

Dated: December 15, 1986.

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Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 86-28494 Filed 12-18-86; 8:45 am]

BILLING CODE 6560-50-M

#### 40 CFR Part 799

[OPTS-42087A; FRL-3094-1]

#### 2-Ethylhexanol; Proposed Test Rule

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing that manufacturers and processors of 2-ethylhexanol (EH; CAS No. 104-76-7) be required, under section 4 of the Toxic Substances Control Act (TSCA), to conduct 2-year oral oncogenicity bioassays in rats and mice.

**DATES:** Submit written comments on or before February 17, 1987. If persons request an opportunity to submit oral comment by February 2, 1987, EPA will hold a public meeting on this rule in Washington, DC. For further information on arranging to speak at the meeting see Unit VIII of this preamble.

**ADDRESS:** Submit written comments, identified by the document control number (OPTS-42087A), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-G004, 401 M St., SW., Washington, DC 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 a.m. to 4 p.m., Monday through Friday, except legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460, (202-554-1404).

**SUPPLEMENTARY INFORMATION:** EPA is proposing oncogenicity testing of EH for the reasons described below.

#### I. Introduction

##### A. Chemical Recommendation

Oncogenicity testing for 2-ethylhexanol (EH) was planned by the National Toxicology Program (NTP); however, NTP has indicated that it no longer plans to conduct a bioassay for EH. The Agency also has an established interest in obtaining information on this chemical. EPA believes that the 2-ethylhexanol moiety, which occurs in EH

and in other chemical substances, may be an active oncogenic agent to which people may be exposed. In addition, the Agency's general interest in alkyl phthalates which are subject to testing under a negotiated testing agreement (47 FR 53775; October 30, 1981 and 47 FR 335; January 5, 1982), and its final test rule on 2-ethylhexanoic acid (EHA), which proposed to utilize the NTP testing of EH to assess the oncogenic potential of EHA (51 FR 40318; November 6, 1986), support the need for this testing. The Agency proposes to use the testing authority of section 4 of TSCA to obtain data needed to better assess the oncogenic potential of EH.

Additional testing of EH beyond the oncogenicity testing proposed here may be warranted. However, in the interest of obtaining the oncogenicity test results as soon as possible, the Agency has limited this proposed test rule to oncogenicity testing only. Once oncogenicity testing is under way the Agency can evaluate the need for additional testing and, if necessary, initiate a separate rulemaking to require such testing of EH.

##### B. Test Rule Development Under TSCA

Under section 4(a) of TSCA, EPA 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 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 effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in determining whether

4(a)(1)(A)(i) finding; both exposure and toxicity information are considered in determining whether available data support a 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 significant or substantial human exposure or release to the environment. For the findings under sections 4(a)(1)(A)(ii) and (B)(ii), 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 finding under section 4(a)(1)(A)(iii) or (B)(iii) that testing is necessary, EPA considers whether 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 apply is described in detail in its first and second proposed test rules, published in the Federal Register of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) findings are discussed at 46 FR 48524 and 46 FR 30300, and the section 4(a)(1)(B) findings are discussed at 46 FR 30300.

In evaluating the need for oncogenic testing of EH, EPA considered all readily available relevant information, including published and unpublished data available to the Agency. From its evaluation, EPA is proposing oncogenicity testing requirements for EH under TSCA sections 4(a)(1)(A) and (B).

#### II. Review of Relevant Data

##### A. Human Exposure and Environmental Release

##### 1. Use Profile and Production

EH is a colorless liquid with a musty odor. It has molecular weight of 130, a vapor pressure of 0.5 torr at 20 °C, boils at 181-183 °C at 743 mm Hg and is 0.1 percent soluble in water. Approximately 80 percent of the production is used as an intermediate for the production of the ester derivatives of various acids, such as, phthalic, adipic, and phosphoric acid which are used as plasticizers. Approximately 10 percent is used as an intermediate to make ethylhexyl acrylate. The remaining 10 percent is used for miscellaneous purposes including use as a wetting agent in the mercerization of cotton, as a defoamer in textile printing, as a solvent for gums and resins, as a solvent extractant, and

as a miscellaneous chemical intermediate.

There are 10 domestic manufacturers and 8 importers of EH (Ref. 1). Domestic manufacturers include Eastman Kodak Co., Tenn-USS Chemical Co., Dow Badische Co., Shell Oil Co., Oxochem Enterprise, Union Carbide Corp., Alcolac Inc., and Cochran Chemical Co. Two other manufacturers have claimed their identities as Confidential Business Information (CBI). Importers include BASF Wyandotte Corp., Mitsubishi International Corp., Ciba-Geigy Corp., Henkel, Inc., EM Laboratories, Inc., Miljac Inc., Sandoz Colors and Chemicals, and Cellex Services, Inc. The annual U.S. supply (domestic production plus imports) of EH is currently over \$35 million pounds (Ref. 2). The annual growth rate is estimated at 4.2 percent through 1988 (Ref. 2).

2. Exposure During Manufacturing and Processing

The National Occupational Hazard Survey (NOHS) done by the National Institute for Occupational Safety and Health (NIOSH) estimated that 45,000 workers in 62 occupations are potentially exposed to 2-ethylhexanol or products containing EH (Ref. 3). The more recent National Occupational Exposure Survey (NOES), a survey that more closely represents actual observations, estimates that approximately 11,530 workers may be exposed to EH (Ref. 4).

EPA believes that exposure will result from the widespread and variable conditions under which the large volume of EH is manufactured, processed, and used (e.g., transferring, drumming, undrumming, maintenance, cleaning, sampling reactor loading, unloading, and possible spray application) (Ref. 5). The various conditions under which the large volume of EH is encountered include variations in industrial hygiene practices and engineering controls at hundreds of sites. These variations may affect exposure to thousands of workers. The physico-chemical properties of EH do not force workers to avoid its contact. The major potential exposure is expected to occur dermally. However, because EH is moderately volatile (Ref. 5) there may be some inhalation exposure. Inhalation exposure is more likely to be significant during manufacturing and during use as a solvent, particularly during packaging and in spray applications. The Agency has conducted a detailed exposure analysis which further supports its section 4 findings (Ref. 3).

3. Exposure Associated With Consumer Goods

In addition to its use as an intermediate for commercial purposes, EH is believed to be used in a variety of products, such as paints, lacquers, inks, and lubricants, which some consumers may use (Ref. 2). These uses may result in potential dermal and/or inhalation exposure to consumers (Ref. 5).

4. Environmental and General Population Exposure.

The literature suggests that EH may be widespread in the environment. It is discharged in plant effluents. In samples taken in 1976 from the Delaware River, a major source of drinking water for many surrounding cities EH was detected in the concentration range of 3 to 5 ppb (Ref. 7).

EH has been detected in ground water samples near disposal sites in the United States and Japan (Refs. 6, 7, and 8), indicating the potential for ground water and drinking water contamination which may lead to general population exposure.

Use of EH in defoaming agents for manufacture of paper products, and use as a lubricant may also contribute to environmental and general population exposure (Ref. 1). The Agency is uncertain as to the extent to which environmental and general population exposure results from the hydrolysis of di(2-ethylhexyl) phthalate (DFHP) to EH or from the use of EH as an inert ingredient in pesticide products. EH is a hydrolysis product of the commonly found plasticizer DEHP, and DEHP enters the environment in a myriad of ways—as manufacturing waste, from food packaging materials, and other phthalate-based plasticizers (Ref. 1).

5. Summary

The Agency believes that dermal, oral, and inhalation exposure to EH may be of significant concern as a result of the manufacturing, processing, distribution in commerce, use, and disposal of EH.

B. Health Effects—Carcinogenic Potential

From an initial review of available information, EPA has concluded that EH may have oncogenic potential. Presently the Agency is unaware of any epidemiological data or long-term bioassays on this chemical. However, chemicals containing the 2-ethylhexyl moiety have been shown to have oncogenic potential. These chemicals are expected to metabolize to EH which is hypothesized to be the oncogenic agent.

Among these chemicals are DEHP, DEHA, TEHP, and EHS. The chemical structures for these and for EH appear below:

1. Di (2-ethylhexyl) phthalate (L)
$$\begin{array}{c}
 \text{O} \quad \text{C}_2\text{H}_5 \\
 \parallel \quad | \\
 \text{C} \text{---} \text{O} \text{---} \text{CH}_2 \text{---} \text{CH} \text{---} \text{C}_4\text{H}_9 \\
 \parallel \quad | \\
 \text{O} \quad \text{C}_2\text{H}_5
 \end{array}$$
2. Sodium 2-Ethylhexyl Sulfate (EHS)
$$\begin{array}{c}
 \text{C}_4\text{H}_9 \text{---} \text{CH} \text{---} \text{CH}_2 \text{---} \text{O} \text{---} \text{SO}_3^- \text{Na}^+ \\
 | \\
 \text{C}_2\text{H}_5
 \end{array}$$
3. Di (2-ethylhexyl) adipate (DEHA)
$$\begin{array}{c}
 \text{O} \quad \text{C}_2\text{H}_5 \\
 \parallel \quad | \\
 \text{CH}_2 \text{---} \text{CO} \text{---} \text{CH}_2 \text{---} \text{CH} \text{---} \text{C}_4\text{H}_9 \\
 | \\
 (\text{CH}_2)_2 \\
 | \\
 \text{CH}_2 \text{---} \text{C} \text{---} \text{O} \text{---} \text{CH}_2 \text{---} \text{CH} \text{---} \text{C}_4\text{H}_9 \\
 \parallel \quad | \\
 \text{O} \quad \text{C}_2\text{H}_5
 \end{array}$$
4. Tris (2-ethylhexyl) Phosphate (TEHP)
$$\begin{array}{c}
 (\text{C}_4\text{H}_9 \text{---} \text{CH} \text{---} \text{CH}_2 \text{---} \text{O})_3 \text{---} \text{P} \text{---} \text{O} \\
 | \\
 \text{C}_2\text{H}_5
 \end{array}$$
5. 2-Ethylhexanol (EH)
$$\begin{array}{c}
 \text{C}_4\text{H}_9 \text{---} \text{CH} \text{---} \text{CH}_2 \text{---} \text{OH} \\
 | \\
 \text{C}_2\text{H}_5
 \end{array}$$

Three of these chemicals (DEHP, DEHA, and TEHP) have been shown by NTP bioassays to cause increased occurrence of hepatocellular tumors, principally carcinomas, in female mice (Refs. 9 through 13). DEHP and DEHA also caused hepatocellular tumors in male mice. In addition, DEHP caused hepatocellular tumors in both male and female rats. Preliminary data on the fourth chemical (EHS) suggests that it may be oncogenic at the female mouse liver as well.

Additional supporting evidence may come from the fact that EH causes peroxisomal proliferation. There is evidence suggesting an association between peroxisomal induction and hepatocarcinogenicity in rats and mice (Refs. 14 through 17). However, there is currently insufficient information to understand the nature and importance of this association.

The Agency has conducted a detailed oncogenicity hazard analysis which

further supports its 4(a)(1)(A) findings (Ref. 14).

### III. Findings

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

1. Under section 4(a)(1)(A)(i), EPA finds that the manufacture, processing, distribution in commerce, use, and disposal of EH may present an unreasonable risk of injury to human health because of potential oncogenic effects for the reasons presented in Unit II.B. above.

The finding for oncogenicity is based on studies conducted on other chemical substances containing the 2-ethylhexyl moiety which suggest that EH may possess some carcinogenic hazard.

Data available to EPA indicate that more than 635 million pounds of EH are produced annually for intermediate uses and for merchant sale. An estimated 11,550 workers are exposed to EH in its manufacture, processing, distribution, and use. Potential for consumer and general population exposure also exists through use and disposal.

2. Under section 4(a)(1)(B)(i), EPA finds that EH is produced in substantial quantities and that there may be substantial human exposure from its manufacture, processing, and use. As stated above, approximately 635 million pounds of EH are produced annually (Ref. 1). In addition, according to the National Occupational Exposure Survey of 1985 (NOES), 11,550 workers are estimated to have actual exposure to EH. EH is used as an intermediate for the manufacture of acrylates, phthalates, and the octyl ester of 2,4-dichlorophenoxyacetic acid. It is also used as a defoaming agent, a cellophane lubricant, a solvent in coatings, inks, and dyes; a wetting agent in ceramics and paper coatings; and a mercerizing agent in textiles.

3. Under sections 4(a)(1)(A)(ii) and (B)(ii), EPA finds that there are insufficient data and experience from which the potential oncogenic effects of the manufacture, processing, distribution, use, and disposal of EH can reasonably be determined or predicted.

4. Under sections 4(a)(1)(A)(iii) and (B)(iii), EPA finds that testing EH for oncogenicity is necessary to develop such data.

### IV. Proposed Rule

#### A. Proposed Testing and Test Standards

EPA is proposing that oncogenicity testing be conducted on EH in accordance with the TSCA test guidelines for oncogenicity specified in

40 CFR 798.3300, published in the *Federal Register* of September 27, 1985 (50 FR 39252) and modified as proposed in the *Federal Register* of January 14, 1986 (51 FR 1522). This testing shall be performed with the Fisher 344 rat and B6C3F1 mouse, because of their demonstrated sensitivity to other ethylhexyl compounds; the route of exposure shall be oral. Furthermore, based upon experience at NTP, the EH shall be microencapsulated in the diet (Ref. 18). A subchronic study should be conducted to sufficiently determine dose levels and characterize subchronic effects for the bioassay.

#### B. Test Substance

The proposed test substance is 2-ethylhexanol (EH; CAS No. 104-76-7) of at least 99.0-percent purity, which is a commercially available grade.

#### C. Persons Required To Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Agency 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 ("process" is defined in section 3(10) of TSCA as the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce). 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 existing data and experience are insufficient to reasonably determine or predict the potential oncogenic effects of the manufacture, processing, distribution in commerce, use, or disposal of EH, the Agency is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, EH at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements in this proposed rule. The end of the reimbursement period will be 5 years after the last final report is submitted or an amount of time after the submission of the last final report required under the test rule equal to that which was required to develop data, if more than 5 years.

Because TSCA contains provisions to avoid duplicative testing, every person subject to the proposed rule must individually conduct

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 the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the *Federal Register* to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for EH. As noted in Unit IV. B. above, EPA is interested in evaluating the effects attributable to EH itself and has specified a nearly pure substance for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

#### D. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) standards which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans no later

than 45 days before the start of each study.

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. The Agency is proposing that the oncogenicity testing shall be completed and the final report submitted to EPA within 53 months of the effective date of this test rule. Progress reports for the proposed test are required at 6-month intervals starting 6 months from the effective date of the final test rule.

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).

Persons who export a chemical substance or mixture which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) appear in 40 CFR Part 707. In brief, as of the effective date of this test rule, an exporter of EH must report to EPA the first annual export or intended export of EH to any one country. EPA will notify the foreign country about the test rule for the chemical.

#### E. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 4 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 regulation or 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 inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated EPA representatives to determine compliance with any final

rule for EH. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, and that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the 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 manufacturers that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions. This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.49(b)). Intentional 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 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.

#### V. Issues for Comment

1. Should EPA require that two species be tested in the oncogenicity study in conformance with the Agency's normal test guidelines or are adequate data now available to indicate that the mouse is the most sensitive species and that testing should be limited to that species? In addition, are the Fisher 344 rat and B63CF1 mouse the most appropriate strains in which to perform the bioassay?

2. The Agency solicits comments on alternative dosing strategies.

3. The Agency solicits comments on its using 7.3 percent as the real cost of borrowed capital in the economic analysis for this testing (see unit VI).

#### VI. Economic Analysis of Proposed Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (Ref. 2) that evaluates the potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of EH: price sensitivity of demand, industry cost characteristics, industry structure, and market expectations. If there is no indication of adverse effect, no further economic analysis will be performed; however, if the first level of analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted which more precisely predicts the magnitude and distribution of the expected impact.

Total testing costs for the final rule are estimated to range from \$783,000 to \$1,073,000. In order to predict the financial decision-making practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period in order to finance the testing expenditure in the first year.

The annualized costs range from \$88,000 to \$120,000. In calculating these annualized costs, EPA has utilized a 7.3 percent real (i.e., net of inflation) cost of capital and a 15-year cost recovery

period. In previous section 4 testing rules, the direct testing costs of subject chemicals were annualized using a 25 percent real cost of capital, in accordance with comments submitted by E.I. DuPont de Nemours in response to the first proposed test rule [45 FR 48524]. Subsequent comments from the chemical industry have led to a reexamination of the cost of capital to the chemical industry.

An analysis of publicly-available financial data on the chemical industry has led EPA to the tentative determination that 7.3 percent represents a more appropriate measure of the real, after-tax cost of capital for this industry. EPA intends to utilize this figure in future test rule economic analyses where more specific data are not available.

Based on the 1984 production volume for EH of 635 million pounds, the unit test costs will be about 0.02 cent per pound. In relation to the selling price of 32 cents per pound of EH, these costs are equivalent to 0.06 percent of price.

Based on these costs, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is extremely low.

Refer to the economic analysis for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

#### VII. 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. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," can be obtained through the NTIS (PB 82-146773). 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.

#### VIII. Public Meetings

If persons indicate to EPA that they wish to present oral 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 subsequent to the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (O): (202-534-

1404) by February 2, 1987. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. 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 verify whether a 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.

#### IX. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-42087A). This record contains the basic information considered by the Agency in developing this proposal and appropriate Federal Register notices.

This record includes the following information:

##### Supporting Documentation

- (1) Federal Register notices pertaining to this proposed rule consisting of:
  - (a) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).
  - (b) Notice of interim final rule on procedures governing Testing Consent Agreements and Test Rules and Exemption Procedures (51 FR 23706; June 30, 1986).
  - (c) Notice of final rule on data reimbursement policy and procedures (48 FR 31786; July 11, 1983).
  - (d) Toxic Substances Control Act Test Guidelines; Final Rules (50 FR 38252; September 27, 1985).
  - (e) Revisions to the Toxic Substances Control Act Test Guidelines; Proposed Rule (51 FR 1522; January 14, 1986).
- (2) Communications before proposal; contact reports of telephone conversations.

##### References

- (1) National Toxicology Program (NTP). "Summary of Data for Chemical Selection" prepared for The National Cancer Institute by SRI International under contract No. N01-CP-95807 9/80, Rev. (April 1981).
- (2) U.S. Environmental Protection Agency (USEPA). Economic Impact Analysis of Proposed Test Rule for 2-Ethylhexanol. Mathtech, Inc. Contract number 68-02-4235. Washington, DC, Office of Pesticides and Toxic Substances. (September 3, 1986).
- (3) National Institute for Occupational Safety and Health (NIOSH). National Occupational Hazard Survey Data Base (NOHS), Washington, DC, U.S. Department of

Health and Human Services. Computer print out. (August 8, 1984).

(4) NIOSH. National Occupational Exposure Survey Data Base (NOES). Washington, DC, U.S. Department of Health and Human Services. Computer print out. (July 16, 1984).

(5) USEPA. 2-Ethylhexanol Worker Exposure Analysis. Washington, DC, Office of Pesticides and Toxic Substances. (August 13, 1986).

(6) Samoloff, M.R., Bell, J., Birkholz, D.A., Webster, G.R.B., Arnott, E.G., Palak, R., Madrid, A. "Combined bioassay-chemical fractionation scheme for the determination and ranking of toxic chemicals in sediments." *Environmental Science and Technology*. 17:329-34. (1983).

(7) Sheldon, L.S. and Hites, P.A. "Organic Compounds in the Delaware River." *Environmental Science and Technology*. 12:1188-94. (1978).

(8) Yasuhara, A., Shirashi H., Tsuji, M., and Okuno, T. "Analysis of organic substance in highly polluted water by mass spectrometry." *Environmental Science and Technology*. 15:570-3. (1981).

(9) U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. Carcinogenesis Bioassay of Di(2-ethylhexyl) phthalate (CAS No. 117-81-7) in F344 Rats and B6C3F mice (Feeding Study). National Toxicology Program. Technical Report Series No. 217.

(10) U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. Carcinogenesis Bioassay of Di(2-ethylhexyl) Adipate (CAS No. 103-23-1) F344 Rats and B6C3F mice (Feed Study). National Toxicology Program Technical Report Series No. 212.

(11) U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. Carcinogenesis Bioassay of Sodium 2-Ethylhexyl Sulfate (CAS No. 126-92-1) in F344N Rats and B6C3F Mice (Feed Study). Draft NTP Technical Report. Prepared for the Board of Scientific Counselors. (September 2, 1982).

(12) U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. NTP Technical Report on the Toxicity and Carcinogenicity of Triis(2-ethylhexyl) Phosphate (CAS No. 78-42-2) in F344N Rats and B6C3F Mice (Gavage Study). Draft NTP Technical Report. (September 8, 1983).

(13) U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. Memorandum with Attachment from W. Kluwe to 12 Addressees. Attachment: Comparative Chronic Toxicities and Carcinogenic Potentials of Four 2-Ethylhexyl-Containing Compounds in Rats and Mice. (December 19, 1983).

(14) USEPA. Memorandum. Testing Agreement on 2-Ethylhexanol. From Karl P. Baetcke, Health and Environmental Review Division to Frank Benenati Test Rules Development Branch. Office of Pesticides and Toxic Substances, Washington, DC (October 22, 1986).

(15) Moody, D.E. and Reddy, J.K. "Hepatic Peroxisomes (Microbody) proliferation in Rats Fed plasticizers and Related Compounds."

*Toxicology and Applied Pharmacology*, 45:497-507, (1979).

(16) Moody, D.E. and Reddy J.K. "Serum Triglyceride and Cholesterol Contents in Male Rats Receiving Diets Containing Plasticizers and Analogues of the Ester 2-Ethylhexanol." *Toxicology Letters* 10:379-383, (1982).

(17) Warren, J.R., Lalwani, N.D., and Reddy, J.K. "Phthalate Esters as Peroxisome Proliferator Carcinogens." *Environmental Health Perspectives* 45:35-40, (1982).

(18) National Institute of Environmental Health Sciences (NIEHS). Microencapsulation Report: 2-Ethyl-1-hexanol—Conformance of Microencapsulated Chemical to Specifications. Midwest Research Institute, (July 3, 1986).

#### X. Other Regulatory Requirements

##### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major", and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it will not have an annual effect on the economy of at least \$100 million, will not cause a major increase in prices and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

##### B. 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 are not expected to perform testing themselves, or to 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.

##### C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070-0033. Submit comments on these requirements to the Office of Information and Regulatory Affairs: OMB, 726 Jackson Place, NW., Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements.

##### List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous substances, Chemicals, Recordkeeping and reporting requirements.

Dated: December 9, 1986.

John A. Moore,  
Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Part 799 be amended as follows:

#### PART 799—[AMENDED]

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

Authority: 15 U.S.C. 2803, 2611, 2825.

2. By adding § 799.1645 to read as follows:

##### § 799.1645 2-Ethylhexanol.

(a) *Identification of test substance.* (1) 2-Ethylhexanol (CAS No. 104-76-7) shall be tested in accordance with this section.

(2) 2-Ethylhexanol 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.* All persons who manufacture or process, or intend to manufacture or process 2-ethylhexanol, other than as an impurity, from the effective date of this rule (44 days after the publication date of the final rule in the Federal Register to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data as specified in this section, Subpart A of this part, and Parts 790 and 792 of this chapter or exemption applications in accordance with Part 792 of this chapter for single-phase rulemaking.

(c) *Health effects—(1) Oncogenic effects—(i) Required testing.* Oncogenicity tests shall be conducted in Fisher 344 rats and B6C3F1 mice by the oral route with 2-ethylhexanol, in accordance with § 798.3300 of this chapter.

(ii) *Modification.* 2-Ethylhexanol shall be microencapsulated before being added to the diet.

(iii) *Reporting requirements.* (A) The study plan for the oncogenicity test shall be submitted at least 45 days before the initiation of testing.

(B) The oncogenicity testing shall be completed and final results submitted to the Agency within 53 months of the effective date of the final rule.

(C) Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule.

(2) [Reserved]

(Reporting and recordkeeping requirements contained in paragraph (c) were approved by the Office of Management and Budget under control number 2070-0033.)

[FR Doc. 86-28242 Filed 12-18-86; 8:45 am]  
BILLING CODE 6560-50-4