

**ENVIRONMENTAL PROTECTION  
AGENCY**

40 CFR Part 799

(OPTS-42044; FRL 2465-2)

**Hexafluoropropylene Oxide Proposed  
Test Rule**

**AGENCY:** Environmental Protection  
Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Interagency Testing Committee (ITC) recommended that EPA consider requiring health effects testing of halogenated alkyl epoxides. Under section 4(a) of the toxic Substances Control Act (TSCA), EPA is proposing that the manufacturers and processors of hexafluoropropylene oxide (HFPO), one member of the category of halogenated alkyl epoxides, test HFPO for mutagenicity, oncogenicity, and reproductive effects. EPA is not proposing that HFPO be tested for teratogenicity as recommended by the ITC because the Agency has found no evidence to suggest that HFPO may produce teratogenic effects. EPA is also not proposing an epidemiology study for HFPO because a suitable cohort is not available. EPA is not initiating rulemaking to require testing of other members of the category of halogenated alkyl epoxides at this time. A separate notice published in today's Federal Register explains that decision.

**DATES:** The public is asked to submit written comments on this proposed rule on or before February 28, 1984. If persons request time for oral comment by February 13, 1984, EPA will hold a public meeting on March 14, 1984, to receive oral comments on this proposed rule in Washington, D.C. For further information on arranging to speak at the meeting see Unit VI of this preamble.

**ADDRESS:** Address written comments identified by the document control number (OPTS-42044) in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St. SW., Rm. E-108, Washington, D.C. 20460.

A public version of the administrative record supporting this action, with 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), Office of Toxic Substances, 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**

Section 4(a) of TSCA (Pub. L. 94-489, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations requiring testing of chemical substances and mixtures to develop data relevant to determining the risks that such chemicals may present to health and the environment.

Section 4(e) of TSCA established an 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 halogenated alkyl epoxides for priority consideration in its Second Report, published in the Federal Register of April 19, 1978 (43 FR 18684). The ITC defined this category of halogenated alkyl epoxides as "halogenated noncyclic aliphatic hydrocarbons with one or more epoxy functional groups." Seven specific compounds in this category were discussed in the ITC's Report: 1-chloro-2,3-epoxy propane (epichlorohydrin or ECH); 1,1,1-trichloro-2,3-epoxypropane (TCPO); 1-bromo-2,3-epoxybutane (epibromohydrin or EBH); 1,4-dichloro-2,3-epoxybutane (DCBO); 1,1,1-trichloro-3,4-epoxybutane (TCBO); tetrafluoroethylene oxide (TFEO); hexafluoropropylene oxide (HFPO).

The ITC recommended that halogenated alkyl epoxides be considered for testing for carcinogenicity, mutagenicity, teratogenicity, and other chronic effects, and that epidemiology studies should be considered. The ITC's recommendations for this category were based on: (1) High production levels for one member of the chemical category (500 million pounds annually for epichlorohydrin), (2) a National Institute for Occupational Safety and Health (NIOSH) estimate that between 50,000 and 140,000 workers are exposed to epichlorohydrin annually, (3) expected increases in the use of other halogenated alkyl epoxides, and (4) limited studies on oncogenic, mutagenic, teratogenic, and other chronic effects of halogenated alkyl epoxides.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance or mixture to develop health or environmental 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 is or 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 effect is necessary to develop such data.

EPA uses a weight of evidence approach in making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure, and release information to determine if there is or may be substantial production and substantial or significant 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 process for determining when these findings apply is described in detail in EPA's first and second proposed test rules. The section 4(a)(1)(A) findings are discussed in the Federal Register of July 13, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300) and the section 4(a)(1)(B) findings are discussed in the Federal Register of June 15, 1981 (46 FR 30302).

In evaluating the ITC's testing recommendations for halogenated alkyl

epoxides. 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 halogenated alkyl epoxides under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); unpublished health and safety studies submitted by manufacturers of halogenated alkyl epoxides under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716); and other published and unpublished data available to the Agency. On the basis of its evaluation as described in this preamble and the accompanying technical support document, EPA is proposing mutagenicity, oncogenicity, and reproductive effects testing requirements for hexafluoropropylene oxide under section 4(a)(1)(A) of TSCA. EPA is not initiating rulemaking to require testing of other members of the category of halogenated alkyl epoxides at this time. A separate notice published elsewhere in this issue of the Federal Register explains that decision.

## II. Hexafluoropropylene

### A. Profile

Hexafluoropropylene oxide, CAS No. 428-59-1, is a gas at ambient temperature and pressure. Only one company produces HFPO in the United States. Specific production, use, exposure, and release data submitted by the manufacturer to EPA were claimed confidential. HFPO is reported in the open literature to be used as a chemical intermediate in the manufacture of fluorinated substances.

### B. Findings

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

1. EPA finds that the manufacture and processing of HFPO may present an unreasonable risk of injury to the health of workers. EPA has reached this conclusion because: (1) Available information indicates that the manufacture and processing of HFPO are the principal sources of exposure to this substance; (2) monitoring data indicate there is workable exposure to HFPO at levels that may elicit the effects of concern; and (3) substances that are structurally similar to HFPO have demonstrated oncogenic, mutagenic, and reproductive activity in animals and EPA believes there is the potential for HFPO to elicit similar effects. In addition, a subchronic study on HFPO, in which reduced spermatogenesis was

observed, raises concern that HFPO may produce reproductive effects.

2. EPA finds that there are insufficient data to reasonably determine or predict the oncogenic, mutagenic, and reproductive effects of HFPO. EPA has reached this conclusion because there are no test data on HFPO relating to oncogenic and mutagenic effects. With regard to reproductive effects, the existing data on HFPO suggest that HFPO can produce reproductive effects, but are not sufficient to reasonably evaluate HFPO's potential to cause such effects.

3. EPA finds that testing of HFPO for oncogenicity, mutagenicity, and reproductive effects is necessary to develop data needed to evaluate that health risks posed by exposure to HFPO.

On the basis of these findings, the Agency is proposing a 2-year oncogenicity bioassay in animals as a basis for determining the oncogenic potential of HFPO. The Agency is also proposing a battery of short-term tests for gene mutation and chromosomal aberrations which it believes will provide an adequate basis for determining whether HFPO has mutagenic activity. The National Toxicology Program (NTP) is planning to conduct a *Salmonella typhimurium* mammalian microsomal reverse mutation assay (Ames assay) for HFPO, the results of which should be available in 1984. If NTP conducts an Ames assay for HFPO before this rule is final and the test is adequate, the selection of tests for gene mutation in the final rule will be based on the results of the Ames assay performed by NTP. In addition, EPA is proposing a 2-generation reproductive effects study in animals to provide an adequate basis for assessing HFPO's ability to produce reproductive effects.

EPA is not proposing that HFPO be tested for teratogenicity because there is no evidence to suggest that HFPO or structural analogues may produce teratogenic effects; therefore, a finding of potential risk cannot be made for this effect.

EPA is not proposing additional chronic effects testing other than the oncogenicity bioassay because EPA believes information from the bioassay, in conjunction with data from the subchronic study already performed on HFPO, will be sufficient to characterize the chronic effects of HFPO.

EPA is not proposing an epidemiology study of HFPO because a cohort large enough for a meaningful epidemiology study is not available at this time.

EPA does not find that the number of people exposed to HFPO is substantial

or involves a significant segment of the population or that HFPO enters the environment in substantial quantities; consequently, the Agency is not proposing testing of HFPO under section 4(a)(1)(B) of TSCA.

The analyses on which these findings are based are presented in the technical support document for this rulemaking, "Assessment of Testing Needs: Hexafluoropropylene Oxide," which is available from the TSCA Assistance Office. The ITC's recommendations and EPA's proposed testing requirements are summarized below.

### TESTING FOR HFPO

Test or study	ITC recommendation	EPA proposal
Carcinogenicity	Yes	Yes
Mutagenicity	Yes	Yes
Teratogenicity	Yes	No
Reproductive effects	No	Yes
Other chronic effects	Yes	No
Epidemiology	Yes	No

### C. Test Substance

EPA is proposing that HFPO of at least 99 percent purity be used as the test substance. EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to HFPO itself.

### D. Persons Required To Test

Section 4(b)(3)(B) specifies that the activities for which the Administrator makes section 4(a) findings (manufacture, processing, distribution, 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 the manufacture and processing of HFPO may present an unreasonable risk to human health, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process HFPO 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 test rule.

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 (as discussed in Unit ILF, below).

#### *E. Approach To Adoption of Test Rules*

1. *General Process.* On March 28, 1982, EPA announced a new approach to adoption of test rules (47 FR 13012). EPA intends to promulgate a general procedural rule in 40 CFR Part 770 which will contain the procedural requirements for this approach. However, because 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 proposal becomes final, the HFPO final rule will be modified to comport with the general procedural provisions.

Under the approach being followed for HFPO, test rule development will be a two-phase process. In phase I, EPA will propose that specific testing be required for HFPO. This phase of the rulemaking will allow the public to comment on the decision to require testing and the specific types of tests to be 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 HFPO to perform certain test sets. (The term "test set" is used because certain mutagenicity tests in the proposal are tiered, and EPA is proposing that the person who tests must perform all the required tests in that tier.) Once the rule is in effect, 30 days after publication in the Federal Register, each current manufacturer would have 30 days to submit, for each required test set in paragraph (j) of the rule, either a letter of intent to perform the test set or an application for exemption. Each manufacturer who submitted a letter of intent to perform a specific test set would be obligated,

first, to submit, within 90 days of the effective date, a proposed study plan for the test set and, ultimately, to perform the testing.

If manufacturers of HFPO performed all the required test set, processors of HFPO 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 HFPO submitted a letter of intent to perform a particular test set within the 30-day period, EPA would publish a notice in the Federal Register to notify all processors of HFPO. The notice would state that EPA had not received letters of intent to perform certain test sets and that current processors would have 30 days to submit, for each test set remaining, either a letter of intent to perform the test set or an exemption application for that test set. Each processor who submitted a letter of intent to perform a specific test set would be obligated, first, to submit, within 90 days of the publication of the Federal Register notice, a proposed study plan for the test set and, ultimately, to perform the testing.

If no manufacturer or processor submitted a letter of intent to perform a particular test set, EPA would notify all manufacturers and processors, by letter or through the Federal Register, that all exemption applications would be denied and that within 30 days all manufacturers and processors would be in violation of the rule until a proposed study plan is submitted for that test set.

Any person not manufacturing HFPO at the time the rule goes into effect, who later begins manufacturing before the end of the reimbursement period, would be required to submit a letter of intent to test or an exemption application for each required test set 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 test sets, any person not processing HFPO at the time the rule goes into effect, who later begins processing before the end of the reimbursement period, would be required to submit a letter of intent to test or an exemption application for each test set specified in the Federal Register notice by the day the person begins processing.

3. *Submission and Adoption of Study Plans.* Any manufacturer of HFPO who submitted a letter of intent to perform a test set would have to submit, within 90 days after the effective date of the rule, a proposed study plan for that test set.

In the event manufacturers do not submit letters of intent for all the required test sets, any processor who submits a letter of intent to perform a specific test set would have to submit, within 90 days of the publication of the Federal Register notice notifying processors, a proposed study plan for that test set. Paragraph (e) of the rule describes the contents of a proposed study plan.

EPA proposed generic test methodology requirements (generic test standards) in the Federal Register of May 9, 1979 (44 FR 27334), July 28, 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), 53285 Port Royal Road, Springfield, VA, (703-482-4650), 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 28, 1979 (44 FR 44054). GLP standards for development of data on physical and chemical properties, persistence, and ecological effects on 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 TSCA GLP standards will apply to the HFPO test rule.

For guidance in preparing study plans, EPA recommends that test sponsors consult the TSCA Test Guidelines and the TSCA GLP standards as referenced above, the Organization for Economic Cooperation and Development's (OECD) Guidelines, as adopted by the OECD Council on May 12, 1981, or the FIFRA Pesticide Registration Guidelines: Proposed Data Requirements published by the NTIS (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 applications, and study plans.

If the proposed study plan is complete, EPA would propose the study plan for comment. In particular, the request for comments would focus on whether the study plan will ensure that data from the test set 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 set.

The person who submitted the proposed study plan would be required to perform the testing according to that standard. Failure to perform the testing 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 below 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 HFPO rule will be modified to comport with the general procedural provisions.

Any manufacturer or processor of HFPO 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 set and has adopted the plan as the test standard, EPA would conditionally grant all exemption applications for that test set. If the test sponsor later fails to perform the testing, EPA would notify all persons who had submitted exemption applications for that test set 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 HFPO. As noted in Unit I.L.C., EPA is interested in evaluating the effects attributable to HFPO 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 its final GLP standards which will appear in 40 CFR Part 792.

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) 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

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. 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 rule issued under 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 conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of EPA for the purpose of determining compliance with any final rule for HFPO. 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 GLP standards and the test standards established 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)(B) 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 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 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturer, processors that fail to submit a letter or 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 one 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 16. 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.

### I. Issues

1. As an alternative to testing, manufacturers and processors of HFPO could commit themselves to control the levels of HFPO to which workers are exposed based on control levels to be decided for epichlorohydrin, a structural analog of HFPO. Several bioassays indicate that epichlorohydrin is an oncogen in rats and provide sufficient information to assess the oncogenic hazard of epichlorohydrin. On the basis of these data, EPA has initiated an evaluation of the need to control exposure to epichlorohydrin to reduce its risk to humans. Because fluorinated compounds generally have been found to be less toxic than chlorinated analogs, EPA believes that the toxicity of HFPO is likely to be less than that of epichlorohydrin and that control of HFPO based on levels established for epichlorohydrin would provide a correspondingly greater degree of protection against risk from HFPO. In conjunction with the adoption of exposure controls by current manufacturers and processors of HFPO, EPA also would consider the need to promulgate a significant new use rule under section 5(a)(2) of TSCA to ensure adequate control of exposures to HFPO from any future expansion in the production or uses of this chemical substance. EPA requests comments on this alternative to testing of HFPO.

2. EPA is proposing that mutagenicity testing be performed for HFPO. The proposed mutagenicity testing is divided into two tiered schemes—chromosomal aberrations and gene mutation. To avoid delays in performing the tiered testing, EPA is proposing that as single manufacturer or processor perform all the tiered tests in the chromosomal aberrations scheme and that a single manufacturer or processor perform all the tiered tests in the gene mutation scheme. In addition, EPA is proposing that the manufacturer or processor that indicates its intent to perform the tests in one of these schemes must submit protocols for all of the tiered tests in the scheme at the time it submits its study plan. EPA has chosen this approach to avoid delays in performing the tiered testing under the two-phase rulemaking process.

As an alternative, EPA could allow manufacturers and processors to submit protocols for only the tests in the first two tiers at the time they submit their study plans. If testing were required in the third tier, EPA could require submission of the protocol for the third tier test later and conduct an expedited phase II rulemaking for that test. EPA solicits comments on the these

approaches to submission of protocols for tiered testing.

### 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 consists of evaluating each chemical substance 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, along with the consideration of the costs of the required tests indicate whether the possibility of a significant adverse economic impact exists. Where the indication is negative, no further economic analysis is done for that chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted. This Level II analysis attempts to predict more precisely the magnitude of the expected impact.

Total testing costs for the proposed rule for HFPO are estimated to range from \$318,000 to \$960,000. The Level I economic analysis suggests that there is some potential for adverse economic impact as a result of these test costs, however, based on present analysis, the magnitude of the impact is not projected to be significant.

### IV. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA 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 NTIS (PB 82-140773).

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

### V. Environmental Impact Statement

EPA is not required to prepare Environmental Impact Statements (EISs), 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 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 84174).

### 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), 5258 Port Royal Road, Springfield, VA 22161, (703-487-4650).

NRS Publication No.	Title	Price
PB 82-232984	TSCA Guidelines—Health Effects	\$40.00
PB 82-232982	TSCA Guidelines—Environmental Effects	60.00
PB 82-233008	TSCA Guidelines—Chemical Fate	40.00
AD 250 504 (PB 83-153916)	Pesticide Assessment Guidelines	11.50

### VII. 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 14, 1984 in Washington, D.C. Persons who wish to present comments at the meeting should call the TSCA Assistance Office (TAO); Toll Free: (800-424-9085); In Washington, D.C.: (554-1404); Outside the U.S.A. (Operator 202-554-1404), by February 13, 1984. The meeting will not be held if members of the public do not indicate that they wish to make oral presentations. 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. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to check whether the meeting will be held.

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.

### VIII. Rulemaking Record

EPA has established a record for this rulemaking, docket number (OPTS-42044). This record includes basic

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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 rulemaking on HFPO.

(b) Notice containing the ITC designation of halogenated alkyl epoxides to the Priority List.

(c) Notices relating to EPA's health effects test guidelines and GLP standards.

(d) Notice of proposed rulemaking on exemption policy and procedures.

(e) Notice of final rule on reimbursement policy and procedures.

(2) Support Documents: consisting of:

(a) HFPO technical support document.

(b) HFPO economic analysis.

(3) Minutes of informal meetings.

(4) Communications before proposal consisting of:

(a) Written public and intra- or interagency memoranda and comments.

(b) Telephone conversations.

(c) Meetings.

(d) Reports published and unpublished factual materials, including contractors' reports.

(5) Study on the availability of test facilities and personnel (Chemical Testing Industry: Profile of Toxicological Testing).

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.

#### IX. 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. 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 cost of all the proposed testing for HFPO is \$318,000 to \$960,000 or less than \$1 million over the testing and reimbursement period. Second, the cost of the testing is not likely to result in a major increase in users' costs or prices. Finally, based on our present analysis, EPA does not believe that there will be a significant adverse effect 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 from OMB to EPA, and any EPA response to those comments, will be included in the rulemaking record.

#### X. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (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 businesses because: (1) They will not perform testing themselves, or will not participate in the organization of the testing effort; (2) they will experience only very minor costs in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

#### XI. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

(Sec. 4, Pub. L. 94-469, 90 Stat. 2003; (15 U.S.C. 2061))

#### List of Subjects in 48 CFR Part 799

Testing, Environmental protection. Hazardous material, Chemicals.

Dated: December 21, 1983.

William D. Rockelshans,  
Administrator.

#### PART 799—[AMENDED]

Therefore, it is proposed that a new § 799.2150 be added to Subpart B of proposed Part 799 to read as follows:

§ 799.2150. Hexafluoropropylene oxide.

(a) *Identification of test substance.* (1) Hexafluoropropylene oxide (CAS No. 428-59-1) (hereinafter "HFPO") shall be tested in accordance with this section.

(2) HFPO of at least 99 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 HFPO from the effective date of this section (30 days from the publication date of the final rule in the Federal Register) 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), (j), and (k) 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 HFPO as of the effective date of this section must, for each test set required by paragraph (j) (1), (2), (3), and (4) of this section, either notify EPA by letter of its intent to perform the test set or submit an application for an exemption from the study plan submission and testing requirements for the test set.

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

(3) Any person not manufacturing HFPO as of the effective date of this section who, before the end of the reimbursement period, manufactures HFPO 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 paragraphs (c)(2) or (d)(4) of this section, any person not processing HFPO as of the effective date of this section who, before the end of the reimbursement period, processes HFPO must comply with the requirements of paragraphs (c)(2) and (d)(2) of this section. For purposes of this paragraph

(c)(4), 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 HFPO, which has notified EPA under paragraph (c)(1), (2), (3), or (4) of this section of its intent to perform testing for a test set required by paragraph (j) of this section, must submit a proposed study plan for the test set as required in paragraph (d) of this section and must perform that test set in accordance with the test standards in paragraph (k) of this section.

(d) *Submission of proposed study plans.* (1) Manufacturers of HFPO which notify EPA under paragraph (c)(1) of this section that they intend to perform a test set must submit a proposed study plan for the test set 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 set jointly. Any manufacturer which, having notified EPA of its intent to perform a test set, fails to submit a proposed study plan for that test set will have been in violation of this section as if no letter of intent to perform the test set had been submitted.

(2) Processors of HFPO which notify EPA under paragraph (c)(2) of this section that they intend to perform a test set must submit a proposed study plan for the test set 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 set jointly. Any processor which, having notified EPA of its intent to perform a test set, fails to submit a proposed study plan for that test set will have been in violation of this section as if no letter of intent to perform the test set 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 set had been submitted.

(4) If either (i) By the date specified in paragraph (d)(1) of this section a manufacturer of HFPO, which notified

EPA of its intent to perform a test set, has failed to submit a proposed study plan for that test set, 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 set. The requirement 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 HFPO has notified EPA of its intent to perform testing for any test set identified in a Federal Register notice published under paragraph (c)(2) or (d)(4) of this section,

(ii) by the date specified in paragraph (d)(2) of this section any processor of HFPO, 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 set involved will automatically be denied. EPA will notify each manufacturer and processor of HFPO, which applied for an exemption for the specific test set involved, of this automatic denial either by letter or by notice in the Federal Register. Each manufacturer or processor of HFPO 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 30 days from the time that the notice is published in the Federal Register, whichever comes first. The violation will continue until a manufacturer or processor of HFPO submits a proposed study plan for each test set involved.

(6) Any manufacturer or processor of HFPO may submit a proposed study plan for any test set 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 set.

(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 set covered by the study plan.

(ii) (A) the names and addresses of the test set 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 (a)(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 this 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 set 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 HFPO in paragraph (k) of this section.

(g) *Modification of study plans during conduct of study*—(1) *Application*. Any test set sponsor who wishes to modify the adopted study plan for any test set 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) if 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 notice in the Federal Register indicating that the study plan has been modified.

(h) *Exemption applications*. (1) Any manufacturer or processor of HFPO may submit an application to EPA for an exemption from submitting proposed study plans for and from performing any or all of the test sets specified in paragraph (j) 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 from which the exemption is sought.

(2) No manufacturer or processor of HFPO will be in violation of the requirement to perform a specific test set under paragraph (j) of this section if it has submitted a timely application for an exemption for that test set and the application has not been denied by EPA.

(3) EPA will conditionally grant any requested exemption for a specific test set required by paragraph (j) of this section if EPA has received a complete proposed study plan for that test set in accordance with paragraph (e) of this section and has adopted the study plan in accordance with paragraph (f)(2) of this section.

(4) EPA will deny any exemption for a specific test set in paragraph (j) of this section if the test set sponsor fails to perform the test set or to submit data as required in the test standards adopted under paragraph (k) of this section.

(5) If manufacturers of HFPO perform all the test sets required by paragraph (j) of this section, processors of HFPO will automatically be granted an exemption from the study plan submission and testing requirements of this section without the need to file an application for exemption.

(i) *Test results*. Except as set forth in paragraph (k) of this section, a positive or negative test result in any of the health effects tests enumerated in paragraph (j) of this section is defined as specified in the TSCA Health Effects Test Guidelines published by the National Technical Information Service (NTIS) under publication number PB 82-232984.

(j) *Health Effects Testing*—(1) *Mutagenic Effects—Chromosomal aberrations*—(i) *Required testing*. (A) An *in vitro* cytogenetics test shall be conducted with HFPO.

(B) An *in vivo* cytogenetics test shall be conducted for HFPO if the *in vitro* cytogenetics tests conducted pursuant to paragraph (j)(1)(i) (A) of this section produces a negative result.

(C) A dominant lethal assay shall be conducted for HFPO if either the *in vitro* or *in vivo* cytogenetics test conducted pursuant to paragraph (j)(1)(i) (A) or (B) of this section produces a positive result.

(D) A heritable translocation assay shall be conducted for HFPO if the dominant lethal assay conducted pursuant to paragraph (j)(1)(i) (C) of this section produces a positive result.

(ii) *Study plans*. For guidance in preparing study plans the TSCA Health Effects Guidelines for Chromosomal Effects, published by NTIS (PB 82-232984), should be consulted. Additional

guidance may be obtained from the Pesticide Assessment Guidelines, published by NTIS (PB 83-153916).

(2) *Mutagenic effects—Gene mutations*—(1) *Required testing*. (A) A *Salmonella typhimurium* mammalian microsomal reverse mutation assay (hereinafter "Ames assay") shall be conducted for HFPO.

(B) A gene mutation in somatic cells assay shall be conducted with HFPO if the Ames assay conducted pursuant to paragraph (j)(2)(i) (A) of this section produces a negative result.

(C) A sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted for HFPO if either the Ames assay of the gene mutation in somatic cells assay conducted pursuant to paragraph (j)(2)(i) (A) or (B) of this section produces a positive result.

(D) A mouse specific locus test shall be conducted for HFPO if the sex-linked recessive lethal test in *Drosophila melanogaster* conducted pursuant to paragraph (j)(2)(i) (C) of this section produces a positive result.

(ii) *Study plans*. For guidance in preparing study plans the TSCA Health Effects Guidelines for Mutagenicity, published by NTIS (PB 82-232984), should be consulted. Additional guidance may be obtained from the Pesticide Assessment Guidelines, published by NTIS (PB 83-153916).

(3) *Oncogenicity*—(1) *Required testing*. A 2-year oncogenicity bioassay shall be conducted with HFPO.

(ii) *Study plans*. For guidance in preparing study plans, the TSCA Health Effects Guidelines for Chronic Exposure/Oncogenicity, published by the NTIS (PB 82-232984), should be consulted. Additional guidance may be obtained from the Organization for Economic Cooperation and Development (OECD) Test Guidelines for Health Effects as adopted by the OECD Council on May 12, 1981, and the Pesticide Assessment Guidelines, published by NTIS (PB 83-153916).

(4) *Reproductive effects*—(i) *Required testing*. A 2-generation reproductive effects test shall be conducted with HFPO.

(ii) *Study plans*. For guidance in preparing study plans, the TSCA Health Effects Test guidelines for Reproduction/Fertility Effects published by NTIS (PB 82-232984), should be consulted. Additional guidance may be obtained from the OECD Test Guidelines for Health Effects as adopted by the OECD Council on May 12, 1981, and the Pesticide Assessment Guidelines, published by NTIS (PB 83-153916).

(k) *Test standards.* (1) Sponsors and testing facilities must adhere to the EPA Good Laboratory Practice Regulations in Part 792 of this chapter.

(2) [Reserved]

(1) *Enforcement.* (1) If a manufacturer or processor, which notified EPA under paragraph (c)(1), (2), (3) or (4) of this section of its intent to perform testing for a test set required by paragraph (j) of this section, fails to perform the test set in accordance with the test standards in

paragraph (k) of this section, that failure will be a violation of this section.

(2) EPA will publish a notice in the Federal Register to inform all manufacturers and processors that all exemptions for performance of that test set will be denied unless, within 30 days of the publication of the notice, a manufacturer or processor of HFPO notifies EPA by letter that it intends to perform that test set in accordance with the test standards in paragraph (k) of this section.

(3) Any person who fails or refuses to comply with any aspect of this section is in violation of section 15 of the Act.

(m) *Availability.* The TSCA and FIFRA guidelines for the various study plans are available from the National Technical Information Service (NTIS). Address and telephone number: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703-487-4650).

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