

January 6, 1989, the Office of Management and Budget waived Tables Two and Three SIP revisions (54 FR 222) from the requirements of section 3 of Executive Order 12291 for a period of 2 years.

Under 5 U.S.C. 605(b), I certify that disapproving this redesignation will not have a significant economic impact on a number of small entities because it imposes no new requirements on anyone. (See 46 FR 8709).

List of Subjects in 40 CFR Part 81

Air pollution control, Environmental protection, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401-7642.

Dated: February 20, 1990.

Frank M. Covington,
Acting Regional Administrator.

[FR Doc. 90-12124 Filed 5-23-90; 8:45 am]

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40 CFR Parts 795 and 799

[OPTS-42111; FRL 3712-5]

Office of Drinking Water Chemicals; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a test rule, under section 4 of the Toxic Substances Control Act (TSCA), that would require manufacturers and processors to test five substances for certain health effects. Oral 14-day repeated dose and oral 90-day subchronic toxicity studies would be performed for each of the following substances: Chloroethane (CAS No. 75-00-3); 1,1-dichloroethane (CAS No. 75-34-3); 1,1,2,2-tetrachloroethane (CAS No. 79-34-5); *n*-propylbenzene (CAS No. 103-65-1); and 1,3,5-trimethylbenzene (CAS No. 108-67-8). This notice also proposes for comment a new testing guideline for a 14-day repeated dose oral toxicity study. This proposed rule supports EPA's effort to develop Health Advisories for unregulated drinking water contaminants that are monitored under section 1445 of the Safe Drinking Water Act (SDWA).

DATES: Submit written comments on or before July 23, 1990. EPA will hold a public meeting on this rule in Washington, DC if persons request an opportunity to submit oral comments by July 9, 1990. For further information on arranging to speak at the meeting, see Unit VII. of this preamble.

ADDRESSES: Submit written comments, identified by the docket number (OPTS-42111), in triplicate to: TSCA Public Docket Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

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

FOR FURTHER INFORMATION CONTACT:

Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543B, 401 M St., SW., Washington, DC 20460, 202-554-1404, TDD: 202-554-0551.

SUPPLEMENTARY INFORMATION: EPA is proposing a test rule under section 4(a) of TSCA to obtain health effects data for five substances that have been identified as potential drinking water contaminants.

I. Introduction

A. Background

EPA's Office of Drinking Water (ODW) needs oral subacute and subchronic health effects data on certain substances to support its efforts to develop Health Advisories (HAs) for unregulated drinking water contaminants. To obtain the needed data, EPA is proposing a TSCA section 4 test rule on the following five substances:

Substances	CAS No.
Chloroethane	75-00-3
1,1-Dichloroethane	75-34-3
1,1,2,2-Tetrachloroethane	79-34-5
<i>n</i> -Propylbenzene	103-65-1
1,3,5-Trimethylbenzene	108-67-8

ODW will use the health effects data developed by this rule to calculate 1-Day, 10-Day, Longer-Term, and Lifetime HAs for these substances. EPA (Ref. 1) discusses how ODW uses health effects data to develop HAs.

B. Test Rule Development Under TSCA

Under section 4(a) of TSCA, EPA shall, by rule, require testing of a chemical substance or mixture (chemical) to develop appropriate test data if the Administrator makes certain findings as described in TSCA under section 4(a)(1)(A) or (B). Detailed discussions of the statutory section 4 findings are provided in EPA's first and

second proposed test rules which were published in the Federal Register of July 18, 1980 (45 FR 48510) and June 5, 1981 (46 FR 30300).

In evaluating the testing needs for these five substances, EPA considered all available published and unpublished information on the production volume, exposure, and toxicity of these substances. From its evaluation of these data, EPA is proposing specific health effects testing for the five substances under TSCA section 4(a)(1)(B).

C. Overview of the Safe Drinking Water Act

The Safe Drinking Water Act of 1974, as amended in 1986, requires EPA to regulate substances that may cause adverse human health effects and are known or anticipated to occur in drinking water. EPA, under section 1445 of the SDWA, requires public water systems to monitor for a list of unregulated drinking water contaminants at least once every 5 years, unless otherwise specified by EPA. EPA will use the monitoring data and available toxicity data to determine whether these contaminants should be regulated in drinking water. A list of contaminants and final monitoring requirements was promulgated July 8, 1987 (52 FR 25709).

In addition to the monitoring requirements for the unregulated contaminants, EPA has begun developing HAs for these substances. HAs provide guidance to Federal, State, and Local officials responsible for protecting health after chemical spills or contaminations. HA levels represent concentrations of the contaminant in drinking water that would not be expected to result in an adverse health effect for 1-day, 10-day, longer-term, or lifetime human exposures based on data describing noncarcinogenic endpoints of toxicity. HAs are established for substances with no national regulations. HAs also provide information on the analytical methods and treatment technologies for drinking water contaminants. In developing a HA, oral studies using an exposure duration comparable to the HA exposure duration, are conducted on the most sensitive animal species or the species with metabolism similar to man. Studies using other routes of exposure have been used in the absence of oral data but often do not accurately reflect the toxicity resulting from oral exposure. Testing is needed since HAs are meant to tell individuals the health effects associated with the substance and the

concentration of the contaminant that is not expected to cause an adverse effect after the various periods of exposure. Based on the results of these health effects studies and the previously mentioned monitoring studies, EPA may propose more health effects testing under another test rule.

II. TSCA Section 4(a) Findings

The proposed health effects testing is based on the authority of section 4(a)(1)(B) of TSCA. EPA finds that: These five substances are produced in substantial quantities; there may be substantial human exposure to these substances; there are insufficient data and experience to determine or predict the effects on human health from disposal of these substances; and testing is necessary to develop these data.

1. *Subject substances are produced in substantial quantities.* All of the substances subject to this proposed test rule are listed on the TSCA Section 4(b) Inventory. Manufacturers have submitted information on recent production volumes of these substances but have claimed this information as Confidential Business Information (CBI). EPA has reviewed these data and has found that the current reported production volume of each substance is substantial.

2. *There may be substantial human exposure to the substances.* EPA believes there may be significant potential for exposure to these chemical substances for humans via drinking water. All five substances have been identified and quantified in soil, ground water and/or surface water samples from numerous locations throughout the

United States (Refs. 2 and 3). The five contaminants have been reported present in or near disposal sites: chloroethane in 17 states; *n*-propylbenzene in 10 states; 1,1-dichloroethane in 24 states; 1,1,2,2-tetrachloroethane in 25 states; and 1,3,5-trimethylbenzene in 7 states (Ref. 3). These data may also indicate a larger problem since they represent only a portion of the hazardous waste sites in the U.S.; not all hazardous waste sites have been sampled. Monitoring data (the number of samples, levels of contaminant in water, and number of affected sites) are summarized in the following tables.

Information on ground water contamination for these five chemical substances as reported in the Hazardous Waste Disposal Site Database is summarized in Table 1:

TABLE 1— SUMMARY OF CHEMICAL CONCENTRATIONS (µg/L) in Ground Water Samples As Reported in the Hazardous Waste Disposal Site Data Bases

Chemical	Samples		Contaminant levels		Sites	
	Total No.	Percent positive ¹	Range (µg/L)	Mean (µg/L)	Total No.	Percent positive ²
Chloroethane.....	10,275	0	3.0 to 521,000	2,638	251	24
1,1-Dichloroethane.....	13,523	15	0.95 to 970,000	2,833	254	43
1,1,2,2-Tetrachloroethane.....	12,817	?	6.3 to 1,390,000	23,337	255	10 ³
<i>n</i> -Propylbenzene.....	NA ³	NA ³	NA ³	NA ³	NA ³	NA ³
1,3,5-Trimethylbenzene.....	11	82	NA ⁴	NA ⁴	1	100

¹ Samples: percent positive includes samples in which the contaminant was positively identified and may include samples where the level of contamination was not measured.
² Site: percent positive is the number of sites with detections of the contaminant in ground water.
³ No information available.
⁴ Detections were not quantified.

Information on ground water contamination for these five chemical substances as reported in the Contract Laboratory Program statistical Database 1980-1983 version is summarized in Table 2:

TABLE 2— SUMMARY OF CHEMICAL CONCENTRATIONS (µg/L) in Ground Water and Surface Water Samples as Reported in CLP1 Databases

Chemical	Positive sites ²	Chemical levels		Samples with levels known ³	Additional detections ⁴
		Mean (µg/L)	Range (µg/L)		
Chloroethane ⁵	31	151	5.3 - 1505	29	8
1,1-Dichloroethane ⁵	72	167	3.3 - 3480	65	40
1,1,2,2-Tetrachloroethane ⁵	28	2785	3.0 - 23800	18	22
<i>n</i> -Propylbenzene ⁵	2	52	1 - 102	2	0
1,3,5-Trimethylbenzene.....	1	NA ⁶	NA ⁶	NA ⁶	1

¹ Contract Laboratory Program Statistical Data Base 1980-1983 Version (Ref. 3).
² Positive sites is the number of sites with the chemical including both quantified and unquantified detections.
³ At certain sites multiple samples were obtained.
⁴ Additional detections include only those samples in which the substances were positively identified but not quantified.
⁵ Medians were 24, 14, 232, and 52 µg/L, respectively.
⁶ Detections were not quantified.

Information on ground water contamination for these five chemicals as reported in the Analytical Results and Quality Database, Diskette Version is summarized in Table 3:

TABLE 3—SUMMARY OF CHEMICAL CONCENTRATIONS ($\mu\text{g/L}$) in Ground Water and Surface Water Samples as Reported in ARQ Database¹

Chemical	Positive sites ²	Chemical levels		Samples with levels known ³	Additional detections ⁴
		Mean ($\mu\text{g/L}$)	Range ($\mu\text{g/L}$)		
Chloroethane ⁵	34	231	3.7 - 3800	59	83
1,1-Dichloroethane ⁶	89	514	1.0 - 9700	214	181
1,1,2,2-Tetrachloroethane	11	NA ⁷	NA ⁷	NA ⁷	59
<i>n</i> -Propylbenzene	NA ⁷	NA ⁷	NA ⁷	NA ⁷	NA ⁷
1,3,5-Trimethylbenzene ⁸	1	290	100 - 400	2	0

¹ Analytical Results and Quality Data Base, Diskette Version (Ref. 3).

² Positive sites is the number of sites with the chemical including both quantified and unquantified detections.

³ At certain sites multiple samples were obtained.

⁴ Additional detections include only those samples in which the substances were positively identified but not quantified.

⁵ Medians were 32, 31, and 290 $\mu\text{g/L}$, respectively.

⁶ Detections were not quantified.

⁷ No information available.

Information on ground water contamination for these five chemicals

as reported in the Analytical Results

and Quality Database, Diskette Version is summarized in Table 4:

TABLE 4—SUMMARY OF CHEMICAL CONCENTRATIONS ($\mu\text{g/L}$) in Ground Water and Surface Water Samples as Reported in ARQ Database¹

Chemical	Positive sites ²	Chemical levels		Samples with levels known ³	Additional detections ⁴
		Mean ($\mu\text{g/l}$)	Range ($\mu\text{g/l}$)		
Chloroethane	NA ⁵	NA ⁵	NA ⁵	NA ⁵	NA ⁵
1,1-Dichloroethane ⁶	6	35	1 to 141	30	0
1,1,2,2-Tetrachloroethane ⁶	2	263	2 to 400	8	0
<i>n</i> -Propylbenzene	NA ⁵	NA ⁵	NA ⁵	NA ⁵	NA ⁵
1,3,5-Trimethylbenzene	NA ⁵	NA ⁵	NA ⁵	NA ⁵	NA ⁵

¹ Analytical Results and Quality Assurance Data Base, Focus Version (Ref. 3).

² Positive sites is the number of sites with the chemical including both quantified and unquantified detections.

³ At certain sites multiple samples were obtained.

⁴ Additional detections include only those samples in which the substances were positively identified but not quantified.

⁵ No available information.

⁶ Medians were 29 and 300 $\mu\text{g/L}$, respectively.

In addition to these quantitative data, *n*-propyl-benzene and 1,3,5-trimethylbenzene are also suspected contaminants at an additional nine and six sites, respectively (Ref. 3). The Safe Drinking Water Hotline at EPA has also received inquiries about health effects resulting from ingestion of these two substances. The data in tables 1 through 4 are from hazardous waste disposal sites, many of which have qualified for the National Priorities List (NPL). Ranking of facilities nationally for remedial action is based primarily on the migration score from the Hazardous Ranking System (HRS) (Ref. 8). This migration score is calculated by ranking of factors for three routes: ground water, surface water and air. The population potentially affected, water use, and distance to well or water intake, are considered during scoring. Route characteristics that are known to contribute to migration of contaminants; characteristics of the waste such as quantity, toxicity and persistence are also factored into the ranking. EPA believes that potential for substantial human exposure exists since many of

these sites were chosen out of concern for the potential for contamination of water sources used for drinking water. In addition, many hazardous waste sites are located in highly populated areas. Therefore, EPA believes a substantial number of people may potentially be exposed to these substances.

Additional exposure data for trimethylbenzene, propylbenzene and chloroethane are expected from monitoring drinking water for chemicals listed under section 1445 of the SDWA. Some of these data have been submitted but have not been evaluated. The available exposure data indicate the need to propose testing for these substances. However, EPA encourages the submission of additional data.

3. *Insufficient data to determine or predict.* One substance, 1,3,5-trimethylbenzene, has been the subject of a previous TSCA section 4 rule requiring health effects testing. EPA published a final rule on May 17, 1985 (50 FR 20662), requiring mutagenicity, developmental toxicity, neurotoxicity, reproductive effects, and oncogenicity (if triggered) testing of a mixture of five

commercial C9 solvents containing a minimum of 15 percent trimethylbenzenes. These tests provided sufficient data on the subchronic effects of C9 solvent mixtures. However, the subchronic tests were done by inhalation and did not use pure 1,3,5-trimethylbenzene. ODW has determined that these inhalation data on the mixture are not adequate to determine reliable HAs for drinking water exposures to this substance; subchronic data on the pure substance from an oral route of exposure are needed.

EPA has performed a search of the published literature and health effects data bases for the five substances in this proposed rule. The search focused on locating any oral subacute and subchronic toxicity data.

EPA did not locate any oral 14-day subacute or 90-day subchronic toxicity test data for chloroethane or 1,3,5-trimethylbenzene. Although 2-year carcinogenicity bioassays in rats and mice via gavage have been performed with 1,1-dichloroethane, and 1,1,2,2-tetrachloroethane (Refs. 4 and 5), EPA

has determined that the resulting data are inadequate for estimating reliable 10-Day, Longer-Term, and Lifetime HAs. The subchronic range-finding studies for these bioassays were only 6 weeks long and did not include histopathology. In the rat bioassays, there were also dose-related mortalities that may have been a result of chronic pneumonia, making these test results questionable.

While Gohlke et al. (Ref. 6) observed degeneration in several organs of rats at doses of 3.2 and 8 mg/kg/day 1,1,2,2-tetrachloroethane for 120 days, NCI (Ref. 5) observed no "treatment related" histopathology in rats at doses ranging from 43 to 108 mg/kg/day for 78 weeks. The results of the Gohlke and the NCI studies are not in agreement and neither is considered adequate for risk assessment.

A 6-month feeding study in rabbits was performed with *n*-propylbenzene (Ref. 7), but insufficient data were reported from this study to adequately determine the toxicity of *n*-propylbenzene.

Therefore, under section 4(a)(1)(B)(ii) of TSCA, EPA has determined that for each substance examined, there are insufficient data upon which the effects from disposal of the substance and migration into drinking water resources on human health can reasonably be determined or predicted. Environmental release may also occur from the manufacturing and processing of these substances. However, to expedite rulemaking, EPA did not consider the amount of these substances released during these activities. Rather EPA has found the available health effects data inadequate to assess the effects from disposal of these substances. Since both manufacturers and processors distribute and dispose of these substances, both are subject to the rule (see Unit III. C. of this preamble). EPA encourages the submission of any available data equivalent to the testing proposed in this rule.

4. Testing is necessary and relevant. EPA believes that oral, repeated-dose subacute and subchronic testing of the subject substances is necessary in order to determine or predict the effects these substances may have on human health as a result of drinking water exposures. Testing for other endpoints (i.e. mutagenicity, neurotoxicity, reproductive effects, developmental toxicity, and oncogenicity) might also be necessary but in order to expedite this rulemaking and obtain the minimal data for establishing HAs EPA had decided to defer consideration of these endpoints until receipt of data from these tests and monitoring data under section 1415 of the SDWA of 1974. EPA

needs these data to establish HAs for each of the substances. Therefore, EPA finds under section 4(a)(1)(B)(iii) of TSCA that the testing of the substances included in this proposed rule is needed, and believes that the proposed health effects studies are capable of developing the necessary information. EPA further believes that the data generated from this testing will be relevant in determining whether the disposal of these five substances does or does not present an unreasonable risk of injury to human health.

5. They may reasonably be anticipated to enter the environment in substantial quantities. In addition to the finding for substantial human exposure, EPA may make a finding that these substances may reasonably be anticipated to enter the environment in substantial quantities. The Toxic Release Inventory (TRI) compiled under section 313 of the Emergency Planning and Community Right-to-Know Act (Ref. 9) lists releases of chloroethane and 1,1,2,2-tetrachloroethane during manufacturing, processing and use. The TRI reports that in 1987 over 4 million pounds of chloroethane were released to air. The TRI data demonstrate that there is substantial release of chloroethane to the environment during manufacture and processing; however, the data for 1,1,2,2-tetrachloroethane show less release during these activities. EPA believes that substantial release of all five substances occurs from disposal of these substances, especially as spent solvents, but such information is not reported for TRI. EPA is soliciting information that will better characterize the extent of release to the environment for all five substances, especially for 1,1-dichloroethane, 1,1,2,2-tetrachloroethane, *n*-propylbenzene, and 1,3,5-trimethylbenzene.

III. Proposed Rule

A. Proposed Testing and Test Standards

On the basis of the findings given in Unit II. of this preamble, EPA is proposing health effects testing for the substances included in this proposed rule (see Unit I.A. of this preamble). A 14-day oral subacute and a 90-day oral subchronic study are proposed for each substance. The studies are to be conducted in accordance with EPA's TSCA Good Laboratory Practice Standards in 40 CFR part 792 and the specific TSCA test guidelines as enumerated in 40 CFR parts 795 and 798, as amended in this proposed rule.

EPA is proposing that these five substances undergo subacute testing according to the EPA-developed guideline at 40 CFR 798.207 and

subchronic testing using the TSCA Test Guideline at 40 CFR 798.2650. The studies should be performed using drinking water as the route of exposure. If this route is not feasible, the substances may be administered by gavage, in the diet, or in capsules. The tests will be performed with two species, preferably a rodent and a non-rodent to help determine the most sensitive species and most meaningful endpoint of toxicity.

EPA is proposing that the above-referenced health effects test guidelines, and any modifications to these guidelines, be the test standards for testing these substances.

B. Test Substance

EPA is proposing that each of the five substances tested be at least 99 percent pure. EPA has specified relatively pure substances for testing because it is interested in evaluating the effects attributable to the chemicals themselves. This requirement lessens the likelihood that any effects seen are due to impurities or additives.

C. Persons Required to Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which EPA makes section 4(a) findings (manufacture, processing, distribution in commerce, use, and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing, which includes importing and production of these substances as a byproduct ("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 causing 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 disposal of the substances subject to this test rule, EPA is proposing that persons who manufacture, import, and/or process (including inadvertent, byproduct manufacture as defined in 40 CFR 791.3), or who intend to manufacture or process these substances at any time from the effective date of the final test rule to the end of the reimbursement period, be subject to the testing requirements in this proposed rule. The end of the reimbursement period will be 5 years after the last final report is submitted, or an amount of time equal to that which was required to develop the data, whichever is longer.

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D. Repo

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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 this 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. EPA 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 agree to perform all the required tests, processors will be granted conditional exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, EPA will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR part 790.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for the substances subject to this proposed test rule. As noted in Unit III.B. of this preamble, EPA is interested in evaluating the effects attributable to each of the substances themselves and has specified almost pure substances for testing.

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

D. Reporting Requirements

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

In accordance with 40 CFR part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 45 days prior to the 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. EPA is proposing specific reporting requirements for each of the proposed test standards as follows:

1. The 14-day, repeated-dose, subacute toxicity study on each substance shall be completed and the final report submitted to EPA within 12 months of the effective date of the final test rule. A progress report shall be submitted 6 months after the effective date of the final test rule.
2. The 90-day subchronic toxicity study on each substance shall be completed and the final report submitted to EPA within 15 months of the effective date of the final test rule. A progress report on this test shall be submitted 9 months from the effective date of the final test rule.

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

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

E. Enforcement Provisions

EPA 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: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by TSCA or any regulation or rule issued under TSCA.

Also 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 substances are manufactured, processed, stored, or held before or after their distribution in commerce. EPA

considers a testing facility to be a place where the substance is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits may be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated EPA representatives to determine compliance with the final rule for these substances. 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 that there has been compliance with TSCA GLP Standards and the test standards established in the rule.

EPA's authority to inspect a test 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 to include other requirements as 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 provisions 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 \$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 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 EPA has notified them of their obligation to submit such documents (see 40 CFR 790.48(h)). Knowing and willful violations could lead to the imposition of criminal penalties of up to \$25,000 for each day of violation, imprisonment for up to 1 year, or both. 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. At its discretion, EPA may proceed against individuals as well as companies. 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.

IV. Issues For Comment

1. The proposed 14-day repeated dose oral toxicity test guideline is a new guideline developed by EPA. EPA requests comments on the ability of this proposed guideline to identify short-term adverse health effects relative to other test guidelines (e.g. acute and subchronic). These data are used to determine the risk of adverse health effects from short-term exposure to contaminants in drinking water which may be experienced following a chemical spill.

2. The available exposure and lack of adequate toxicity data for these five substances led EPA to propose testing for them. Before promulgating final rules for these proposed requirements, however, EPA is seeking additional information on exposure and oral toxicity of these substances. Such information may cause EPA to alter its decision on the need for testing of one or more of these substances.

The available data as presented in this notice for *n*-propylbenzene and 1,3,5-trimethylbenzene, while legally sufficient to support this proposed test rule, are less supportive than those available for 1,1-dichloroethane, 1,1,2,2-tetrachloroethane, and chloroethane. However, EPA believes the frequency of requests for health effects information on these two substances indicates additional areas of potential exposure and supports including them in this proposal. EPA especially encourages the submission of additional exposure information on these two chemicals. EPA may defer promulgation of the testing requirements for these two substances until and if supported by the monitoring data being developed under section 1445 of the SDWA.

3. EPA requests that interested parties submit information which will allow EPA to better characterize the impact of the testing requirements on these substances, especially on 1,3,5-trimethylbenzene. This information includes production volumes (including import volumes), prices, uses, production processes, substitutes, and market characteristics. In its economic impact analysis, the only price

information EPA had on 1,3,5-trimethylbenzene was from a specialty chemical supplier. These suppliers usually charge more for their substances than the normal market price. Upon receipt of comments, EPA will reevaluate the potential for significant economic impact of this testing on industry.

V. Economic Analysis of Proposed Rule

To assess the potential economic impact of this rule, EPA has prepared an economic impact analysis (contained in the public docket for this rule) that evaluates the potential for significant economic impact of this testing on industry. The economic analysis estimates the costs of conducting the required testing for each of the five substances and evaluates the potential for significant adverse economic impact as a result of those costs. The analysis incorporates an impact measure based upon unit test cost as a percent of price. When there is no indication of adverse effect for a particular substance, EPA will not perform any further economic analyses. However, if the cost of testing a particular substance indicates a potential for significant economic impact, EPA will conduct a more detailed analysis to more precisely predict the magnitude of the expected impact.

The total testing cost for each of the five substances is estimated to range from \$396,130 to \$579,590. 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 7 percent cost of capital over 15 years, range from \$43,493 to \$63,636. Given the current and anticipated future production levels of these five substances, EPA believes the probability of adverse economic impact for four substances is low, while for one substance, 1,3,5-trimethylbenzene, it may be high.

In the preparation of the economic impact analysis for the final rule, EPA will address any comments received from the public concerning the economic impact of this rule on individual substances.

Refer to the economic impact 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. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing" PB-82-140773, can be obtained for a fee through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA, 22161. A microfiche copy of this study is also included in the docket for this rule and is available to the public for copying. On the basis of this study, EPA believes that there will be available test facilities and personnel to perform the testing specified in this proposed rule.

VII. Public Meetings

If persons inform EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting soon after the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (202-554-1404; TDD: 202-554-0551) by July 9, 1990. A meeting will not be held unless members of the public indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arrange to present comments and to designated EPA participants. Attendees should call the TSCA Assistance Office before making travel plans to verify whether a meeting will be held.

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

VIII. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-42111). This record contains the information EPA considered in developing this proposal and appropriate Federal Register notices and includes:

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 consent order and test rule development 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) Notice of final rule on health effects testing of the C9 aromatic hydrocarbon fraction (50 FR 20662; May 17, 1985).

(2) Support documents consisting of:

(a) Economic impact analysis of NPRM for the substances contained in this proposed rule.

(b) Safe Drinking Water Act, as amended in 1986 (42 U.S.C. 300f).

(3) TSCA testing guideline § 795.2650, Oral toxicity (subchronic exposure).

(4) Reports - published and unpublished factual materials including "Chemical Testing Industry: Profile of Toxicological Testing."

B. References

(1) U.S. Environmental Protection Agency (USEPA), Office of Drinking Water Health Advisories, "Reviews of Environmental Contamination and Toxicology." Ed. G. W. Ware, Vol. 104: pp.1-8, (1988).

(2) Plumb, R. H. Lockheed Engineering and Management Services Company, Las Vegas, Nevada 89119. Computer printouts and letter to S. J. Ellis, Test Rules Development Branch, U.S. Environmental Protection Agency, Washington DC 20460. (June 9, 1986).

(3) Eckel, W. Contract Laboratory Program Sample Management Office, U.S. Environmental Protection Agency, Alexandria VA. 22313. Computer printouts and letter to J. Fisk, Analytical Operations Branch, U.S. Environmental Protection Agency, Washington, DC 20460. (June 21, 1988).

(4) National Cancer Institute (NCI). "Bioassay of 1,1-dichloroethane for possible carcinogenicity." NCI/National Toxicology Program (NTP) TR066. Department of Health Education and Welfare (DHEW) Pub. No. National Institutes of Health (NIH) 78-1318. (1978).

(5) NCI. "Bioassay of 1,1,2,2-tetrachloroethane for possible carcinogenicity." NCI-CG-TR-27. DHEW Pub. No. (NIH) 78-827. (1978).

(6) Gohlke, R., P. Schmidt, and H. Bahmann. "1,1,2,2-Tetrachloroethane and heat stress in animal experiment - morphological results." *Z. Gesamte Hyg.* 278-282. (German), (1977).

(7) Gerarde, H. W. and D.B. Ahlstrom. "Toxicologic studies on hydrocarbons. XI. Influence of dose on the metabolism of monon-alkyl derivative of benzene." *Toxicology and Applied Pharmacology*. 9:185-190. (1966).

(8) U.S. Environmental Protection Agency (USEPA): Office of Solid Waste and

Emergency Remediation (OSWER).

"Uncontrolled Hazardous Waste Site Ranking System: a Users Manual". OSWER directive 9355.0-3. (Originally published in the Federal Register on July 16, 1982).

(9) U.S. Environmental Protection Agency (USEPA). Toxic Release Inventory System computer printout for chloroethane and 1,1,2,2-tetrachloroethane. (April 6, 1989).

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.

IX. Other Regulatory Requirements**A. Executive Order 12291**

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

This proposed rule 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 few small manufacturing firms will be subject to this rule, and in those cases in which small firms will be subject, the testing costs for those firms will be relatively low. Since manufacturers and processors only bear test costs proportionate to their market shares, the relatively larger manufacturers would pay a relatively larger share of the test costs. Also, the testing costs for each substance are not high, no more than \$500,000.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this proposed rule under the provisions of

the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned an OMB control number of 2070-0033.

Public reporting burden for this collection of information is estimated to average 1083 hours per respondent, including time for: Searching existing data sources; submitting letters of intent or exemption requests; preparing study plans, progress reports and final reports; laboratory testing; and sponsor review. Send comments regarding the reporting burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC, 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

List of Subjects in 40 CFR Parts 795 and 799

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

Dated: May 16, 1990.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended as follows:

PART 795—[AMENDED]**1. In part 795:**

a. The authority citation for part 795 is revised to read as follows:

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

b. By adding § 795.257 to subpart D to read as follows:

§ 795.257 Repeated dose, oral.

(a) *Purpose.* To assess and evaluate the toxic characteristics of a substance, the determination of subacute toxicity should be carried out after initial information on toxicity has been obtained by acute testing. The 14-day repeated dose oral study provides information on the health hazard likely to arise from repeated short-term exposure by the oral route over a very limited period of time. It has been designed to permit the determination of the no-observed-adverse-effect level and toxic effects associated with continuous or repeated exposure to a

test substance for 14 days and to evaluate reversibility, persistence, and delayed occurrence of toxic effects during a 14-day follow-up recovery period. The test is not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life shortening). It will provide information on target organs and the possibility of accumulation, and can be used in selecting dose levels for subchronic studies and for establishing criteria for human exposure.

(b) *Definitions.* (1) Subacute oral toxicity is the manifestation of adverse effect(s) occurring as a result of the repeated daily exposure of experimental animals to a substance by the oral route for 14 days.

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

(3) No-observed-adverse-effect level (NOAEL) is the maximum dose used in a test which produces no observed adverse effects. A NOAEL 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 NOAEL is expressed as mg/kg of food or 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 14 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, except the satellite group, are necropsied and histopathological examinations are carried out. The satellite group is necropsied after the 14-day recovery period.

(d) *Limit test.* If a test at one dose level of at least 1,000 mg/kg body weight (expected human exposure may indicate the need for a higher dose level), using the procedures described for this study, produces no observable toxic effects and if toxicity would not be expected based upon data from structurally related compounds, then a full study at five dose levels is not necessary.

(e) *Test procedures—(1) Animal selection—(i) Species and strain.* Two mammalian species shall be tested, preferably a rodent and a non-rodent, but two rodents may be used. A variety of rodent species may be used, but the rat is preferred. If a second rodent is selected, the mouse should be used. Commonly used laboratory strains shall be used.

(ii) *Age.* (A) *General.* 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) *Rodents.* Dosing shall begin as soon as possible after weaning, ideally before the rats are 6 weeks old, and in any case, not more than 8 weeks old.

(C) *Non-rodent.* Dosing shall commence after acclimatization.

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

(B) The females shall be nulliparous and nonpregnant.

(iv) *Numbers.*—(A) *Rodents.* At least 20 animals (10 females and 10 males) shall be used at each dose level.

(B) *Non-rodents.* At least eight animals (four females and four males) shall be used at each dose level.

(C) If interim sacrifices are planned, the number shall be increased by the number of animals scheduled to be sacrificed.

(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.* (Rodent only) A satellite group of 20 animals (10 animals per sex) shall be treated with the high dose level for 14 days and observed for reversibility, persistence, and delayed occurrence of toxic effects for a post-treatment recovery period of at least 14 days.

(4) *Dose levels and dose selection.* (i) In subacute toxicity tests, it is desirable to have a dose response relationship as well as a NOAEL. Therefore, at least 5 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 shall be spaced appropriately to produce test groups with a range of toxic effects. The data should be sufficient to produce a dose-response curve.

(ii) The highest dose level in rodents should result in toxic effects but not produce an incidence of fatalities which would prevent a meaningful evaluation of the test results; for non-rodents, there should be no fatalities.

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

(iv) Ideally, the intermediate dose levels should produce minimal observable toxic effects. The dose levels should be spaced to produce a gradation of toxic effects.

(5) *Exposure conditions.* The animals are dosed with the test substance every day for 14 days.

(6) *Observation period.* (i) All animals shall be observed daily during the 14-day exposure period.

(ii) Animals in the satellite group scheduled for follow-up observations shall be kept for at least 14 days further without treatment to detect recovery from, or persistence of, and delayed onset of toxic effects and shall be observed daily.

(7) *Administration of the test substance.* (i) The test substance should be administered in drinking water. If this is not feasible, the test substance may be administered by gavage, in the diet, or in capsules.

(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 drinking water, by gavage, in the diet, or in capsules, 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 in the final test report.

(v) For a substance administered by gavage or capsule, the dose shall be given at approximately the same time each day, and adjusted on day 7 to

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maintain a constant dose level in terms of animal body weight.

(8) *Observation of animals.* (i) Each animal shall be observed daily and, if necessary, handled to appraise its physical condition.

(ii) Additional daily observations may be necessary in order to take appropriate actions to minimize loss of animals to the study (e.g., necropsy or refrigeration of those animals found dead and isolation of weak animals). Moribund animals shall be removed and sacrificed when noticed.

(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 at least weekly of feed consumption or water consumption when the test substance is administered in the feed or drinking water, respectively.

(vi) Animals shall be weighed at least weekly.

(vii) At the end of the 14-day exposure period, all survivors except those in the satellite group shall be necropsied. All survivors in the satellite group shall be necropsied after a recovery period of at least 14 days.

(9) *Clinical examinations.* (i) The following examinations shall be made on all animals of each sex in each treatment group and satellite group for rodents, and on all animals when non-rodents are used.

(A) Certain-hematology determinations shall be carried out at least two times during the test period: just prior to initiation of dosing if adequate historical baseline data are not available (baseline data) and just prior to terminal sacrifice at the end of the test period. Hematology determinations which are appropriate to all studies are: Hematocrit, hemoglobin concentration, erythrocyte count, total and differential leukocyte count, and a measure of clotting potential such as clotting time, prothrombin time, thromboplastin time, or platelet count.

(B) Certain clinical biochemistry determinations on blood shall be carried out at least two times: just prior to initiation of dosing (if adequate historical baseline data are not available) and just prior to terminal sacrifice at the end of the test period. Test areas which are considered appropriate to all studies: Electrolyte balance, carbohydrate metabolism, and liver and kidney function. The selection

of specific tests will be influenced by observations on the mode of action of the substance. Suggested determinations: Calcium, phosphorus, chloride, sodium, potassium, fasting glucose (with the period of fasting appropriate to the species), 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, albumin, 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 of observed effects.

(ii) The following examinations shall be made on high dose and control groups. If changes in the eyes are detected, the eyes of all animals should be examined.

(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.

(B) Urinalysis is not recommended on a routine basis, 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 as soon as possible after death or sacrifice, 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, and gonads shall be weighed wet, as soon as possible after dissection to avoid drying. In addition, for the rodent, the brain; for the non-rodent, the thyroid with parathyroids also shall be weighed wet.

(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; lungs - which should be removed intact, weighed and treated with a suitable fixative to ensure that lung structure is maintained (perfusion with the fixative is considered to be an effective procedure); nasopharyngeal tissues; brain - including sections of medulla/pons, cerebellar cortex, and cerebral cortex; pituitary; thyroid/parathyroid; thymus; trachea; heart; sternum with

bone marrow; salivary glands; liver; spleen; kidneys; adrenals; pancreas; gonads; uterus; accessory genital organs (epididymis, prostate, and, if present, seminal vesicles); aorta; (skin); gall bladder (if present); 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 (zygomatic and exorbital lachrymal glands).

(11) *Histopathology.* The following histopathology shall be performed:

(i) Full histopathology on the organs and tissues listed in paragraph (e)(10)(iii) of this section of all rodents in the control and high dose groups, all nonrodents, and all rodents that died or were sacrificed during the study.

(ii) All gross lesions in all animals.

(iii) Target organs in all animals.

(iv) The tissues mentioned in parentheses in paragraph (e)(10)(iii) of this section if indicated by signs of toxicity or target organ involvement.

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

(vi) Histopathology shall be performed on tissues and organs from animals in the satellite groups (rodents) identified as showing effects in the treated groups.

(f) *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 types of lesions, and the percentage of animals displaying each type of lesion.

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

(2) *Evaluation of the study results.* (i) The findings of a subacute 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 will 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. A properly conducted subacute test should provide a satisfactory estimation of a NOAEL.

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

(3) *Test report.* In addition to the reporting requirements as specified under 40 CFR part 792, subpart J, the following specific information shall be reported.

(i) *Group animal data.* Tabulation of toxic response data by 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) Date of death during the study or whether animals survived to termination.

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

(C) Body weight data.

(D) Feed 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.

(g) *References.* For additional background information on this test guideline, the following references should be consulted:

(1) Boyd, E. M. "Chapter 14—Pilot Studies, 15—Uniposal Clinical Parameters, 16—Uniposal Autopsy Parameters." *Predictive Toxicometrics*. (Baltimore: Williams and Wilkins, 1972).

(2) Fitzhugh, O. G. "Subacute Toxicity," *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics*. The Association of Food and Drug Officials of the United States, pp. 26-35. (1959, 3rd Printing 1975).

(3) Food Safety Council. "Subchronic Toxicity Studies," *Proposed System for Food Safety Assessment*. (Columbia: Food Safety Council) pp. 83-96. (1978).

(4) National Academy of Sciences. "Principles and Procedures for Evaluating the Toxicity of Household Chemicals." A report prepared by the Committee for the Revision of NAS Publication 1138, under the auspices of the Committee on Toxicology, National Research Council, National Academy of Sciences, Washington, DC (1977).

(5) World Health Organization. "Part I. Environmental Health Criteria 6," *Principles and Methods for Evaluating the Toxicity of Chemicals*. (Geneva: World Health Organization, 1978).

PART 799—[AMENDED]

2. In part 799:

a. The authority citation would continue to read as follows:

Authority: 16 U.S.C. 200a, 2001, 2025.

b. By adding § 799.5075 to subpart D to read as follows:

§ 799.5075 *Drinking water contaminants subject to testing.*

(a) *Identification of test substances.*

(1) The following substances identified as drinking water contaminants shall be tested in accordance with the requirements under paragraphs (c) and (d) of this section:

Substance Name	CAS No.
Chloroethane	75-00-3
1,1-Dichloroethane	75-34-3
1,1,2,2-Tetrachloroethane	79-34-5
n-Propylbenzene	103-65-1
1,3,5-Trimethylbenzene	109-67-6

(2) Chloroethane, 1,1-dichloroethane, 1,1,2,2-tetrachloroethane, n-propylbenzene, and 1,3,5-trimethylbenzene of at least 99 percent purity shall be used as the test substances.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import and by-product manufacture) or process the substances listed in paragraph (a) of this section after the effective date of this rule to the end of the reimbursement period shall submit letters of intent to test, submit study plans, conduct tests, and submit data, or submit exemption applications as specified in this section, subpart A of this part, and parts 790 and 792 of this chapter for singlephase rulemaking.

(c) *Health effects testing—(1) Subacute toxicity—(i) Required testing.* Oral 14-day repeated dose toxicity tests shall be conducted with each of the substances designated in paragraph (a) of this section in accordance with § 795.257 of this chapter. The tests should be performed using drinking water. However, if due to poor stability or palatability, a drinking water test is not feasible for a given substance, that substance shall be administered by oral gavage, in the diet, or in capsules.

(ii) *Reporting requirements.* (A) Each

subacute test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

(B) For each test, a progress report shall be submitted to EPA 6 months after the effective date of the final rule.

(2) *Subchronic toxicity—(i) Required testing.* Oral 90-day subchronic toxicity tests shall be conducted with each of the substances designated in paragraph (a) of this section in accordance with § 795.2650 of this chapter. Each substance shall be tested in two species, preferably a rodent and non-rodent. If, due to poor stability or palatability, a drinking water test is not feasible for a given substance, that substance shall be administered by oral gavage, in the diet, or in capsules.

(ii) *Guideline modifications.* (A) A satellite group of test organisms shall be included in all tests using rodents in order to observe reversibility, persistence, and delayed toxicity.

(B) At least five dose groups shall be employed in each test.

(iii) *Reporting requirements.* (A) Each subchronic test shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) For each test, a progress report shall be submitted to EPA 9 months after the effective date of the final rule.

(d) *Effective date.* (1) This rule will be effective 44 days after the date of publication of the final rule in the Federal Register.

(2) The guidelines and other test methods cited in this section are referenced as they exist on the effective date of the final rule.

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

[FR Doc. 90-12125 Filed 5-23-90; 8:45 am]
BILLING CODE 6950-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 90-228, RM-7293]

Radio Broadcasting Services;
Healdsburg, CA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed on behalf