:

(i) A citation to this section and the specific test covered by the study plan.

(ii)(A) The names and addresses of the test sponsors.

(B) The names, addresses, and telephone numbers of the responsible administrative officials and project manager(s) in the principal sponsor's organization.

(C) The name, address, and telephone number of the appropriate individual for

oral and written communications with EPA.

(D)(1) The name and address of the testing facility and the names, addresses, and telephone numbers of the testing facility's administrative officials and project manager(s) responsible for this testing.

(2) Brief summaries of the training and experience of each professional involved in the study including study director, veterinarian(s), toxicologist(s), pathologist(s) and pathology assistants.

(iii) Identity and data on the chemical substance being tested, including appropriate physical constants, spectral data, chemical analysis, and stability under test and storage conditions.

(iv) Study protocol, including rationale for: species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; a description of diet to be used and its source, including nutrients and contaminants and their concentrations; for *in vitro* test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

(v) Schedule for initiation and completion of major phases of long-term tests; schedule for submission of interim progress and final reports to EPA.

(2) Information specified under paragraph (e)(1)(ii)(D) of this section is not required in proposed study plans if the information is not available at the time of submission; however, the information must be submitted before the initiation of testing.

(f) *Review and adoption of study plans.* (1) Upon receipt of a proposed study plan, EPA will review the study plan to determine whether it complies with paragraph (e) of this section.

(i) If EPA determines that the proposed study plan does not comply with paragraph (e) of the section, EPA will notify the submitter that the submission is incomplete and will identify the deficiencies and the steps necessary to complete the submission. The submitter will have 15 days from the day it receives this notice to submit appropriate information to make the study plan complete. If the submitter fails to provide appropriate information to complete the study plan within this time, the submitter will have been in violation of this section as if no study plan had been submitted.

(ii) If EPA determines the proposed study plan complies with paragraph (e) of this section, EPA will publish a notice in the Federal Register requesting comments on the ability of the study plan to ensure that data from the test will be reliable and adequate. EPA will

provide a 45-day comment period and will provide an opportunity for an oral presentation upon request of any person. EPA may extend the comment period if it appears from the nature of the issues raised by EPA's review or from public comments that further comment is warranted.

(2) After receiving and considering public comment, EPA will adopt the study plan, including time deadlines and reporting schedules, as proposed or as modified in response to EPA review and public comments, as test standards for the testing of propylene oxide in paragraph (j) of this section.

(g) *Modification of study plans during conduct of study.* (1) *Application.* Any test sponsor who wishes to modify the adopted study plan for any test or study required under this section must submit an application in accordance with this paragraph. Application for modification shall be made in writing to the Chief, Test Rules Development Branch, Office of Toxic Substances, or by phone with written confirmation to follow as soon as feasible. Applications must include appropriate explanation of why the modification is necessary.

(2) *Adoption.* To the extent feasible, EPA will seek public comment on all substantive changes in study plans. EPA will issue a notice in the Federal Register requesting comments on requested modifications. However, EPA will act on the requested modification without seeking public comment if either: (i) EPA believes that an immediate modification to a study plan is necessary in order to preserve the accuracy or validity of an ongoing study, or

(ii) EPA determines that a modification clearly does not pose any substantive issues. EPA will notify the sponsor of EPA's approval or disapproval. When EPA approves a modification, it will publish a note in the Federal Register indicating that the study plan has been modified.

(h) *Exemption applications.* (1) Any manufacturer or processor of propylene oxide may submit an application to EPA for an exemption from submitting proposed study plans for and from performing any or all of the tests specified in paragraph (i) of this section. The application must include the name and address of the manufacturer or processor and must identify the specific requirements of this section for which the exemption is sought.

(2) No manufacturer or processor of propylene oxide will be in violation of the requirement to perform a specific test under paragraph (i) of this section if it has submitted a timely application for