DATE: This rule becomes effective September 2, 1987.

FOR FURTHER INFORMATION CONTACT: For general information contact: the RCRA Hotline at (800) 424–9346 toll-free or (202) 382–3000. For information on specific aspects of this rule contact: Michael Petruska, Office of Solid Waste (WH–562B), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 475–6676.

SUPPLEMENTARY INFORMATION:

A. Final Rule

In the May 6, 1987 proposed rules on boilers and industrial furnaces, EPA proposed to amend existing regulations to state with absolute clarity that the scope of the listing of Hazardous Waste K062 applies to pickle liquor from steel finishing operations at facilities within the iron and steel industry (SIC Codes 331 and 332). When EPA first promulgated this amendment on May 28, 1986, the Agency erroneously described the scope of the listing as applying to plants that actually produce iron and steel. *See* 51 FR 19320. This error was inadvertent and obviously unintended given that EPA had never proposed such a change, and in the relevant preambles, the Agency repeatedly described its action as applying to all plants in the iron and steel industry (*See* 50 FR 36966 (column 1), 36967 (column 1), 36967 (column 2) (Sept. 10, 1985) and 51 FR 19320 (column 2), 19321 (column 1) (May 28, 1986)). In addition, if the listing was to apply only to facilities actually producing iron and steel, then the listing would be narrower than the accompanying exclusion from the subject listing *i.e.*, "waste pickle liquor sludge generated by lime stabilization of spent pickle liquor from the iron and steel industry (SIC Codes 331 and 332)" (§ 261.3(c)(2)(ii))—a facial contradiction since one cannot exclude more than one has listed.

For these reasons, on September 22, 1986, EPA corrected the error by means of a technical correction (see 51 FR 33612). One person questioned this change arguing that it was in fact substantive rulemaking requiring prior notice and comment. EPA does not agree, but proposed to amend the rule to remove any possible doubt. No commenters seriously contended that the listing should not apply to all pickle liquor generated by plants in the iron and steel industry. Accordingly, for all of the reasons stated in the preamble to the proposed rule, and in the earlier **Federal Register** notices there cited, EPA has determined to adopt a final rule stating that the listing applies to spent pickle liquor produced by any plant in the iron and steel industry.

B. Effective Date

RCRA section 3010(b) indicates that final regulations implementing the requirements of Subtitle C take effect 6 months from date of publication. The Agency may waive this requirement when it finds that the regulated community does not need that time to come into compliance. That is the case here, since existing regulations already contain the same language as today's rule, and, at the very least, EPA's consistent and longstanding interpretation is that the scope of the K062 listing applies to spent pickle liquor produced by any iron and steel industry plant. For these reasons, the six month effective date is unnecessary here.

Regulatory Impacts

A. Results of Regulatory Impact Studies

1. Executive Order 12291

As defined by Executive Order 12291, today's regulation is not a "major rule." Therefore, no Regulatory Impact Analysis (RIA) is required. This rule will not have an annual impact on the national economy greater than $100 million. In fact, EPA anticipates no impact at all because existing requirements are identical. In addition, this regulation will not significantly affect competition, employment, productivity or innovation.

This rule was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291.

2. Regulatory Flexibility Act

We have determined that today's rule will not have significant impact on a substantital number of small businesses and, therefore, that no Regulatory Flexibility Analysis (RFA) is required under the Regulatory Flexibility Act.

3. Paperwork Reduction Act

The requirements of the Paperwork Reduction Act of 1960 (PRA), 44 U.S.C. 3501 et seq., were considered in developing this regulation. We believe that the rule imposes no new reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 261

Hazardous material, Waste treatment and disposal, Recycling.

Dated: July 22, 1987.

Lee M. Thomas,

Administrator.

For the reasons set out in the Preamble, Title 40 of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for Part 261 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6922.

2. Section 261.32 is amended by revising the entry under the iron and steel industry for the hazardous waste listing K062 to read as follows:

§ 261.32 Hazardous wastes from specific sources.

* * * * *

Industry and EPA hazardous waste No.	Hazardous waste	Hazardous code
•	•	•
Iron and steel:		
K062	Spent pickle liquor generated by steel finishing operations of facilities within the iron and steel industry (SIC Codes 331 and 332).	(C,T)

[FR Doc. 87–17344 Filed 7–31–87; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Part 799

[OPTS–42087B; FRL–3241–4]

2-Ethylhexanol; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final 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-ethylhexanol (EH; CAS No. 104–76–7) to conduct a 2-year oncogenicity bioassay. This action follows EPA's proposed rule of December 19, 1986 (51 FR 45487).

DATES: In accordance with 40 CFR Part 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern daylight time on August 17, 1987. This rule shall become effective on September 16, 1987.

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 EH.

I. 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 (chemicals).

Under section 4 of TSCA, EPA must require testing of a chemical to develop health or environmental data if the Administrator makes certain findings as described in TSCA under section 4(a)(1)(A) or (B). (15 U.S.C. 2603(a)(1)(A) and (B)). A discussion of the statutory section 4 findings is provided in the Agency's first and second proposed test rules published in the **Federal Registers** of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

II. Regulatory History

In the **Federal Register** of December 19, 1986 (51 FR 45487), the Agency proposed to use the authority under section 4 of TSCA to require testing to obtain data needed to better assess the oncogenic potential of EH. As stated in the proposed rule, the Agency believes that the 2-ethylhexyl moiety, which occurs in EH and in other chemicals, may be an active carcinogenic agent to which people may be exposed. Refer to the EH proposed rule for additional discussion of EH's chemical profile, potential health hazard, exposure, and environmental release (51 FR 45487; December 19, 1986).

To obtain oncogenicity test data on EH as soon as possible, the Agency has limited its analysis of testing needs to oncogenicity testing. Once oncogenicity testing is underway, the Agency will evaluate available data including a recent section 8(e) submission (Ref. 24) to determine the need for additional testing and, if necessary, initiate a separate rulemaking to require such testing of EH.

Interested parties were solicited by the Agency for development of a testing consent order for EH (51 FR 28886; August 12, 1986). Plans for adopting a consent order were terminated because mutually agreeable terms could not be reached.

III. Response to Public Comments

The EH Panel of the Chemical Manufacturers Association (the Panel) submitted comments on the proposed test rule (Ref. 11). The public comment period for submitting written comments on the proposed rule closed on February 17, 1987. The Panel presented oral comments on the proposed test rule in a public meeting held in Washington, DC, on March 18, 1987 (Ref. 14). The following is a discussion of the Agency's response to the Panel's comments. No other public comments were received by EPA.

A. Health Effects

The Panel commented that the available scientific evidence does not support the section 4(a)(1)(A) finding for carcinogenicity. The Panel contends that EH is non-genotoxic and is a very weak peroxisome proliferator. In addition, the Panel contends there is growing evidence that a threshold level of exposure is necessary for peroxisome-related rodent liver tumors and that primates are markedly less susceptible than rodents to peroxisome proliferation.

EPA believes additional research is needed to establish the specific mechanism of action of EH carcinogenicity. Moreover, even if one assumes that EH is a very weak peroxisome proliferator, further research is needed to establish the nature of the relationship between peroxisome proliferation and carcinogenicity. Because of the limitations of the scientific data, EPA believes that it cannot justify assuming a specific mechanism of action for EH carcinogenicity at this time, including the presumption of a threshold.

EPA has reviewed readily available information on the genotoxicity of EH; but, because the case for EH oncogenicity testing is compelling, the Agency has decided to focus this rule on oncogenicity testing only. A full evaluation of the genotoxicity of EH and the need for additional genotoxicity testing may be completed after oncogenicity testing is underway. In any case, evidence of no genotoxicity does not negate a substance's carcinogenic potential, as there are non-genotoxic mechanisms of carcinogicity.

As stated in the EH proposed test rule, chemicals containing the ethylhexyl moiety have been shown to have carcinogenic potential. These chemicals are all expected to hydrolyze to EH; therefore, the Agency believes EH may also be a carcinogenic agent. Peroxisome proliferation is an additional piece of evidence to support this structure-activity based finding. Therefore, because there is strong evidence that chemicals containing the EH moiety are carcinogenic in rodents and because there is an absence of data on the potential carcinogenicity of EH, the Agency believes that oncogenicity testing of EH is warranted and indeed necessary to obtain data for determining if EH presents an unreasonable risk of cancer.

B. Testing Program for Peroxisome Proliferation

The Panel urges EPA to address testing needs for EH as part of a comprehensive testing program for structurally-related compounds with peroxisome-inducing potential. As an alternative to requiring that an oncogenicity bioassay be conducted on EH, the Panel proposed that testing should focus on obtaining a better understanding of the relationship between peroxisome proliferation of rodent liver tumors and the implications of these phenomena for human risk assessment. The Panel provided EPA with information on peroxisome proliferation in an attempt to support the Panel's belief that peroxisome proliferation is the mechanism of action for potential EH carcinogenicity, and that data on peroxisome proliferation should be the basis for prioritizing oncogenicity testing.

EPA believes the alternative testing program suggested by CMA is inappropriate (Refs. 21 and 22) and would unnecessarily delay oncogenicity testing for EH. As stated in Unit III.A. above, the Agency believes additional research is needed to establish the nature of the relationship between peroxisome proliferation and carcinogenicity. The Agency further believes the ethylhexyl moiety may be the proximate carcinogenic agent and that there is inadequate scientific justification to base the potential for EH oncogenicity solely on peroxisome proliferation. The Panel, however, is free to conduct research on peroxisome proliferation in conjunction with completing the bioassay on EH.

C. Exposure

The Panel believes the information used to evaluate exposure to EH is limited and largely out-of-date. The Panel plans to conduct a survey of EH producers and users to obtain current use and exposure information. The Panel requested that the rule be deferred until the results of the survey are available.

The Panel was informed of the information the Agency would use to evaluate exposure of EH in meetings held with the Panel since July 18, 1986. Only at the close of the comment period in February 1987 did the Panel decide to initiate a survey to collect more detailed use and exposure information. The best and most current information available to EPA indicates that production volume (635 million pounds per year) and potential exposure (11,550 to 45,000 workers) (Refs. 2, 3, 17, and 18) are

substantial. The Panel did not submit any exposure information which disputed these production or exposure figures. Moreover, even if this estimate is overstated, given its potential to be a carcinogen, the Agency's concern for the potential hazard of EH is high. When the hazard potential is believed to be serious, even a relatively low exposure to EH would warrant concern for testing under section 4(a)(1)(A) of TSCA (see 45 FR 48528 (July 18, 1980)). Therefore, EPA believes that a survey developed by the Panel would not alter the Agency's decision to finalize this rule. Thus, to delay testing to obtain such information is not in the public interest.

D. Test Species

The Panel believes a bioassay on EH should not be conducted in the B6C3F1 mouse. The Panel maintained that, because the mouse has a high incidence of spontaneous liver tumors, the Panel considers it a poor model for oncogenicity testing for EH. The Panel adds that there is a considerable body of data relating to peroxisome proliferation and tumor development in the rat, but very little data for the mouse.

EPA believes, based on National Toxicology Program (NTP) bioassay data for chemicals related to EH and on a recently published position paper by the NTP, there is a concern for liver tumor variability primarily in B6C3F1 males (Refs. 4 through 8, 19, and 20). However, in bioassays conducted on di(2-ethylhexyl) phthalate (DEHP), di(2-ethylhexyl) adipate (DEHA), and tris (2-ethylhexyl) phosphate (TEHP), upon which EPA based its (4)(a)(1)(A) findings for EH, a statistically significant increase in liver tumors occurred not only in male mice but also in female mice where the background incidence of liver tumors is low (Refs. 4 through 7). The Agency is aware that the male mice may have a variable rate of background liver tumors, and this will be considered with other evidence in estimating potential human risk from EH. NTP continually evaluates species used in NTP oncogenicity studies and, in a recent publication, NTP concluded that at the present time, even with the variable rate of background liver tumors in males, the B6C3F1 mouse is an acceptable species for oncogenicity studies (Ref. 19). Ethylhexyl-containing chemicals (DEHP, DEHA, TEHP, and sodium 2-ethylhexyl sulfate (EHS)) used in structure-activity analysis for EH were tested in the B6C3F1 mouse. More important, however, since the mouse appears more sensitive than the rat to these ethylhexyl-containing chemicals (Refs. 4 through 8), EPA considers the mouse appropriate for testing the potential cancer risk of EH.

As stated before, although the proliferation of peroxisomes may add to the weight of the evidence that a chemical may present risks of cancer, studies on peroxisome proliferation cannot provide data sufficient to evaluate the oncogenicity of a substance. Thus, although there may be more available data concerning peroxisome proliferation in the rat, these data as stated in Unit III.A. above do not negate the need for testing EH in two mammalian species, i.e., the mouse and the rat, in accordance with the EPA test guideline at 40 CFR 798.3300(b).

E. Route of Administration

The Panel believes that administering EH via microencapsulation, as EPA proposed, is unlikely to yield reliable and adequate data and that the Agency should require preliminary studies to determine the advantages of dermal, oral, and inhalation methods of administering EH before selecting the route for the chronic study.

This final test rule does not preclude administration by gavage provided that test sponsors validate the test methodology according to the TSCA Good Laboratory Practice Standards (40 CFR Part 792).

This final rule requires an oral route of administration so that the data can be compared with other data for EH and with data on related chemicals like EHA, DEHP, DEHA, TEH, and EHS.

NTP is completing studies evaluating the use of the microencapsulation methodology for administering EH.

To evaluate reports that EH may not be stable in dry feed (Ref. 16), the Panel initiated a detailed study using radiolabeled EH and several extraction techniques (Refs. 11, 12, and 13). The Panel has confirmed that EH is not stable in dry feed (Ref. 23). Thus, EH must be administered either by microencapsulation or by gavage.

F. Need for the EH Bioassay

The Panel believes that test data on DEHA are adequate to characterize the oncogenicity of EH since EH is a principal metabolite of DEHA.

EPA has several reasons for believing that using DEHA oncogenicity data (Ref. 5) as a surrogate for data on EH is inadequate. The DEHA oncogenicity data are insufficient to determine if the response is due to the intact DEHA molecule, DEHA partially metabolized to the monoester and EH, or EH itself. DEHA was only positive in the mouse, but EH could be positive in the mouse and the rat as was DEHP. Therefore, the Agency believes the dose-response data from the DEHA bioassay are not appropriate for assessing risk from exposure to EH. Furthermore, EPA believes the use of structure-activity relationship data is appropriate when no other bioassay data is available or attainable on a chemical. However, in the case of EH, the relevant bioassay data can be obtained because the evidence supports section 4(a)(1) (A) and (B) findings and thus a requirement to conduct testing.

G. Reporting Deadline

The Panel commented that the 53-month reporting requirement is unrealistic. They believe that, given the nature of the studies proposed, to validate the bioavailability of EH administered by microencapsulation and subsequent dietary incorporation would require extensive preliminary studies. Based on the time required for the additional testing, as well as the bioassay, the Panel has estimated that final test results cannot be reported in less than 105 to 109 months.

EPA believes that because the NTP is completing validation studies on microencapsulation of EH, and because the Panel has completed studies of the stability of EH in dry feed, validation will have been initiated before the rule becomes effective. Therefore, at this time, the additional time requested by the Panel to perform the validation studies will not be necessary. From experience with other bioassays and NTP's experience with microencapsulation, the Agency believes that 53 months provides adequate time to conduct the study by gavage and 56 months provides adequate time to conduct the study by microencapsulation.

H. Economic Impact

The Panel believes the Agency neglected to account for the cost of preliminary pharmacokinetic studies and additional dose groups needed to validate microencapsulation and interpret the bioassay results when developing cost estimates for the bioassay.

The Agency believes that for industry to repeat the preliminary studies being completed by NTP to validate administration of EH by microencapsulation is unnecessary. In addition, $140,000 to $250,000 have been included in the Agency's cost estimate to account for additional costs from microencapsulation procedures (Ref. 2). The additional dose groups proposed by the Panel may not be necessary because the capsule material will represent a small part of the animal's diet.

Furthermore, if industry chooses to conduct this testing by gavage, costs should be less.

Refer to Unit VI. in the proposed EH rule (51 FR 45490; December 19, 1986) and to the economic impact analysis (Ref. 2) for a more detailed discussion of the economic impact of this rule.

I. Manufacturers

Alcolac was listed in the proposed EH rule as a manufacturer of EH. Alcolac informed the Agency that it does not manufacture or import EH and has no plans to do either in the future (Ref. 15). Thus, it would not be subject to this test rule unless it begins any such activities.

IV. Final Test Rule for EH

A. Findings

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

1. Under section 4(a)(1)(A)(i), EPA finds that the manufacture, processing, distribution in commerce, use, and disposal of EH may present an unreasonable risk of injury to human health because of its potential to cause carcinogenic effects. The finding for potential carcinogenicity is based on studies conducted on other chemicals containing the ethylhexyl moiety which suggest that EH may possess a carcinogenic hazard. See Unit II.B. of the proposed rule for a more complete discussion of carcinogenicity hazard potential.

In addition, data available to EPA indicate that more than 635 million pounds of EH is produced annually for intermediate uses and for merchant sale, and that an estimated 11,550 to 45,000 workers are potentially exposed to EH during its manufacture, processing, distribution, and use. Potential for consumer and general population exposure also exists through use and disposal (Refs. 1, 2, 3, 17, and 18).

2. Under section 4(a)(1)(B)(i), EPA finds that EH is produced in substantial quantities and that there is or may be substantial human exposure from its manufacture, processing, use, and disposal. As stated above, approximately 635 million pounds of EH are produced annually, and 11,550 to 45,000 workers in 62 occupations are estimated to have actual exposure to EH or products containing EH (Refs. 1, 2, 3, 17, and 18). EH is used as an intermediate for the manufacture of acrylates, phthalates, and the octyl ester of 2,4-dichlorophenoxyacetic acid (Ref. 2). It may also be used in several other industrial processes and uses, and there is potential for consumer and general population exposure (Ref. 1, 25, 26, and 27).

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

4. Under sections 4(a)(1) (A)(iii) and (B)(iii), EPA finds that testing EH for oncogenicity is necessary to develop such data. EPA believes that the data resulting from this test rule will be relevant to a determination as to whether the manufacture, distribution in commerce, processing, use, and disposal of EH presents an unreasonable risk of injury to human health.

B. Required Testing

On the basis of these findings, the Agency is requiring oncogenicity testing of EH. Data from these bioassays in rats and mice will assist the Agency in conducting risk assessments for EH and thus will be of critical importance in determining whether EH presents an unreasonable risk of cancer.

The Agency is requiring the oncogenicity testing to be conducted on EH in accordance with the TSCA test guidelines for oncogenicity specified in 40 CFR 798.3300, published in the **Federal Register** of September 27, 1985 (50 FP 39252) and modified in the **Federal Register** of May 20, 1987 (52 FR 19056). EPA proposed these revisions to the guidelines in the **Federal Register** of January 14, 1986 (51 FR 1522), and responded to comments on the proposed revisions in the record for that rulemaking (Ref. 10).

The testing required in this final rule shall be performed with the Fisher 344 rat and B6C3F1 mouse. These species and strains have demonstrated sensitivity to other ethylhexyl compounds. The route of exposure shall be oral. Based upon experience at NTP (Ref. 9), the EH can be microencapsulated in the diet or administered by gavage. A subchronic study should be conducted using the same exposure method as selected for the lifetime bioassay to determine dose levels and characterize target organ effects for the bioassay.

C. Test Substance

The test substance shall be 2-ethylhexanol (EH; CAS No. 104-76-7) of at least 99-percent purity, which is a commercially available grade.

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 assess the health risks from the manufacture, processing, distribution, use, and disposal of EH, EPA is requiring that persons who manufacture or process, or intend to manufacture or process, EH at any time from the effective date of this final test rule to the end of the reimbursement period are subject to the oncogenicity testing requirements contained in this final rule. While EPA has not identified any byproduct manufacturers of EH, such persons are covered by the requirements of this rule. The end of the reimbursement period will be 5 years after the last final report is submitted for EH, 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 this 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 this 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 EH. EPA is interested in evaluating the effects attributable to EH and, as noted in Unit IV.C. above, 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 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 the start of each test.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is requiring that the oncogenicity testing shall be completed and the final report submitted to EPA within 53 months of the effective date of this test rule if EH is administered by gavage. However, if EH is administered by microencapsulation, the final report is to be submitted within 56 months of the effective date of this rule. Progress reports are required at 6-month intervals beginning 6 months from the effective date of the rule.

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; December 16, 1980). In brief, as of the effective date of this test rule, an exporter of EH must report to EPA the first annual export or intended export of EH to each country. EPA will notify the foreign country concerning the test rule for the chemical. Export of EH in any amount or at any concentration, including as an impurity, if known to the exporter, is subject to the section 12(b) reporting requirement.

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 this final rule for EH. These inspections may be conducted for purposes which include verification that testing has begun, schedules are being met, and reports accurately reflect the underlying raw data, interpretations, and evaluations to determine compliance with TSCA GLP standards and the test standards established in this 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 ensure 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 provisions 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)). Knowing and willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator, as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

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

V. Economic Analysis

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (Ref. 2) that evaluates the potential for significant economic impact on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of EH: price sensitivity of demand, industry cost characteristics, industry structure, and market expectations. Because there was

no indication of adverse effect, no further economic analysis was performed; however, had the first level of analysis indicated a potential for significant economic impact, a more comprehensive and detailed analysis would have been conducted to more precisely predict the magnitude and distribution of the expected impact.

Total testing costs for the final rule are estimated to range from $881,000 to $1,198,200. To better evaluate the impact on financial decisionmaking of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period in order to finance the testing expenditure in the first year.

The annualized costs range from $96,700 to $131,600. In calculating these annualized costs, EPA has utilized a 7 percent real (i.e., net of inflation) cost of capital and a 15-year cost recovery period. An analysis of publicly available financial data on the chemical industry has led EPA to the determination that 7 percent represents an appropriate measure of the real, after-tax cost of capital for this industry.

Based on the 1984 production volume for EH of 635 million pounds, the unit test costs will be about 0.02 cent per pound. In relation to the selling price of 32 cents per pound of EH, these costs are equivalent to 0.06 percent of price. Based on these costs, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is extremely low.

Refer to the economic analysis for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs (Ref. 2).

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 (Ref. A.(3)). 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 (docket number OPTS-42087B). This record includes basic information considered by the Agency in developing this rule and appropriate **Federal Register** notices.

This record includes the following information:

A. Supporting Documentation

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

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

(b) Notice of interim final rule on procedures governing Testing Consent Agreements and Test Rules and Exemption Procedures (51 FR 23706; June 30, 1986).

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

(d) Toxic Substances Control Act Test Guidelines; Final Rule, 40 CFR Parts 796, 797, and 798, (50 FR 39252; September 27, 1985).

(e) Revisions to the Toxic Substances Control Act Test Guidelines; Final Rule (52 FR 19056; May 20, 1987).

(f) Notice of Proposed Test Rule for 2-Ethylhexanoic Acid (50 FR 20678; May 17, 1985).

(g) Notice of Proposed Test Rule for 2-Ethylhexanol (51 FR 45487; December 19, 1986).

(h) Notice of Final Rule for 2-Ethylhexanoic Acid (51 FR 40318; November 6, 1986).

(i) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(2) Communications concerning the rule including contact reports of telephone conversations, and public comments.

(3) U.S. Environmental Protection Agency (USEPA). Chemical Testing Industry Profile of Toxicological Testing. Development Planning and Research Associates, Inc. and ICF Incorporated. Contract number 68-01-6064 and Task 7, Contract No. 68-01-6287. (October, 1981).

B. References

(1) National Toxicology Program (NTP). "Summary of Data for Chemical Selection" prepared for The National Cancer Institute by SRI International. Contract No. NOI-CP-95607 9/80 (Rev. April 1981).

(2) U.S. Environmental Protection Agency (USEPA). Economic Impact Analysis of Final Test Rule for 2-Ethylhexanol. Mathtech, Inc. Contract number 68-02-4235. Office of Pesticides and Toxic Substances. Washington, DC (March 20, 1987).

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

(4) U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health (USDHHS; PHS; NIH). Carcinogenesis Bioassay of Di (2-ethylhexyl) phthalate (CAS No. 117-81-7) in F344 Rats and B6C3F1 Mice (Feeding Study). NTP Technical Report Series No. 217.

(5) USDHHS; PHS; NIH. Carcinogenesis Bioassay of Di (2-ethylhexyl) Adipate (CAS No. 103-23-1) in F344 Rats and B6C3Fl Mice (Feed Study). NTP Technical Report Series No. 212.

(6) USDHHS; PHS; NIH. Carcinogenesis Bioassay of Sodium 2-Ethylhexyl Sulfate (CAS No. 126-92-1) in F344/N Rats and B6C3F1 Mice (Feed Study). Draft NTP Technical Report. Prepared for the Board of Scientific Counselors. (September 2, 1982).

(7) USDHHS; PHS; NIH. NTP Technical Report on the Toxicity and Carcinogenicity of Tris (2-ethylhexyl) Phosphate (CAS No. 78-42-2) in F344/N Rats and B6C3F1 Mice (Gavage Study). Draft NTP Technical Report. (September 8, 1983).

(8) USDHHS; PHS; NIH. Memorandum with Attachment from W. Kluwe to 12 Addressees. Attachment: Comparative Chronic Toxicities and Carcinogenic Potentials of Four 2-Ethyhexyl-containing Compounds in Rats and Mice (December 19, 1983).

(9) NTP, National Institute of Environmental and Health Sciences. Microencapsulation Report 2-Ethyl-1-hexanol—Conformance of Microencapsulated Chemical to Specifications. Midwest Research Institute. NIEHS Contract No. Nol-ES-45060. (July 3, 1986).

(10) USEPA. Response to Public Comments, Proposed Revision of TSCA Test Guidelines (51 FR 1522; January 14, 1986), see the **Federal Register** of May 20, 1987 (52 FR 19056).

(11) Chemical Manufacturers Association (CMA). Comments of the 2-Ethylhexanol Panel of the Chemical Manufacturers Association on EPA's Proposed Test Rule for 2-Ethylhexanol, Washington, DC (February 17, 1987).

(12) CMA. Letter from Geraldine V. Cox, Vice President-Technical Director, CMA, to Charles L. Elkins, Director, Office of Toxic Substances, USEPA, Extension of Comment Period on 2-EH Test Rule Proposal. Washington, DC (February 10, 1987).

(13) CMA. Letter from Geraldine V. Cox, Vice President-Technical Director, CMA, to Gary E. Timm, Chief, Test

Rules Development Branch, USEPA, re: Issues for Discussion at 2-Ethylhexanol Public Meeting. Washington, DC (March 13, 1987).

(14) USEPA. Transcript of Proceedings From the Public Meeting to Present Oral Comments on 2-Ethylhexanol; Proposed Test Rule. Washington, DC (March 19, 1987).

(15) Alcolac. Letter from Daniel Greenfield, Director: TSCA Compliance, Alcolac, to the TSCA Public Information Office, USEPA, Washington, DC (April 15, 1987).

(16) NTP. National Institute of Environmental and Health Sciences. Standard analysis new Report, Chemical Characterization and Dosage Formulation Studies for 2-Ethylhexanol. Midwest Research Institute. NIEHS contract No. Nol-ES-45060. (October 4, 1985).

(17) National Institute for Occupational Safety and Health (NIOSH). National Occupational Hazard Survey Data Base (NOHS), USDHHS, Washington, DC. Computer printout. (May 31, 1985).

(18) NIOSH. National Occupational Exposure Survey Data Base (NOES). USDHHS, Washington, DC. Computer printout. (June 4, 1985).

(19) NTP. Maronpot, R.R. "Liver lesions in B6C3Fl Mice: The National Toxicity Program, Experience and Position." Research Triangle Park, NC (1987).

(20) NTP. Haseman, J. K. "Comparative Results of 327 Chemical Carcinogenicity Studies." Research Triangle Park, NC (May 30, 1987, in press).

(21) NTP. Letter from Ronald L. Melnick, to Frank Benenati, Office of Toxic Substances, USEPA, Washington DC (October 3, 1986).

(22) USEPA. Memorandum re: Ethylhexanol test program, from Carl Baetcke, Health and Environmental Review Division, to Frank Benenati, Office of Toxic Substances, USEPA, Washington, DC (October 3, 1986).

(23) CMA. Letter from Geraldine V. Cox, Vice President-Technical Director, CMA, to John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, USEPA, re: route of administration for 2-EH Bioassay. Washington, DC (June 2, 1987).

(24) Shell Oil Company. Hansen, R.E., letter to the USEPA Re: 2-Ethylhexanol-Teratogenic Effects. (May 14, 1987).

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

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

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

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 Rm., NE-G004, 401 M St., 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. enterprises 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 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

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 control number 2070–0033.

List of Subjects in 40 CFR Part 799

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

Dated: July 27, 1987.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, Chapter I of Title 40, Part 799, of the Code of Federal Regulations is amended as follows:

PART 799—[AMENDED]

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

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

2. By adding new § 799.1645 to read as follows:

§ 799.1645 2-Ethylhexanol.

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

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

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

(c) *Health effects*—(1) *Oncogenic effects*— (i) *Required testing.* (A) Oncogenicity tests shall be conducted in Fisher 344 rats and B6C3Fl mice by the oral route with 2-ethylhexanol in accordance with § 798.3300 of this chapter, except for the provisions in § 798.3300(b)(6).

(B) For the purpose of this section, the following provisions also apply to the oncogenicity tests: (*1*) *Administration of the test substance.* 2-Ethylhexanol shall be administered either by microencapsulation before adding it to the diet or by gavage.

(*2*) [Reserved]

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

(B) The oncogenicity testing shall be completed and final report submitted to the Agency within 53 months of the effective date of this final rule if 2-ethylhexanol is administered by gavage or within 56 months of the effective date of this final rule if administered by microencapsulation.

(C) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(2) [Reserved]

(d) *Effective date.* The effective date of this final rule requiring oncogenicity testing of 2-ethylhexanol is September 16, 1987.

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

[FR Doc. 87-17514 Filed 7-31-87; 8:45 am]

BILLING CODE 6560-50-M

COMMISSION ON THE BICENTENNIAL OF THE UNITED STATES CONSTITUTION

45 CFR Part 2002

Regulations on Donations; Technical Amendments

AGENCY: Commission on the Bicentennial of the United States Constitution.

ACTION: Final rule.

SUMMARY: This notice announces amendments made by the Commission on the Bicentennial of the United States Constitution to the Regulations on Donations which were published as an Interim Rule on January 24, 1986 [51 FR 3173] and adopted as a Final Rule on August 7, 1986 [51 FR 28384]. The enactment of Pub. L. 99-549, 100 Stat. 3063, signed by the President on October 27, 1986, requires these amendments in order to implement the actions of Congress and conform the Commission's existing regulations with the new authority granted by Congress. The effect of these amendments is to raise the contribution ceilings for individuals and corporations.

EFFECTIVE DATE: August 3, 1987.

FOR FURTHER INFORMATION CONTACT: Joseph B. McGrath, General Counsel, Commission on the Bicentennial of the United States Constitution, 736 Jackson Place, NW., Washington, DC 20503; telephone: (202) 275-9178.

SUPPLEMENTARY INFORMATION: These amendments are required and approved in order to implement changes made by Pub. L. 99-549, 100 Stat. 3063, to the statute which created the Commission, Pub. L. 98-101, 97 Stat. 719. The new law, among other things, raised the annual limits on individual and corporate contributions to the Commission. The limit on annual contributions was raised from $25,000 to $250,000 for individual donors and from $100,000 to $1,000,000 for corporate and other business organization donors.

Paperwork Reduction Act: There are no information collection requirements subject to the Paperwork Reduction Act of 1980.

List of Subjects in 45 CFR Part 2002

Donations, U.S. Constitution Bicentennial.

Issued in Washington, DC, on July 28, 1987.

Mark W. Cannon,

Staff Director.

PART 2002—[AMENDED]

1. The authority citation for Part 2002 is revised to read as follows:

Authority: Section 5(h)(3) of Pub. L. 98-101; 97 Stat. 719; as amended by Pub. L. 99-549, 100 Stat. 3063; 5 U.S.C. 552.

§ 2002.21 [Amended]

2. Section 2002.21 is amended as follows:

a. Paragraph (a) is amended by inserting "as amended", after "97 Stat. 721,".

b. Paragraph (a)(1) is amended by striking "$25,000" and inserting in lieu thereof "$250,000".

c. Paragraph (a)(2) is amended by striking "$100,000" and inserting in lieu thereof "$1,000,000".

§ 2002.22 [Amended]

3. Section 2002.22 is amended as follows:

a. Paragraph (b) is amended by striking "$100,000" and inserting in lieu thereof "$1,000,000".

[FR Doc. 87-17483 Filed 7-31-87; 8:45 am]

BILLING CODE 6340-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 86-29; RM-4941]

Radio Broadcasting Services; Greenup, KY

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 289B1 for Channel 288A at Greenup, Kentucky and modifies the license of Station WLGC-FM, Greenup to specify the new channel at the request of Greenup County Broadcasting, Inc. A counterproposal to allot the channel to Athens, Ohio is denied. With this action the proceeding is terminated.

EFFECTIVE DATE: September 4, 1987.

FOR FURTHER INFORMATION CONTACT: D. David Weston, Mass Media Bureau (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 86-30, adopted July 9, 1987, and released July 20, 1987. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments is amended by substituting Channel 289B1 for Channel 288A at the entry for Greenup Kentucky.

Federal Communications Commission.

Bradley P. Holmes,

Chief, Policy and Rules Division Mass Media Bureau.

[FR Doc. 87-17550 Filed 7-31-87; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF DEFENSE

48 CFR Parts 204, 215, 230, and 253

Department of Defense Federal Acquisition Regulation Supplement; DoD Profit Policy

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Defense Acquisition Regulatory Council has approved revisions to Subparts 204.6, 215.9, 230.70 and 253.3 of the DoD FAR Supplement with respect to profit policy.

EFFECTIVE DATE: August 1, 1987.