reductions which are significantly greater than those otherwise required; or

c. That additional time is necessary to allow for the development of low solvent systems when the only alternative is the application of add-on emission control equipment which would cause an undue economic burden.

Furthermore, the DCO must contain a commitment to install add-on emission control equipment if the low solvent development program is not successful.

There are four substantive changes to the current section 512.G. represented by the proposed amendment:

(1) A final compliance date of June 30, 1985, is replaced with the date of April 21, 1987;

(2) The conditions to be satisfied to qualify for a DCO are modified by deleting explicit reference to specific add-on emission control equipment and by deleting the participation in a state-wide control prioritization program;

(3) The subsection pertaining to Graphic Arts—Nonporous Substrates is deleted in entirety;

(4) The required commitment to install add-on control equipment if the low solvent development program fails, currently applicable to the nonporous substrate graphic arts sources, is extended to apply to all surface coating and graphic arts sources.

The rules and regulations of the Commonwealth of Pennsylvania, which pertain to the surface coating and graphic arts sources, are equivalent to the proposed rules for Allegheny County. The revision to section 512.G. was proposed by the ACHD in order to have equitable treatment of the same classes of sources in and adjacent to Allegheny County.

In accordance with 40 CFR 51.4, a public hearing was held and an opportunity for submitting written comments was announced. The public hearing was held on June 18, 1985. The amendment was approved and adopted by the Board of County Commissioners on June 27, 1985.

On March 12, 1986, (51 FR 8581) EPA published a proposed rule to approve the revision to the Allegheny County portion of the SIP. Public comment on the proposed revision was invited. Within the 30 day comment period only one comment was received. An attorney, representing a graphic arts source, stated that the proposed revision should be approved by EPA.

Final Action

EPA has reviewed the information submitted by the State and is approving the revision to the Allegheny County portion of the SIP. The revision will permit, with sufficient justification, the extension of final compliance dates for graphic arts sources in Allegheny County.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 5, 1987. This action may not be challenged later in proceedings to enforce its requirements (See 307(b)(2)).

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and recordkeeping requirements, Incorporation by reference.

Note.—Incorporation by reference of the State Implementation Plan for the State of Pennsylvania was approved by the Director of the Federal Register on July 1, 1982.

Dated: October 17, 1986.

Lee M. Thomas,

Administrator.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Title 40, Part 52, Subpart NN of Code of Federal Regulations is amended as follows:

Subpart NN—Pennsylvania

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

2. Section 52.2020 is amended by adding paragraph (c)(67) as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(67) Amendment to section 512.G. Extensions, of Article XX, Rules and Regulations of the Allegheny County Health Department providing authority to grant compliance date extensions for surface coating and graphic arts sources, submitted by DER Secretary Nicholas DeBenedictis on August 13, 1985.

(i) Incorporation by Reference.

(A) Letter of August 13, 1985 to EPA from the Pennsylvania Department of Environmental Resources, and Appendix 22, Amendment to section 512.G., Allegheny County portion of the Pennsylvania State Implementation Plan (extension of final air pollution compliance dates for surface coating and graphic arts) adopted by the Board of County Commissioners of June 27, 1985.

[FR Doc. 86–25103 Filed 11–5–86; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Parts 795 and 799

[OPTS–42065A; FRL–3080–4]

2-Ethylhexanoic Acid; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final test rule.

SUMMARY: EPA is issuing a final test rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring manufacturers and processors of 2-ethylhexanoic acid (EHA, CAS No. 149–57–5) to conduct 90-day subchronic toxicity, developmental toxicity, and pharmacokinetics (i.e., absorption, distribution, metabolism, and excretion) studies. This action follows EPA's proposed rule of May 17, 1985 (50 FR 20678).

DATE: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern daylight time on November 20, 1986. These regulations shall become effective on December 20, 1986. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Office of the Federal Register as of December 20, 1986.

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 issuing a final test rule under section 4(a) of TSCA to require health effects testing of EHA.

I. Introduction—Test Rule Development Under TSCA

This notice is part of the overall implementation of section 4 of TSCA (Pub. L. 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require development of data relevant to assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop health or environmental data if the Administrator 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.

A more complete understanding of the statutory section 4 findings is provided in the Agency's first proposed test rule published in the **Federal Register** of July 18, 1980 (45 FR 48510).

II. Background

A. Profile

EHA is a colorless liquid with a mild odor. It has a vapor pressure of 0.03 torr at 20°C, boils at 226.9°C at 760 torr, and is 0.1 percent soluble in water at 20°C. EHA is used exclusively as a chemical intermediate or reactant in the production of 2-ethylhexanoate metal soaps, peroxy esters, or other derivatives (Refs. 1 and 2).

There are two domestic manufacturers and three importers of EHA (Ref. 3). Eastman Kodak Co. is the primary domestic manufacturer of EHA. Union Carbide Corp. is also a domestic manufacturer of EHA; American Hoechst Corp., BASF Wyandotte Corp., and Filo Chemical Inc. are importers of EHA. The annual U.S. supply (domestic production plus imports) of EHA is currently between 20 to 25 million pounds. The import level of EHA is about 1 to 2 million pounds annually (Ref. 4).

The total weight of evidence overwhelmingly suggests that EHA has strong developmental toxicity potential. Furthermore, the potential health hazards of EHA are expected to be high because of EHA's structural similarity to several chemicals that have been associated with oncogenicity, developmental toxicity, and subchronic toxicity, the metabolic interrelationships of these chemicals to EHA, and the suggestive evidence that chemicals that induce peroxisomal proliferation may have oncogenic potential.

EPA believes exposure to EHA is inherent from the widespread and variable conditions under which the 20 to 25 million pounds per year of EHA is encountered during manufacturing, processing, and use (i.e., transfers, drumming, undrumming, shipping, loading, unloading, maintenance, clean-up, and sampling). The various conditions under which the large volume of EHA is encountered include variations in industrial hygiene practices and engineering controls at 2 manufacturing and about 100 processing sites. These variations may affect exposure to about 400 workers. The physicochemical properties of EHA do not force workers to avoid contact with EHA. Dermal exposure is expected because protective equipment may not be used and may not be fully effective. Refer to the proposed rule (50 FR 20678) published in the **Federal Register** May 17, 1985 for a detailed discussion of the potential health hazards and exposure for EHA.

Based on current information, environmental release is considered negligible, and the physical and chemical properties of EHA suggest that, if released, it would not persist or bioaccumulate. If EHA were disposed of in a surface impoundment, however, it may potentially leach to contaminate ground water.

B. Regulatory History

The Interagency Testing Committee (ITC) designated EHA for priority consideration for health effects tests in its 14th Report, published in the **Federal Register** of May 29, 1984 (49 FR 22389). The ITC recommended that EHA be tested for chronic health effects including carcinogenicity. The ITC further identified, although it did not specifically recommend for testing, the following biological effects of concern to human health: Acute toxicity, teratogenicity/embryotoxicity, metabolism and pharmacokinetics, genotoxicity, and other effects (peroxisome induction).

EPA responded to the ITC's recommendations for EHA by publishing in the **Federal Register** of May 17, 1985 (50 FR 20678) a proposed test rule for EHA that would require developmental toxicity, subchronic toxicity, and pharmacokinetics (i.e., absorption, distribution, metabolism, and excretion) tests. EPA also made the findings for oncogenicity testing, but did not propose testing at that time because a bioassay was planned by the National Toxicology Program (NTP) for 2-ethylhexanol. The Agency planned to evaluate data from this bioassay along with other information to determine whether oncogenicity testing of EHA is necessary. Refer to the proposed rule for details of EPA's findings and the proposed test standards and reporting requirements. Subchronic oral toxicity testing proposed under 40 CFR 798.75 and pharmacokinetics testing proposed under 40 CFR 798.460 have been redesignated as 40 CFR 795.260 and 795.223, respectively, in this final rule, and the standard for 2-ethylhexanoic acid proposed under 40 CFR 799.2050 has been redesignated as 40 CFR 799.1650 in this final rule.

On October 8, 1985, EPA held a public meeting to hear and discuss comments presented on the proposed rule. The transcript of the public meeting is included in the docket for this rulemaking (Ref. 35), and substantive comments are addressed in Unit III. of this notice.

Following publication of the proposed rule, new information was received by the Agency which relates to the potential developmental toxicity of EHA and potential exposure to EHA. The new information consisted of a study and supplemental data by Ritter *et al.* (Refs. 6 and 7), which reported that a single dose of EHA administered during pregnancy resulted in fetal resorption and malformation in rats and a series of studies conducted by Nau (Refs. 8 and 9) and Nau and Loscher (Ref. 10), which provides additional suggestive evidence of EHA's potential developmental toxicity. The first two studies in the series by Nau (Refs. 8 and 9) describe the parental and fetal pharmacokinetics of valproic acid, a known human and animal developmental toxicant that is structurally related to EHA. The remaining study (Ref. 10) compares the developmental effects of valproic acid and a number of structurally similar compounds including other ethylhexyl-containing acids. The results suggest that as a class these compounds have potential developmentally toxic effects. In addition, industry conducted an industrial hygiene survey and a glove permeability study (Ref. 12). These studies were reviewed by the Agency and found not to support industry's contention that exposure is negligible and fully controlled.

III. Response To Public Comments

The Agency received comments, summarized below, from the Chemical

Manufacturers Association (CMA) thylhexanoic Acid Program Panel (the anel) on the proposed test rule for EHA. The Panel members include Eastman Kodak Co., Union Carbide Corp., BASF Wyandotte Corp., American Hoechst Corp., and Filo Chemical Inc.

A. Exposure

1. *Review of the 1985 Survey of Safety Procedures for EHA.* The Panel contends that EHA has insufficient exposure potential to pose an unreasonable risk of injury, and, that without the potential for exposure, the Agency does not have the regulatory authority to require testing. In support of this claim, the results of a questionnaire survey regarding EHA safety procedures were submitted to the Agency (Ref. 12). The Panel claims that the survey results refute EPA's "speculation" that gloves and other protective equipment may not be used by all employees who could be exposed to EHA.

The Agency has reviewed the survey and has several concerns with regard to study design and execution. By its very nature, the questionnaire survey is a simplified form of an industrial hygiene audit. That is, an audit is a process used to determine the presence or absence of dustrial hygiene program elements ef. 13). What is lacking from the audit process and from this survey are the necessary measures of program performance and effectiveness. The questionnaire survey succeeds only in providing mere indicators of activity, not compliance.

Moreover, the survey was designed and administered as a self-audit involving plant management and/or supervisory personnel. No indication is given that workers or their union representatives participated in the survey. This type of selection bias will predictably lead to diminished confidence in the objectivity of the responses.

Control of dermal exposures involves a combination of effective engineering controls, proper work practices, personal hygiene, and protective clothing. These are factors which can only be properly addressed through on-site industrial hygiene surveys, and not by questionnaire audits. Furthermore, there can be expected to exist considerable plant-to-plant variation in chemical control procedures (e.g., storage and loading facilities, physical plant conditions, waste disposal practices, etc.) and critical event planning (e.g., fire, explosion, chemical ll, etc.). These variables will impact nificantly on the potential for worker exposure. Furthermore, according to the American Insurance Institute, the most important factors contributing to compensable losses in the chemical industry are equipment and operational failures (Ref. 14). Such failures may result in significant worker exposures to chemicals and are not reflected in the results of the questionnaire survey.

2. *Glove permeability test.* To demonstrate that glove materials used by industry are an effective barrier to EHA, the Panel submitted data from a glove permeation test. The test measured nitrile and neoprene glove materials using ASTM procedure F739-81 (Ref. 15). Although the data show no EHA breakthrough after 7 hours of continuous exposure, the data fail to establish the steady-state permeation rate for EHA as prescribed in the ASTM procedure. Data on the permeation rate are necessary in order to determine if EHA may eventually permeate the glove material and eventually, through persistent permeation, occur on the inside surface of the glove (Ref. 15). Permeation information would be significant for prolonged or repeated use of the gloves.

The survey of safety procedures (Ref. 12) indicated that glove materials other than nitrile and neoprene (e.g., rubber, polyvinyl chloride, latex, and cotton) are used by some workers potentially exposed to EHA. Since the selection of the type of glove material and use of gloves by specific industries is voluntary, the potential for dermal exposure is likely to be variable among the companies that manufacture and use EHA.

EHA will be processed in mineral spirits, but the data fails to show the breakthrough or permeation rate of EHA in mineral spirits. Data on the migration of the pure component of a mixture may vary drastically with data for a mixture (Ref. 16). Because the materials tested do not necessarily represent materials used by industry, because the ASTM procedure was not completed to show the permeation rate for the material tested, and because actual exposure will likely be with EHA in mineral spirits and not with pure EHA, EPA believes the glove permeation data do not provide conclusive evidence that worker exposure to EHA will be precluded by industries' use of gloves.

3. *Dermal contact determination for EHA.* The Panel believes that EPA's estimate of "worst-case" dermal exposure to hands (500 mg/kg/contact) in the proposed rule is excessive.

EPA agrees and, based on a model for incidental hand exposure which the Panel and EPA believes more accurately describes exposure for EHA, the "worst case" exposure to EHA is revised to 60 mg/kg/contact.

Both Eastman Kodak Co. (Ref. 17) and Union Carbide Corp. (Ref. 18) report that EHA is a mild to moderate dermal irritant, and it is labeled as a mild acid. EPA believes that the acute effects from EHA and the current label do not preclude dermal exposure to EHA, but suggest a greater potential for lax industrial hygiene practices and a greater potential for dermal exposure than if the compound was labeled as a more severe hazard or was more acutely toxic.

B. Health Effects

1. *Developmental toxicity test.* The Panel made several comments on the adequacy of the study conducted by Ritter *et al.* (Ref. 6). The Ritter study was a single high dose (12.5 mmol/kg, approximately 1.8 g/kg) and a second lower dose (6.25 mmol/kg approximately 0.9 g/kg) administered on day 12 of gestation to pregnant Wistar rats via the oral route. In the control group, the incidence of total fetal toxicity was 4.4 percent as compared to 71.1 percent in the high dose EHA-treated group. In addition, the low dose EHA-treated group had an incidence of 7.1 percent for total embryo toxicity. The data from the Ritter study are consistent with the hypothesis that EHA causes developmental toxicity. Although submitted after the proposed EHA rule was published, the Ritter study was shared with industry in time to be included with other industry comments. Industry stated that the study was not reported in sufficient detail to allow adequate evaluation of the study design and results, and that the study was not state-of-the-art. The Panel also commented that a single high dose as reported in this study is inappropriate, that the authors did not report on maternal toxicity, and that there was no indication that a negative control was included in the study. EPA agrees the study is not of state-of-the-art design and would be inappropriate for assessing human risk. The Agency believes, however, that this study and other available data raise sufficient concern about the potential for developmental toxicity of EHA to support the hazard component of the "may present an unreasonable risk" finding. If these studies were of sufficient quality to fully assess the potential for developmental toxicity of EHA, further testing would be unnecessary.

The Panel believes that human exposure cannot be equated in magnitude with the single high dose

exposure used in the Ritter study (Ref. 6). The Panel cited evidence from Johnson (Ref. 23) that states that short duration high dose level studies have little value in establishing human safety guidelines. EPA generally agrees with this finding, but EPA disagrees that this supposition should modify the decision to test. The report by Johnson suggests that any effects of one-day exposures would also be discovered in longer duration segment II studies. The type of developmental effect produced would, of course, be dependent on the gestational stage(s) insulted and more severe effects would be elicited at lower doses since treatment is prolonged. Until an adequate state-of-the-art is performed, the no-observed-effect level for the developmental effects of EHA will remain undetermined.

The Panel believes tests conducted by Hazelton Laboratories (Ref. 19) were severely compromised, since all compounds at the dose tested produced overt signs of maternal toxicity. In addition, the Panel does not consider [[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenly]methyl]thio] acetic acid, 2-ethylhexyl ester, which was tested by CIBA–GEIGY (Ref. 20), an adequate analogue for EHA. EPA believes these studies viewed by themselves would be of little assistance in the evaluation of EHA; but, when considered along with other evidence of the potential developmental toxicity of EHA, they add to the weight of evidence supporting the potential developmental toxicity of EHA and thus the need for more definitive testing.

The Panel suggests the comparison between EHA and valproic acid is not justified based largely on the Panel's belief that the study of Brown and Coakley (Ref. 21) "does not provide any evidence to warrant a comparison of EHA to valproic acid." The comparison, however, is based on both structural similarities and the evidence of Brown and Coakley. Both EHA and valproic acid are isomeric acids which differ only in the placement of a –COOH group on an octane backbone. Thus, EHA corresponds to 3-carboxyoctane, and valproic acid corresponds to 4-carboxyoctane. There is a great deal of evidence as stated in the review by Gram and Bentsen (Ref. 22) that valpoic acid is both an animal and human developmental toxicant. The structural similarity alone between these two acids would support making the "may present" finding. The major significance of the Brown and Coakley study is that it describes the similarity in biologic effects between EHA and valprioc acid, which is supported by the previously discussed structural similarity.

The Agency believes that the total weight of evidence presented in the proposed test rule for EHA is adequate to support the Agency's finding that EHA may present an unreasonable risk for developmental effects. Since the proposed test rule, EPA has obtained additional information that further supports the Agency's hazard finding. In addition to the study by Ritter discussed above, in a series of studies in mice conducted by Nau (Refs. 8 and 9) and Nau and Loscher (Ref. 10), several short-chain acids were examined for fetal effects at doses of 600 mg/kg given on day 8 of gestation. Neural tube defects were observed in offspring of groups treated with valproic acid, 2-propylhexanoic acid, 2-butylhexanoic acid, and 2-ethylpentanoic acid. Furthermore, the Agency has evaluated results from a preliminary study (Ref. 11) reporting that decreases in pup weight on days 1 and 3 after parturition were observed in groups of mice exposed by gavage to EHA at 1,000 mg/kg on days 7 through 13 of gestation. Although these studies are not of adequate design to allow full assessment of the effects of EHA on fetal development, the studies do add further support to the need for testing.

2. *Subchronic toxicity testing.* The Panel does not believe that sufficient justification exists for the Agency to require subchronic toxicity testing. The Panel believes: (1) The study by Moody and Reddy (Ref. 24) used by EPA is inadequate justification; (2) data from related compounds suggest a low order of subchronic toxicity; and (3) the NTP subchronic study on 2-ethylhexanol should provide adequate data to evaluate EHA.

The objective of this test is to characterize fully the subchronic toxicity of EHA, and since the Agency may use a bioassay to be conducted on 2-ethylhexanol to evaluate whether oncogenicity testing of EHA will be required, the subchronic test is necessary to compare 2-ethylhexanol and EHA. At this time, it is not clear whether NTP will conduct the subchronic toxicity study of 2-ethylhexanol.

In the study by Moody and Reddy (Ref. 24), EHA exposure resulted in a greater than 50 percent increase in liver weight and substantial changes in certain measured biochemical parameters. These effects, observed in a study of only 3 weeks duration, are of a magnitude which EPA believes would indicate that a toxic process was involved rather than a simple adaptation. These data are sufficient to raise concern for the potential chronic toxicity of EHA.

Valproic acid, a close structural analogue of EHA, has been shown to be toxic to the liver in both humans and animals (Refs. 36 through 39), and this increases concern for potential liver effects from EHA.

In its comments on the relative subchronic toxicity of EHA, the Panel suggets EHA is less toxic compared with other chemicals tested because, on a molar basis, up to 3 times more EHA is required to produce similar effects. The Agency believes that in comparing the toxicity of EHA with other chemical substances, the comparison should be made on the relative molar levels of the 2-ethylhexyl moiety since it is this moiety that is hypothesized to be the active agent. Using this assumption, the differences in molar dose are no greater than approximately 50 percent.

3. *Oncogenicity.* The Panel considers the available data insufficient for the Agency to make a finding that EHA may present an unreasonable risk for an oncogenic effect. The Agency based its finding on the structural similarity of EHA with four compounds, which also contain the ethylhexyl moiety [di(2-ethylhexyl) phthalate, sodium 2-ethylhexyl sulfate, di(2-ethylhexyl) adipate, and tris(2-ethylhexyl) phosphate] and have been demonstrated to produce neoplasias in laboratory animals in bioassays conducted by NTP. In addition, EHA has been shown to cause peroxisomal proliferation, an effect produced by many carcinogenic compounds (Ref. 24). Despite possible flaws, the Agency considers that taken together this evidence constitutes sufficient justification for concern that EHA "may present an unreasonable risk" for oncogenicity.

4. *Pharmacokinetic test standard.* The Panel raised several comments regarding the proposed pharmacokinetic test standard, and the Panel submitted an alternative pharmacokinetic test standard. Principal concerns raised by the Panel were: (1) The need to include two experimental animal species, (2) the need to measure placental transfer of EHA, and (3) the need for a repeated dose study. In addition, questions were raised regarding proposed test methods involving: (1) The use of oral versus dermal absorption kinetics to assess bioavailability, (2) isolation of sufficient amounts of urinary metabolites to permit structure elucidation, and (3) the long time interval between blood sampling points.

In response to questions raised by the Panel about the proposed methods, the

Agency has modified the test standard as follows:

1. Intravenous administration has been included in the bioavailability test to provide a base line that is certain to produce 100 percent bioavailability;
2. Up to 10 percent unidentified labeled material is allowed;
3. Shorter blood collection intervals are required during the first hour of the study;
4. The Fischer 344 rat only will be used for the study; and
5. The placental transfer requirement is deleted.

The Panel contends that there are no data to suggest that EPA presents a chronic hazard; thus there is no need for a repeated dose study. Given the postulated exposure scenario for EHA, involving intermittent low-level dermal contact in the workplace the Agency believes data are needed on both repeated dose exposure and single dose exposure. An important pharmacokinetic consideration in toxicology is dose-dependent disposition, involving both dose-dependent availability and concentration-dependent elimination. Since the biotransformation of xenobiotics is controlled by enzymatic processes, metabolism is usually directly proportional to the substrate concentration provided the metabolizing enzymes do not become saturated. Enzyme saturation typically occurs with compounds that are rapidly absorbed and have a large volume of distribution, and is a function of the size and/or number of doses. The consequences of dose-dependent disposition can be a change in the urinary excretion profile for the unchanged parent compound and its metabolites, or large increases in toxic effects with increasing dose beginning at the dose level where saturation occurs. To evaluate the likelihood for dose-dependent disposition to occur, studies should be conducted that compare pharmacokinetics at high and low single doses of the same compound, or single and repeated administration of the substance at a constant dose. In a repeated dose study, however, it is not likely that dose-dependent disposition would be evident unless the dosing interval was less than the elimination half-life. Estimation of the elimination half-life would require the conduct of a preliminary single-dose study.

The rationale for performing a repeated dose pharmacokinetic study for EHA should be viewed in light of current knowledge regarding the metabolism of xenobiotic carboxylic acids. Many carboxylic acids, particularly those with low pK_a values, will be eliminated in the urine without any metabolic alteration (Ref. 26). An important route of carboxylic acid biotransformation is conjugation with glucuronic acid. β-Oxidation and other oxidative pathways to acidic metabolites are also important. Such metabolites are frequently excreted as glucuronides. Therefore, one may expect to find unchanged EHA and/or EHA glucuronide plus other acids and/or their glucuronides in the urine of EHA-dosed rats. The proportions of these metabolites can be expected to vary as pathways become saturated. For valproic acid, the formation of a relatively minor metabolite (2-*n*-propyl-4-pentenoic acid) is critical for the expression of toxicity to the liver (Ref. 36). A similar situation may hold for EHA toxicity.

IV. Final Test Rule for EHA

A. Findings

EPA is basing the final health testing requirements for EHA on the authority of section 4(a)(1)(A) of TSCA.

EPA finds that EHA may present an unreasonable risk of oncogenicity, developmental toxicity, and subchronic toxicity. These findings are based on the strongly suggestive evidence of toxicity discussed in Unit II. of this preamble and in Unit II. of the proposed rule and the potential for dermal exposure of workers engaged in manufacturing, transfer, storage, and processing of EHA. Because EPA believes EHA has a high hazard potential, EPA believes the exposure potential need not be very high to justify the 4(a)(1)(A) finding. Furthermore, although current exposure may appear to be low, future exposure from the same or different uses may change.

Inadequate data exist to characterize oncogenicity, developmental toxicity, subchronic toxicity, and pharmacokinetics of EHA. In addition, the dermal exposure of an estimated 400 workers during the manufacture, transfer, storage, and processng of EHA has not been sufficiently characterized to conclude that there is no unreasonable risk from this exposure to EHA. Furthermore, the potential health hazard of EHA is significant because of: (1) Its structural similarity to several chemicals that have been associated with such health effects; (2) the metabolic interrelationships of certain of these chemicals to EHA; and (3) the suggestive evidence that chemicals such as EHA that induce peroxisomal proliferation may have oncogenic potential. The available data on the health effects of concern are inadequate to reasonably predict or determine the health risks posed by present exposure to EHA. At this time, the Agency does not find that oncogenicity "testing is necessary to develop such data" for EHA. The Agency is currently negotiating with industry to obtain a bioassay for 2-ethylhexanol (EH), the immediate precursor of EHA, under the recently published consent agreement process but will propose such testing if a consent agreement cannot be achieved. The Agency will evaluate data from the EH bioassay along with other information to determine if oncogenicity testing of EHA will be necessary.

Data are not available to characterize the pharmacokinetics, subchronic toxicity, and developmental toxicity of EHA. The Agency is unaware of any on-going or planned testing in these areas of concern. Therefore, the Agency finds that the testing specified below is necessary to characterize these risks.

B. Required Testing

On the basis of these findings, the Agency is requiring developmental toxicity, 90-day subchronic, and pharmacokinetic testing as a basis for determining the health risks of EHA.

The Agency is requiring that the following health effects test guidelines be the test standards for the purpose of testing EHA.

The Agency believes that the pharmacokinetic test standard developed by the Office of Toxic Substances (OTS) for this final rule is appropriate for determining and comparing the absorption, distribution, metabolism, and excretion of EHA for both the oral and dermal routes of administration. Data from these studies are necessary to aid in the evaluation of test results from other toxicology studies and to determine the comparability of oral and dermal dosing.

The Agency requires that 7- to 9-week-old Fischer 344 rats be used for the pharmacokinetics studies. Furthermore, Fischer 344 rats are required for subchronic testing or EHA and have been used extensively by NTP for testing ethylhexyl-containing chemicals. They have also been used extensively in percutaneous absorption studies. Two doses shall be required in the pharmacokinetics studies, a "low" dose and a "high" dose. When administered orally, the "high" dose level should ideally induce some overt toxicity such as weight loss. The "low" dose level should correspond to a no-effect level. The same "high" and "low" dose shall be administered orally and dermally. The required studies evaluate blood levels, urinary and fecal excretion, and biotransformation of

EHA when administered dermally and orally. In addition, the extent to which washing removes dermally-applied EHA is also evaluated.

In response to comments from industry, the final test standards have been modified to include an intravenous administration in the bioavailability test, allow up to 10 percent unidentified labeled material in the urine, and require shorter collection intervals during the first hour of the study.

The Agency believes that this modified pharmacokinetics test methodology represents the state-of-the-art and forms the basis for a valid and scientifically acceptable test standard. This test standard was proposed under 40 CFR 798.460 published in the **Federal Register** of May 17, 1985 (50 FR 20689), and is published in the final rule below under 40 CFR 795.223.

The Agency believes that the subchronic exposure oral toxicity test standard developed by OTS for this final rule is appropriate in determining the subchronic toxicity of EHA. This test permits the determination of the no-observed-effect level, the characterization of toxic effects associated with continuous or repeated exposure for a period of 90 days, and provides information on target organs.

The subchronic test is conducted by administering a chemical substance such as EHA orally for 90 days in graduated daily doses to several groups of experimental animals, one dose level per group. During the period of administration the animals are observed daily to detect signs of toxicity. Animals which die during the period of administration are necropsied, and at the conclusion of the test all surviving animals are sacrificed and histopathological examinations conducted on the tissues. Given the test results of Moody and Reddy (Refs. 24 and 31), the subchronic toxicity evaluation should pay particular attention to hepatotoxicity and serum lipid alterations.

The Agency believes that this subchronic toxicity test methodology represents the state-of-the-art and forms the basis for a valid and scientifically acceptable test standard. This test standard was proposed under 40 CFR 798.75, published in the **Federal Register** of May 17, 1985 (50 FR 20687), and is published in the final rule below under § 795.260.

To determine the developmental hazard of EHA, EPA proposed that testing be conducted by either the OTS guideline, which on May 17, 1985 was titled "Developmental Toxicity (HG-Organ/Tissue-Developmental Toxicity-Oral, OTS Health Effects Test Guidelines)", or the OECD test guideline entitled "Teratogenicity", No. 414, adopted May 12, 1981. No comments were received on either test standard. However, since publication of the proposed rule for EHA, the Agency published the test guideline entitled "Developmental Toxicity Study" under 40 CFR 798.4900 (50 FR 39433; September 27, 1985). The Agency proposed modifications to this guideline in the **Federal Register** of January 14, 1986 (51 FR 1523). These modifications provide more explicit guidance on the necessary minimum elements for this testing. In addition, these revisions avoid repetitive chemical-by-chemical changes to the guidelines in its adoption as a test standard. The OTS guideline proposed for EHA, therefore, will be subject to change. EPA believes, nonetheless, that the OECD test guideline as proposed for EHA represents a state-of-the-art method and forms the basis for a valid and scientifically acceptable test standard.

The developmental toxicity test is conducted by administering a chemical substance such as EHA orally in graduated doses, for at least that part of the pregnancy covering the period of organogenesis, to several groups of pregnant experimental animals, one dose level being used per group. Shortly before the expected date of delivery, the pregnant females are sacrificed, the uteri removed, and the contents examined for structural malformations, *in utero* death, and growth retardation.

Rats and a nonrodent mammalian species should be utilized. EPA recommends rabbits as the nonrodent species. The Agency believes that multispecies testing is a more sensitive means of detecting developmental hazards than single species testing (Refs. 32, 33, and 34). Testing EHA in the rat and a nonrodent mammalian species will provide the Agency with the data needed to reasonably determine or predict whether EHA poses a risk of developmental toxicity to humans.

The Agency believes that the OECD oral developmental toxicity test guideline represents a state-of-the-art methodology and forms the basis for a valid and scientifically acceptable test standard for evaluating the developmental toxicity of a chemical substance such as EHA. The guideline has been reviewed to ensure that it reflects the most current scientific approach to developmental toxicity testing.

C. Test Substance

EPA is requiring that EHA of at least 99 percent purity be used as the test substance. EHA of this purity is commercially available at nominal cost. EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to EHA itself. Radiolabeled ^{14}C-EHA will be needed for the pharmacokinetics testing.

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 existing data are inadequate to assests the health risks from the manufacture, transfer, storage and processing of EHA, EPA is requiring that persons who manufacture or process, or intend to manufacture or process, EHA at any time from the effective date of the final test rule to the end of the reimbursement period are subject to the pharmacokinetic, subchronic toxicity, and developmental toxicity testing requirements contained in the final rule. The end of the reimbursement period will be 5 years after the last final report is submitted for EHA or an amount of time equal to that which was required to develop data if more than 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 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 requiring the submission of equivalence data as a condition for exemption from the required testing for EHA. As noted in Unit IV.C. above, EPA is interested in evaluating the effects attributable to EHA and has specified a relatively 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.

E. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with its final 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 within 45 days before initiation 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. Specific reporting requirements for each of the proposed test standards follow:

The pharmacokinetic test shall be completed, and the final results submitted to the Agency within 1 year of the effective date of the final test rule. An interim progress report shall be provided 6 months from the effective date of this rule.

The subchronic toxicity tests shall be completed, and the final results submitted to the Agency within 15 months of the effective date of the final test rule. Interim progress reports shall be provided 6 months and 12 months from the effective date of this rule.

The developmental toxicity tests shall be completed, and the final results submitted to the Agency within 18 months of the effective date of the final test rule. Interim progress reports shall be provided 6 months and 12 months from the effective date of this rule.

NTP's experience with testing other ethylhexyl moiety substances and the Agency's experience with Negotiated Testing Agreements with industry suggest that this testing can be completed within the specified time. The 18-month extension for pharmacokinetics testing requested by industry is therefore denied at this time. If technical problems arise during this testing, the sponsors may request that the Agency modify this rule requirement.

TSCA section 14(b) governs Agency disclosure of all test data submitted 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) are in 40 CFR Part 707 (45 FR 82844). In brief, as of the effective date of this test rule, an exporter of EHA must report to EPA the first annual export or intended export of EHA to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

F. 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 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 representatives of the EPA for the purpose of determining compliance with the final rule for EHA. 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 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 790.48(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 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. Economic Analysis of Final Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (Ref. 4) 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 EHA: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If there is no indication of adverse effect, no further economic analysis is 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 this final rule are estimated to range from $216,210 to $275,620. 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 test costs (using a cost of capital of 25 percent over a period of 15 years) range from $56,000 to $71,400. Based on an estimated minimum production volume for EHA of 12 million pounds, the unit test costs will be about 0.6 cents per pound. In relation to the selling price of 57 cents per pound for EHA, these costs are equivalent to one percent of price.

Based on these costs and the uses of EHA, the economic analysis indicates that the potential for significant adverse economic impact as a result of this testing rule is low. This conclusion is based on the following observations:

1. EHA is an intermediate whose demand is dispersed over several markets;

2. The dosage requirements of EHA derivatives, notably metal octoates, are very small in relation to their end products;

3. The estimated unit test costs are low, one percent of current price in the upper-bound case; and

4. The unit costs, when dispersed over the production costs of EHA derivatives and their end products, will be significantly reduced due to both the intermediate nature of EHA and the small percent composition requirements of its derivatives.

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

VI. 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 (PB 82-140773)", can be obtained through the National Technical Information Service (NTIS).

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

VII. Rulemaking Record

EPA has established a record for this rulemaking (OPTS-42065A). This record includes basic information considered by the Agency in developing this rule and appropriate **Federal Register** notices.

The record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this decision consisting of:

(a) Notice containing the ITC designation of EHA to the Priority List (49 FR 22389; May 29, 1984).

(b) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).

(c) Notice of final rule on two-phase test rule development and exemption procedures (49 FR 39774; October 10, 1984).

(d) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20678; May 17, 1985).

(e) Notice of final rule on data reimbursement policy and procedures (48 FR 31786; July 11, 1983).

(f) Notices requiring TSCA section 8 (a) and (d) reporting requirements for EHA (49 FR 22284, 22286; May 29, 1984).

(g) Notice of EHA proposed test rule (50 FR 20678; May 17, 1985).

(h) Toxic Substance Control Act Test Guidelines Final Rule, 40 CFR Parts 796, 797, and 798, September 27, 1985.

(i) Notice of final rule amending TSCA section 8(d) reporting requirements for EHA (51 FR 32720; September 15, 1986).

(2) Support documents: consisting of:

(a) Study of availability of test facilities and personnel.

(b) EHA economic analysis.

(3) Records of minutes of informal meetings.

(4) Communications before proposal consisting of:

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

(b) Summaries of telephone conversations.

(c) Reports—published and unpublished factual materials.

(5) Test guidelines proposed as standards.

B. References

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(4) USEPA. Economic Impact Analysis of Proposed Test Rules for 2-Ethylhexanoic Acid. Washington, DC: Office of Pesticides and Toxic Substances. Contract No. 68-02-4235. (August 20, 1986)

(5) Chemical Manufacturers Association. Letter from E.J. Moran to C.R. McCormack on Production, Exposure and Health Effects of 2-Ethylhexanoic Acid. (August 1, 1984)

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(13) Corn, M. and Lees, P.S.J. "The industrial hygiene audit: Purposes and implementation." *American Industrial Hygiene Association Journal.* 44(2):135–141. (1983)

(14) Spiegelman, A. "Hazard control in the chemical and allied industries." Symposium on Control of Workplace Hazards in the Chemical Manufacturing Industry sponsored by Chemical Manufacturers Association and National Institute for Occupational Safety and Health, Philadelphia, PA. (March 11 and 12, 1981)

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(17) Eastman Kodak Co. Material Safety Data Sheet: Kodaflex TEG–EH Triethylene Glycol Di-2-ethylhexanoate. (June 1983)

(18) Union Carbide Corp. Cover letter from G.P. Bigelow, Union Carbide to R. Borghi, Dynamac Corp. (October 14, 1983) Enclosures:

(a) Product Literature on Organic Acids.

(b) Material Safety Data Sheet for 2-Ethylhexanoic Acid.

(19) Hazleton Laboratories America, Inc. Screening of priority chemicals for potential reproductive hazard. Final report. NIOSH Contract No. 200–82–2542. Hazleton Study Nos. 6125–101 through 6125–110. Atlanta, GA: Centers for Disease Control, NIOSH. (1983)

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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. NE–G004, 401 M Street, SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VIII. Other Regulatory Requirements

A. 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. 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. enterprise to compete with foreign enterprises.

This 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 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.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.,* and has assigned them OMB number 2070–0033.

List of Subjects in 40 CFR Parts 795 and 799

Testing, Environmental protection, Hazardous substances, Chemicals, Reporting and recordkeeping requirements, Incorporation by reference.

Dated: October 27, 1986.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

1. By adding new Part 795, consisting at this time of §§ 795.223 and 795.260, to read as follows:

PART 795—PROVISIONAL TEST GUIDELINES

Subpart A—[Reserved]

Subpart B—[Reserved]

Subpart C—[Reserved]

Subpart D—Provisional Health Effects Guidelines

Sec.

795.223 Pharmacokinetic test.

795.260 Subchronic oral toxicity test.

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

Subparts A-C—[Reserved]

Subpart D—Provisional Health Effects Guidelines

§ 795.223 Pharmacokinetic test.

(a) *Purpose.* The purpose of these tests is to determine:

(1) The bioavailability of a test substance after dermal administration.

(2) Whether or not the biotransformation of the test substance is qualitatively and quantitatively the same after dermal and oral administration.

(3) Whether or not the biotransformation of the test substance is changed qualitatively or quantitatively by repeated dosing.

(b) *Definitions*—(1) Bioavailability refers to the rate and extent to which the administered compound is absorbed, i.e., reaches the systemic circulation.

(2) Relative percent of percutaneous absorption is defined as 100 times the ratio between total urinary excretion of compound following topical administration and total urinary excretion of compound following intravenous injection.

(c) *Test procedures*—(1) *Animal selection*—

(i) *Species.* The species utilized for investigating the test substance shall be the rat, a species for which historical data on the toxicity and carcinogenicity of several compounds are available and which is used extensively in percutaneous absorption studies.

(ii) *Animals.* Adult female Fischer 344 rats shall be used. The rats shall be 7 to 9 weeks old and weigh 125 to 175 grams. Prior to testing the animals shall be selected at random for each group. Animals showing signs of ill health shall not be used.

(iii) *Animal care.* (A) The animals should be housed in environmentally controlled rooms with 10 to 15 air changes per hour. The rooms should be maintained at a temperature of 25±2° C and humidity of 50±10 percent with a 12-hour light/dark cycle per day. The rats should be kept in a quarantine facility for at least 7 days prior to use.

(B) During the acclimatization period, the rats should be housed in cages on hardwood chip bedding. All animals shall be provided with conventional laboratory diets and water *ad libitum.*

(2) *Administration of test substance*—(i) *Test compound.* Test studies require the use of both nonradioactive test substance and ^{14}C-labeled test substance. Both preparations are needed to investigate under paragraph (a)(2) of this section. The use ^{14}C-test substance is required to investigate under paragraphs (a)(1), (2), and (3) of this section because it will facilitate the work, improve the reliability of quantitative determinations, and increase the probability of observing the presence of previously unidentified metabolities.

(ii) *Dosage and treatment.* (A) Two doses shall be used in the study, a "low" dose and a "high" dose. When administered orally, the "high" dose level should ideally induce some overt toxicity such as weight loss. The "low" dose level should correspond to a no-effect level.

(B) The same "high" and "low" doses shall be administered orally and dermally.

(C) Oral dosing shall be performed by gavage or by administering encapsulated test substance. Whichever method is selected for this study shall be the same as used for the 90-day oral subchronic toxicity testing conducted for comparison purposes.

(D) For dermal treatment, the doses shall be applied at a volume adequate to deliver the prescribed doses. The backs of the rats should be lightly shaved with an electric clipper shortly before treatment. The dose shall be applied with a micropipette on 2 cm^2 of the freshly shaven skin. The dosed areas shall be occluded with an aluminum foil patch which is secured in place with adhesive tape.

(iii) *Bioavailability study in rats.* At least eight rats shall receive a single intravenous (low) dose of ^{14}C-test substance and serial samples of blood removed from four animals at 15 minutes, 30 minutes, 1 hour, 8 hours, 24 hours, 48 hours, and 96 hours. All animals shall be housed in metabolism cages and urine and feces collected at 8, 24, 48, 72, and 96 hours. The procedure shall be repeated with eight rats in which ^{14}C-test substance is maintained in contact with the skin for the duration of the study (96 hours). If dermal adsorption cannot be demonstrated, the study should be repeated using a higher dose. Total radioactivity shall be measured in the blood, urine, and feces samples collected from all animals. The results shall be used to construct a blood concentration-time curve and to calculate bioavailability by the ratio of the total 96-hour urinary excretion of radioactivity after dermal and intravenous administration. Bioavailability is expressed as (percent dose dermal/percent dose intravenous)×100=percent dermal absorption. Urine shall be saved for metabolite identification, if it becomes necessary.

(iv) *Biotransformation in rats after oral and dermal administration.* Eight rats shall be dosed orally, and eight rats shall be dosed dermally (96-hour contact) with the high dose of ^{14}C-test substance. The results of the bioavailability study (see paragraph (c)(2)(iii) of this section shall be evaluated first to ensure that the dermal dose applied will result in the appearance of radioactivity in the urine. All animals shall be housed in metabolism cages allowing for separate collection of urine and feces at 8, 24, 48, 72, and 96 hours. The parent compound and any metabolite that comprises greater than 10 percent of the dose shall be identified in the urine. These results shall be qualitatively compared to the urinary excretion data obtained in the low dose bioavailability study (see paragraph (c)(2)(iii) of this section); metabolites in the low dose urine shall also be identified if a different pattern of metabolism is evident.

(v) *Repeated dosing study.* Four rats shall receive a series of single daily oral doses of nonradioactive test substance over a period of at least 14 days, followed at 24 hours after the last dose by a single oral dose of ^{14}C-test substance. Each dose shall be at the low-dose level. If the pattern of urinary metabolite excretion is qualitatively different from that obtained with the orally dosed animals in the single-dose biotransformation study at 24 and 48 hours (see paragraph (c)(2)(iv) of this section), metabolites shall be identified in accordance with the procedure given in paragraph (c)(2)(iii) of this section.

(vi) *Skin washing study.* If greater than 10 percent of test substance is absorbed through the skin (see paragraphs (c)(2) (ii) and (iii) of this section) then a washing efficacy

experiment shall be performed to assess the extent of removal of the applied test substance by washing with soap and water. Four rats should be lightly anesthetized and treated with a dermal dose of test compound previously shown to result in measurable percutaneous absorption greater than 10 percent. Soon after application (5 to 10 minutes) the treated animals shall be washed with soap and water, then housed in individual metabolism cages for excreta collection. Measurements of total radioactivity in urine and feces shall be made in the same manner as described in paragraph (c)(2)(iii) of this section.

(d) *Data and Reporting*—(1) *Treatment of results.* Data shall be summarized in tabular form.

(2) *Evaluation of results.* All observed results, quantitative or incidental, shall be evaluated by an appropriate statistical method.

(3) *Test report.* In addition to the reporting requirements as specified in the TSCA Good Laboratory Practice Standards, 40 CFR Part 792, Subpart J, the following specific information shall be reported:

(i) Species, strain, and supplier of laboratory animals.

(ii) Information on the degree (i.e., specific activity for a radiolabel) and site(s) of labeling of the test substances.

(iii) A full description of the sensitivity and precision of all procedures used to produce the data.

(iv) Relative percent absorption by the dermal route for rats administered low and high doses of ^{14}C-test substance, compared with 100 percent of the intravenous dose.

(v) Quantity of isotope, together with percent recovery of the administered dose, in feces, urine, and blood.

(vi) Biotransformation pathways and quantities of the test substance and metabolites in urine collected after administering single high and low oral and dermal doses.

(vii) Biotransformation pathways and quantities of test substance and metabolites in urine collected after administering repeated low doses of test substance to rats.

§ 795.260 Subchronic oral toxicity test.

(a) *Purpose.* In the assessment and evaluation of the toxic characteristics of a test substance, the determination of subchronic oral toxicity may be carried out after initial information on toxicity has been obtained by acute testing. The subchronic oral study has been designed to permit the determination of the no-observed-effect level and toxic effects associated with continuous or repeated exposure to a test substance for a period of 90 days. The test is not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life shortening). It provides information on health hazards likely to arise from repeated exposure by the oral route over a limited period of time. It will provide information on target organs, the possibilities of accumulation, and can be of use in selecting dose levels for chronic studies and for establishing safety criteria for human exposure.

(b) *Definitions.* (1) Subchronic oral toxicity is the adverse effects occurring as a result of the repeated daily exposure of experimental animals to a chemical for a part (approximately 10 percent for rats) of a life span.

(2) Dose is the amount of test substance administered. Dose is expressed as weight of test substance (g, mg) per unit weight of test animal (e.g., mg/kg), or as weight of test substance per unit weight of food or drinking water.

(3) No-effect level/No-toxic-effect level/No-adverse-effect level/No-observed-effect level is the maximum dose used in a test which produces no observed adverse effects. A no-observed-effect level is expressed in terms of the weight of a substance given daily per unit weight of test animal (mg/kg). When administered to animals in food or drinking water, the no-observed-effect level is expressed as mg/kg of food of mg/ml of water.

(4) Cumulative toxicity is the adverse effects of repeated doses occurring as a result of prolonged action on, or increased concentration of, the administered substance or its metabolites in susceptible tissue.

(c) *Principle of the test method.* The test substance is administered orally in graduated daily doses to several groups of experimental animals, one dose level per group, for a period of 90 days. During the period of administration the animals are observed daily to detect signs of toxicity. Animals which die during the period of administration are necropsied. At the conclusion of the test all animals are necropsied and histopathological examinations carried out.

(d) *Test procedures*—(1) *Animal selection*—

(i) *Species.* Rats and mice shall be used.

(ii) *Age.* (A) Young adult animals shall be employed. At the commencement of the study the weight variation of animals used shall not exceed ± 20 percent of the mean weight for each sex.

(B) Dosing shall begin as soon as possible after weaning, ideally before the animals are 6 weeks old, and in any case not more than 8 weeks old.

(iii) *Sex.* (A) Equal numbers of animals of each sex should be used at each dose level.

(B) The females should be nulliparou and non-pregnant.

(iv) *Numbers.* (A) At least 20 rats anc 20 mice (10 females and 10 males of each species) shall be used at each dos level.

(B) If interim sacrifices are required, the number shall be increased by the number of animals scheduled to be sacrificed before the completion of the study.

(2) *Control groups.* A concurrent control group is required. This group shall be an untreated or sham-treated control group or, if a vehicle is used in administering the test substance, a vehicle control group. If the toxic properties of the vehicle are not known or cannot be made available, both untreated and vehicle control groups are required.

(3) *Satellite group.* A satellite group of 20 rats and 20 mice (10 females and 10 males of each species) shall be treated with the high dose level for 90 days and observed for reversibility, persistence, or delayed occurrence of toxic effects for a post-treatment period of not less than 28 days.

(4) *Dose levels and dose selection.* (i) In subchronic toxicity tests, it is desirable to have a dose response relationship as well as no-observed-toxic-effect level. Therefore, at least three dose levels with a control and, where appropriate, a vehicle control (corresponding to the concentration of vehicle at the highest exposure level) shall be used. Doses should be spaced appropriately to produce test groups with a range of toxic effects. The data shall be sufficient to produce a dose-response curve.

(ii) The highest dose level shall result in toxic effects but not produce an incidence of fatalities which would prevent a meaningful evaluation.

(iii) The lowest dose level shall not produce any evidence of toxicity. Where there is a usable estimation of human exposure the lowest dose level shall exceed this.

(iv) Ideally, the intermediate dose level(s) should produce minimal observable toxic effects. If more than one intermediate dose is used, the dose levels should be spaced to produce a gradation of toxic effects.

(v) The incidence of fatalities in low and intermediate dose groups and in the controls should be low to permit a meaningful evaluation of the results.

(5) *Exposure conditions.* Ideally the animals should be dosed with the test substance on a 7-day per week basis

over a period of 90 days. However, based primarily on practical considerations, dosing by gavage or capsule studies on a 5-day per week basis shall be acceptable.

(6) *Observation period.* (i) Duration of observation shall be for at least 90 days.

(ii) Animals in the satellite group scheduled for followup observations shall be kept for not less than 28 days without treatment to detect recovery from, or persistence of, toxic effects.

(7) *Administration of the test substance.* (i) The test substance shall be administered in the diet or in capsules. Alternatively, it may be administered by gavage or in the drinking water.

(ii) All animals shall be dosed by the same method during the entire experimental period.

(iii) Where necessary, the test substance is dissolved or suspended in a suitable vehicle. If a vehicle or diluent is needed, ideally it should not elicit important toxic effects itself nor substantially alter the chemical or toxicological properties of the test substance. It is recommended that wherever possible the usage of an aqueous solution be considered first, followed by consideration of a solution of oil, and then by possible solution in other vehicles.

(iv) For substances of low toxicity, it is important to ensure that when administered in the diet the quantities of the test substance involved do not interfere with normal nutrition. When the test substance is administered in the diet, either a constant dietary concentration (ppm) or a constant dose level in terms of the animals' body weight shall be used; the alternative used shall be specified.

(v) For a substance administered by gavage or capsule, the dose shall be given at similar times each day, and adjusted at intervals (weekly or biweekly) to maintain a constant dose level in terms of animal body weight.

(8) *Observation of animals.* (i) Each animal shall be handled and its physical condition appraised at least once each day.

(ii) Additional observation shall be made daily with appropriate actions taken to minimize loss of animals to the study (e.g., necropsy or refrigeration of those animals found dead and isolation or sacrifice of weak or moribund animals).

(iii) Signs of toxicity shall be recorded as they are observed including the time of onset, degree, and duration.

(iv) Cage-side observations shall include, but not be limited to, changes in skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity, and behavior pattern.

(v) Measurements shall be made weekly of food consumption or water consumption when the test substance is administered in the food or drinking water, respectively.

(vi) Animals shall be weighed weekly.

(vii) At the end of the 90-day period all survivors in the nonsatellite treatment group shall be sacrificed. Moribund animals shall be removed and sacrificed when noticed.

(9) *Clinical examinations.* (i) The following examinations shall be made on at least five animals of each sex in each group of rats.

(A) Certain hematology determinations shall be carried out just prior to terminal sacrifice at the end of the test period. The following hematology determinations shall be carried out: Hematocrit, hemoglobin concentration, erythrocyte count, total and differential leucocyte count, and a measure of clotting potential such as clotting time, prothrombin time, thromboplastin time, or platelet count.

(B) Certain clinical biochemistry determinations shall be carried out just prior to terminal sacrifice at the end of the test period. The following clinical biochemical test areas shall be carried out: Electrolyte balance, carbohydrate metabolism, and liver and kidney function. The selection of additional tests shall be influenced by observations on the mode of action of the substance. Suggested additional determinations include: calcium, phosphorus, chloride, sodium, potassium, fasting glucose (with period of fasting appropriate to the species/breed), serum glutamic-pyruvic transaminase (now known as serum alanine aminotransferase), serum glutamic oxaloacetic transaminase (now known as serum aspartate aminotransferase), ornithine decarboxylase, gamma glutamyl transpeptidase, urea nitrogen, albumen, blood creatinine, total bilirubin, and total serum protein measurements. Other determinations which may be necessary for an adequate toxicological evaluation include analyses of lipids, hormones, acid/base balance, methemoglobin, and cholinesterase activity. Additional clinical biochemistry may be employed where necessary to extend the investigation observed effects.

(ii) The following examinations shall be made on at least five animals of each sex in each group.

(A) Ophthalmological examination, using an ophthalmoscope or equivalent suitable equipment, shall be made prior to the administration of the test substance and at the termination of the study. If changes in the eyes are detected, all animals shall be examined.

(B) Urinalysis is required only when there is an indication based on expected or observed toxicity.

(10) *Gross necropsy.* (i) All animals shall be subjected to a full gross necropsy which includes examination of the external surface of the body, all orifices, and the cranial, thoracic and abdominal cavities and their contents.

(ii) At least the liver, kidneys, adrenals, gonads, and brain shall be weighed wet, as soon as possible after dissection to avoid drying.

(iii) The following organs and tissues, or representative samples thereof, shall be preserved in a suitable medium for possible future histopathological examination: All gross lesions; brain—including sections of medulla/pons, cerebellar cortex and cerebral cortex; pituitary; thyroid/parathyroid; thymus; lungs; trachea; heart; sternum with bone marrow; salivary glands; liver; spleen; kidneys/adrenals; pancreas; gonads; uterus; accessary genital organs (epididymis, prostrate, and, if present, seminal vesicles); aorta; (skin), (non-rodent gall bladder); esophagus; stomach; duodenum; jejunum; ileum; cecum; colon; rectum; urinary bladder; representative lymph node; (mammary gland), (thigh musculature), peripheral nerve; (eyes), (femur including articular surface), (spinal cord at three levels—cervical, midthoracic and lumbar); and, (rodent-exorbital lachrymal glands).

(11) *Histopathology.* (i) Full histopathology shall be performed on the organs and tissues, listed under paragraph (d)(10) (ii) and (iii) of this section of all animals in the control and high-dose groups, and all animals that died or were killed during the study.

(ii) Histopathology shall be performed on all gross lesions in all animals.

(iii) Histopathology shall be performed on target organs in all animals.

(iv) Histopathology shall be performed on the tissues mentioned in brackets under paragraph (d)(10)(iii) of this section if indicated by signs of toxicity or target organ involvement.

(v) Histopathology shall be performed on lungs, liver, and kidneys of all animals. Special attention to examination of the lungs should be made for evidence of infection since this provides a convenient assessment of the state of health of the animals.

(vi) For the satellite group, histopathology shall be performed on tissues and organs identified as showing effects in the treated groups.

(e) *Data and reporting*—(1) *Treatment of results.*

(i) Data shall be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing lesions, the type of lesions, and the percentage of animals displaying each type of lesion.

(ii) All observed results, quantitative and incidental, shall be evaluated by an appropriate statistical method. Any generally acceptable statistical methods may be used; the statistical methods should be selected during the design of the study.

(2) *Evaluation of the study results.* (i) The findings of a subchronic oral toxicity study should be evaluated in conjunction with the findings of preceding studies and considered in terms of the toxic effects and the necropsy and histopathological findings. The evaluation shall include the relationship between the dose of the test substance and the presence or absence, the incidence and severity, of abnormalities, including behavioral and clinical abnormalities, gross lesions, identified target organs, body weight changes, effects on mortality and any other general or specific toxic effects. The test shall provide a satisfactory estimation of a no-effect level.

(ii) In any study which demonstrates an absence of toxic effects, further investigation to establish absorption and bioavailability of the test substance shall be considered.

(3) *Test report.* In addition to the reporting requirements as specified in the TSCA Good Laboratory Practice Standards, Subpart J of Part 792 of this chapter, the following specific information shall be reported:

(i) *Group animal data.* Tabulation of toxic response data by species, strain, sex, and exposure level for:

(A) Number of animals dying.

(B) Number of animals showing signs of toxicity.

(C) Number of animals exposed.

(ii) *Individual animal data.* (A) Time of death during the study or whether animals survived to termination.

(B) Time of observation of each abnormal sign and its subsequent course.

(C) Body weight data.

(D) Food consumption data when collected.

(E) Hematological tests employed and all results.

(F) Clinical biochemistry tests employed and all results.

(G) Necropsy findings.

(H) Detailed description of all histopathological findings.

(I) Statistical treatment of results where appropriate.

PART 799—[AMENDED]

2. In Part 799:

a. The authority citation for Part 799 continues to read as follows:

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

b. By adding § 799.1650, to read as follows:

§ 799.1650 2-Ethylhexanoic acid.

(a) *Identification of test substance.* (1) 2-Ethylhexanoic acid (CAS No. 149–57–5) (hereinafter "EHA") shall be tested in accordance with this section.

(2) EHA 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.* All persons who manufacture or process EHA other than as an impurity from the effective date of this section, December 20, 1986, to the end of the reimbursement period shall submit an exemption application, or shall submit a letter of intent to conduct testing, 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. The end of the reimbursement period shall be 5 years after the submission of the last final report required under this test rule.

(c) *Health effects testing*—(1) *Pharmacokinetics*—

(i) *Required testing.* Metabolism studies of the oral and dermal routes of exposure shall be conducted with EHA using Fischer 344 rats in accordance with the test standard specified in § 795.223 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) An interim progress report shall be provided to the Agency 6 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 1 year from the effective date of the final test rule.

(2) *Subchronic toxicity*—(1) *Required testing.* Subchronic toxicity tests shall be conducted with EHA using Fischer 344 rats and B6C3F1 mice in accordance with the test standard specified in § 795.260 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) Interim progress reports shall be provided to the Agency 6 months and 12 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 15 months from the effective date of the final test rule.

(3) *Administration of test substance.* Oral dosing for testing required under paragraph (c) (1) and (2) of this section shall be by the same method for both tests, as specified in § 795.223(c)(2)(ii)(C) of this chapter.

(4) *Development toxicity*—(i) *Required testing.* Developmental toxicity tests shall be conducted with EHA using one rodent and one nonrodent mammalian species in accordance with the OECD guideline entitled "Teratogenicity", No. 414, adopted May 12, 1981. The OECD guideline is available in OECD Publication No. ISBN 92–64–12221–4 and is sold by the OECD Publication and Information Center, Room Number 1207, 1750 Pennsylvania Avenue, NW., Washington, DC. Copies of this document may be inspected at the Office of the Federal Register, 1100 L Street, NW., Room 8401, Washington, DC, or the OPTS Reading Room (docket No. OPTS–42065), Room N.E.–G004, Environmental Protection Agency, 401 M Street, SW., Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. These materials are incorporated as they exist on the effective date of this rule; a notice of any change will be published in the **Federal Register.**

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) Interim progress reports shall be provided to the Agency 6 months and 12 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 18 months from the effective date of the final test rule.

(Information collection requirements are approved by the Office of Management and Budget under control number 2070–0033.)

[FR Doc. 86–24992 Filed 11–5–86; 8:45 am]

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–6728]

Changes in Flood Elevation Determinations; Illinois; Correction

AGENCY: Federal Emergency Management Agency.

ACTION: Interim rule; correction.

CAS No.	Substance	Special exemptions	Effective date	Sunset date
96-29-7	2-Butanone, oxime		Dec. 15, 1986	Dec. 15, 1996
1634-04-4	Propane, 2-methoxy-2-methyl-		Dec. 15, 1986	Dec. 15, 1996
3956-55-6	Acetamide, *N*-[5-[bis[2-(acetyloxy) ethyl]amino]-2-[(2-bromo-4,6-dinitrophenol)azo]-4-ethoxyphenyl]-.		Dec. 15, 1986	Dec. 15, 1996

(2) * *

Substance	CAS No.	Special exemptions	Effective date	Sunset date
Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenol)azo]-4-ethoxyphenyl]-	3956-55-6		Dec. 15, 1986	Dec. 15, 1996
2-Butanone, oxime	96-29-7		Dec. 15, 1986	Dec. 15, 1996
Propane, 2-methoxy-2-methyl-	1634-04-4		Dec. 15, 1986	Dec. 15, 1996
2-Propanol	67-63-0		Dec. 15, 1986	Dec. 15, 1996

(Approved by the Office of Management and Budget under control number 2070-0004)

[FR Doc. 25581 Filed 11-13-86; 8:45 am]
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40 CFR Parts 790 and 799

[OPTS-42052C; FRL 3113-3]

Testing Consent Agreement Development for Chemical Substances; Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public meetings.

SUMMARY: EPA has issued an Interim Final Rule that amends EPA's regulations for the development and implementation of testing requirements under section 4 of the Toxic Substances Control Act (TSCA). These amendments provide for testing under consent agreements when EPA and affected manufacturers, processors, and other interested parties achieve timely consensus on appropriate testing programs. EPA will conduct one or more public meetings to discuss the implementation of the consent agreement process to date and ways to make it more effective.

DATES: The first meeting will be held November 20, 1986. Those interested in attending any of these meetings should contact the TSCA Assistance Office address before November 19, 1986.

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

SUPPLEMENTARY INFORMATION: Under section 4 of TSCA, EPA is authorized to promulgate rules requiring manufacturers and processors to test chemicals they manufacture or process. From 1980 though 1983, EPA negotiated agreements with industry to have testing of certain chemicals conducted voluntarily as an alternative to the lengthier process of requiring testing by rule. In 1983, EPA was sued by the Natural Resources Defense Council (NRDC vs. Ruchelshaus, 83 Civ 8844, S.D.N.Y.) on the basis that these negotiated testing agreements were not equivalent to rules and therefore illegal. The court agreed with NRDC. In 1985, NRDC and the Chemical Manufacturer's Association (CMA) suggested to EPA that a procedure be developed that would permit negotiations while preserving the key features of section 4 test rules such as enforceability.

Subsequently, EPA, CMA, and NRDC developed such a procedure in a series of public meetings. This new approach would permit negotiation between EPA, industry, and other interested parties to culminate in a consent order in which test sponsors would be subject to civil penalties if they failed to perform the agreed-upon testing. Such consent agreements would be adopted by EPA only where all interested parties agreed upon an appropriate testing program in a timely manner. Otherwise, EPA would proceed with rulemaking if it remained convinced that testing should be required. This procedure was adopted by EPA in an interim final procedural rule, published in the **Federal Register** of June 30, 1986 (51 FR 23706). EPA stated it would gain experience in using the procedure and base the final rule on both public comment and its experience. The negotiation procedure now has been used with several chemicals including 2-ethylhexanol, 3,4-dichlorobenzotrifluoride, cyclohexane, anilines, and 2,6-di *tertiary* butylphenol.

CMA has recently voiced concerns to EPA about how the procedure is working. CMA feels the procedure, as currently being implemented by EPA, does not offer enough opportunity for free exchange of ideas and exploration of options. EPA believes that issues, especially those relating to exposure to the subject chemicals, may need to be raised earlier in the discussion process to provide such flexibility. In response to these concerns, EPA will hold one or more public meetings to obtain views of interested parties on the implementation of the consent order negotiation process and ways to make it more effective.

Anyone wishing to participate in or be informed of these meetings should contact the TSCA Assistance Office as soon as possible. The first meeting will be held on November 20, 1986.

Dated: November 12, 1986.

Joseph J. Merenda,

Director, Existing Chemical Assessment Division.

[FR Doc. 86-25871 Filed 11-13-86; 8:45 am]
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