VI. Other Regulatory Requirements

A. Executive Order 12291

As explained in the proposal published in the **Federal Register** of October 3, 1991 (56 FR 50190), EPA determined, pursuant to the requirements of E.O. 12291, that the revocation of the food additive tolerance is not a major regulatory action, 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. The Agency's best judgment is that the total impact of this rule may be as high as $50 million per year.

This rule has been reviewed by the Office of Management and Budget (OMB) as required under section 3 of E.O. 12291.

B. Regulatory Flexibility Act

This rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96-354; 94 Stat. 1164, 5 U.S.C. 601 et seq.), and EPA has determined that it will have a minor economic impact on a small number of small businesses, small governments, or small organizations. The reasons for this conclusion are discussed in the October 3, 1991, proposal.

The Delaney Clause does not give EPA the authority to consider economic impact. Accordingly, I certify that this rule does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

C. Paperwork Reduction Act

This regulatory action does not contain any information collection requirements subject to review by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

VII. References for OVP

All references cited in section of this preamble are available for viewing in the Office of Pesticide Program's Public Docket under control number 260053C. The docket is located in Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, telephone: 703-305-5805. The docket is open from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

Copies of the references without an associated Master Record Identification (MRID) number are available to any person, regardless of affiliation. Disclosure of the references identified by an MRID number are subject to the limitations imposed by section 10 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Visitors are required to sign an "Affirmation of Non-multinational Status" form prior to viewing any references identified by an MRID number.

Copies of the references also are available by writing to: Freedom of Information Office (A101), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Disclosure of the references under the Freedom of Information Act are subject to the same limitations as outlined above.

References

1. Two-year Gavage Study of Dichlorvos in F344 Rats (Southern Research Institute, Study No. 05049, May 23, 1983, sponsored by the National Toxicology Program), PWG Report, May 30, 1986. MRID 006019.

2. Haseman et al., JNCI 75:975-984, 1985.

3. See EPA, Office of Pesticide Programs, "4th Peer Review of Dichlorvos" (9/18/89). PWG Dichlorvos Two Year B6C3F1 Mouse Corn Oil Gavage Study. (Southern Research Institute; Study Numbers: 05049 Test 02. NTP C# 00113B, May 23, 1983; sponsored by National Toxicology Program) PWG May 14, 1986. NTP Technical Report No. 342, "A Review of the Interpretation of the NTP Toxicology and Carcinogenesis Studies of Dichlorvos," June 30, 1988, by John H. Mennear, Ph.D., Professor of Toxicology, Campbell University, Buies Creek, North Carolina.

4. The transcript of the NTP panel of experts meeting of July 14, 1987.

5. See Memorandum, from Judith Hauswirth to George La Rocca, EPA, Office of Pesticide Programs, "First Peer Review of Dichlorvos (DDVP)" (Sept. 25, 1987).

6. Same as item 5 of these references.

List of Subjects in 40 CFR Part 185

Environmental protection, Administrative practice and procedure, Agricultural commodities, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 22, 1993.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 185 is amended as follows:

PART 185—[AMENDED]

1. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

2. By revising § 185.1900 to read as follows:

§ 185.1900 2,2-Dichlorovinyl dimethyl phosphate.

A tolerance that expires on March 10, 1994, is established as follows: The food additive 2,2-dichlorovinyl dimethyl phosphate may be present as a residue from application as an insecticide on packaged or bagged nonperishable processed food (see: 21 CFR 170.3(j)) in an amount in such food not in excess of 0.5 part per million (ppm). To assure safe use of the insecticide, its label and labeling shall conform to the label and labeling registered by the U.S.Environmental Protection Agency, and the usage employed shall conform to such label and labeling.

[FR Doc. 93-27607 Filed 11-9-93; 8:45 am]

BILLING CODE 6560-50-F

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40 CFR Part 799

[OPPTS-42111C; FRL 4047-2]

RIN 2070-AB94

Office of Water Chemicals; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: EPA is issuing a final rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring manufacturers and processors to test four chemical substances for certain health effects. Oral 14-day repeated dose and oral 90-day subchronic toxicity studies are required 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); and 1,3,5-trimethylbenzene (CAS No. 108-67-8). This rule also supports EPA's effort to develop Health Advisories (HAs) for unregulated drinking water contaminants that are monitored under section 1445 of the Safe Drinking Water Act (SDWA). The proposed rule which was published on May 24, 1990 was referred to as the Office of Drinking Water Chemicals proposed test rule.

DATES: This rule shall become effective on December 27, 1993. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern daylight time on November 24, 1993.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (MFT-7408), Office of Pollution

Prevention and Toxics, Rm. E–543B, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD: (202) 544–0551.

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA to require health effects testing of four chemical substances that have been identified as drinking water contaminants by the Office of Water. EPA is not requiring testing under section 4(a)(1)(B) for health effects testing of *n*-propylbenzene (CAS No. 103–65–1) because production is not substantial at this time. The required subacute and subchronic test guidelines were proposed under parts 795 and 798, respectively. EPA, however, has decided to require the same subacute testing according to a guideline under part 798 with modifications.

I. Introduction

A. Test Rule Development Under TSCA

This final rule is part of the overall implementation of section 4 of TSCA, 15 U.S.C. 2601 et seq., which contains authority for EPA to require the development of data relevant to assessing the risk to health and the environment posed by exposure to particular chemical substances or mixtures (chemicals).

Under section 4(a) 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). 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). Additional discussion of the TSCA section 4(a)(1)(B) finding can be found in the final statement of policy which articulates the criteria for making that finding (58 FR 28736, May 14, 1993).

B. Background

On May 24, 1990 (55 FR 21393), EPA proposed oral subacute and subchronic health effects testing under TSCA section 4(a)(1)(B) for the following chemicals:

Chemical name	CAS No.	Docket No.
chloroethane	75–00–3	42111C/42162
1,1-dichloroethane	75–34–3	42111C/42163
1,1,2,2-tetrachloroethane	79–34–5	42111C/42164
n-propylbenzene	103–65–1	42111C/42161
1,3,5-trimethylbenzene	108–67–8	42111C/42165

In evaluating the testing needs for these five substances, EPA considered available published and unpublished information on the production volume, exposure, and toxicity of these substances. The proposed testing was intended to support the efforts of EPA's Office of Water (OW) in developing Health Advisories (HAs) for these substances. The subacute and subchronic tests were proposed to be conducted according to TSCA guidelines under 40 CFR 795.257 and 798.2650; however, EPA has decided that because the provisions of the subacute and subchronic test guidelines are essentially identical except for the exposure period, EPA is requiring both tests to be conducted according to § 798.2650 except for modifications for the subacute test which will specify a shorter exposure period and in other ways make it comparable to the proposed 14–day guideline. EPA has decided not to issue the 14–day subacute test guideline, proposed under § 795.257, as a separate guideline. This decision was an outgrowth of EPA's effort to harmonize its testing guidelines with those of the Organization of Economic Cooperation and Development (OECD) and EPA's decision to eliminate the annual publication of testing guidelines in the Code of Federal Regulations. For ease of discussing the comments received on the proposed 14–day guideline, this guideline will be referenced using the same section number under which it was proposed, i.e. § 795.257.

The Safe Drinking Water Act (SDWA) of 1974, as amended in 1986, provides for the regulation of substances that may cause adverse human health effects and that are known or anticipated to occur in drinking water. Under section 1445 of the SDWA, public water systems are to monitor for a list of unregulated drinking water contaminants, including the substances in this rule. Recently, EPA announced the availability of monitoring data for these substances from nine states (AL, FL, IN, MA, MI, NE, PA, RI and WV). These data showed that chloroethane was present in drinking water in four of the nine states; 1,1-dichloroethane in six of the nine states; 1,1,2,2,-tetrachloroethane in five of the nine; *n*-propylbenzene in two of the nine; and 1,3,5-tri[illegible]hylbenzene in three of the nine (Re[illegible]. These d[illegible] confirm that these chemicals are [illegible]nt in drinking water. EPA made the data available for public comment on April 20, 1992 (57 FR 14371) and is using these data to further support its exposure finding in this action. Other monitoring data also showed the presence in drinking water of the five substances in this rule (Ref. 10). These data had not been available when the proposed rule was being developed and were presented in a later notice for public comment on July 15, 1991 (56 FR 32292).

In addition to the monitoring requirements in the SDWA for unregulated contaminants, EPA develops HAs for some of them, as well as for some regulated contaminants. HA levels provide guidance to Federal, State, and local officials responsible for protecting health after chemical spills. HA levels suggest acceptable concentrations of the chemical in drinking water; levels 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, and, where available, data on carcinogenicity. In developing a HA, oral studies in one or more species are used in which the exposure duration is comparable to the HA exposure duration. HAs are intended to inform public health officials of the potential health effects associated with a chemical, as well as the concentration of the chemical that is not expected to cause an adverse effect after exposure of various durations.

II. Public Comment

Comments in response to the proposed test rule for the Office of Drinking Water chemicals were received from the Chemical Manufacturers Association (CMA)(Ref. 1), Dow Chemical Company (Refs. 2 and 3), Eastman Kodak Company (Ref. 4), Halogenated Solvents Industry Alliance (HSIA)(Ref. 5), Monsanto Company (Ref. 6), Shell Oil Company (Ref. 7), Vista Chemical Company (Ref. 8), and Vulcan Chemicals (Ref. 9). No comments were received in response to the notice presenting drinking water monitoring data on July 15, 1991 (56 FR 32292). Comments in response to the notice

announcing the availability of drinking water data on April 20, 1992 (57 FR 14371), were received from Koch Chemical Company (Koch) (Ref. 32), the American Water Works Association (AWWA) (Ref. 33), and the Association of Metropolitan Water Agencies (AMWA) (Ref. 34). These comments and EPA's responses to them are summarized below.

1. *Testing advocated.* The AWWA (Ref. 33) commended EPA in its use of TSCA and data from the SDWA to protect drinking water supplies by requiring testing for development of HAs. The AWWA believes this information is critical for the protection of human health. The AMWA (Ref. 34) commented that it strongly supports the development of national drinking water standards for contaminants which pose a threat to public health and occur in drinking water. AMWA also commented that the drinking water data support the section 4 findings and that it is appropriate to require testing for acute, subacute, and chronic health effects including neurotoxicity and developmental toxicity. The AMWA stated that it strongly supports such testing to help insure the protection of drinking water supplies and public health.

2. *Justification for short-term HAs.* Monsanto Company (Ref. 6) commented that EPA has not provided sufficient justification or rationale for the establishment of HAs, particularly 1–day, 10–day, and Longer-term HAs, in the proposed test rule or in the reference on drinking water health advisories (Ref. 40).

EPA disagrees. In the introduction to the proposed test rule, EPA stated that the HAs are needed to provide guidance to Federal, State, and local officials who are responsible for protecting health after chemical spills or contaminations have occurred. Moreover, this rule does not establish any HAs. HA levels suggest concentrations of a chemical 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 (55 FR 21393, May 24, 1990). Although described as an unlikely scenario by Monsanto, EPA knows chemical spills may result in transient contamination of drinking water supplies for which short-term exposure criteria are more appropriate than are the usually more stringent chronic-exposure criteria. In fact, there have been numerous instances of drinking water supplies (both ground and surface water) being contaminated as a result of chemical spills and accidents and also some cases where the inlet to drinking water supplies has been shut off because of chemical spills in rivers, e.g., Potomac River (Refs. 41–44) and Ohio River (Refs. 45 and 46). In such instances EPA has provided guidance on the hazards of substances detected in drinking water (Ref. 38), and drinking water professionals have commented on how important this guidance is to them (Ref. 33 and 34). Therefore, EPA believes that the establishment of HAs, including the shorter-term HAs, is justified in general and specifically for the substances in this rule, all of which have been found in drinking water. As stated previously, however, this rule does not itself establish any HAs but rather only requires testing to develop data which EPA may use to develop HAs.

3. *Exposure findings—a. Substantial production.* CMA (Ref. 1) commented that EPA did not define substantial production and, along with Monsanto (Ref. 6), commented that EPA did not disclose production volumes because they were Confidential Business Information (CBI). CMA, therefore, suggested EPA use general production ranges to justify its finding for "substantial production." Since these comments were received, EPA has defined what it considers substantial production in the final statement of policy for TSCA section 4(a)(1)(B)(i) findings (58 FR 28736, May 14, 1993). This policy states that aggregate annual production (including imports) in excess of 1 million pounds is considered substantial. By using a 1-million- pound threshold, only the top 11 percent of the chemicals reported on the TSCA inventory are defined as being produced in substantial quantities. Thus, EPA believes it to be a reasonable interpretation of TSCA section 4(a)(1)(B) to consider aggregate annual production in excess of 1 million pounds to constitute "substantial production."

Monsanto (Ref. 6) commented that EPA relied on "obsolete TSCA inventory production information" to support its exposure finding. EPA did not rely only on 1977 TSCA inventory data, but also on the 1986 and 1990 updates of these data and found that chloroethane and 1,1-dichloroethane are produced in volumes over 100 million pounds, and 1,1,2,2-tetrachloroethane and 1,3,5-trimethylbenzene are produced in volumes over 1 million pounds. Because of these production volumes and the reasons set forth in the final statement of policy for TSCA section 4(a)(1)(B)(i) findings, a substantial production finding is made for these four substances. EPA is deferring action on the proposed testing of *n*-propylbenzene under TSCA section 4(a)(1)(B)(i) because production is not substantial at this time. However, because this chemical has been found in drinking water, EPA will monitor future updates of the TSCA inventory data base and will reconsider the need for testing of *n*-propylbenzene at that time. Alternatively, EPA may initiate rulemaking pursuant to sections 8(a) and/or 5(a)(2) of TSCA to monitor for such changes by requiring the notification of the Agency prior to any future manufacture, importation or processing of *n*-propylbenzene.

b. *Substantial release.* Several comments from industry challenged the finding that there is or may be substantial releases of all the subject chemicals. HSIA (Ref. 5) indicated that EPA could not support a finding of potential substantial release for 1,1,2,2-tetrachloroethane since it is a byproduct of the closed system production of methyl chloroform. HSIA concluded that the presence of 1,1,2,2-tetrachloroethane in some ground and surface waters may be due to past land disposal of this chemical which is no longer practiced, and that current environmental contamination should not be used to support a finding of "substantial" environmental release. Vista Chemical Company (Ref. 8) indicated that it is an inadvertent producer of chloroethane, 1,1-dichloroethane, and 1,1,2,2-tetrachloroethane, but that these substances are incinerated and "the potential for environmental releases or public exposure is insignificant." Monsanto (Ref. 6) commented that "in order for EPA to make a finding under the 'enter(s) the environment in substantial quantities' test, there must be a reasonable determination that such is the case."

In the final statement of policy explaining how EPA interprets its legal authority to make TSCA section 4(a)(1)(B)(i) findings, EPA defined substantial release for the majority of chemicals in production as 1 million pounds per year or 10 percent of production, whichever is less (58 FR 28736, May 14, 1993). As stated in the policy, the 1 million pounds per year threshold is based on the existing information EPA has about the releases of existing chemicals. The major source of information EPA has about chemical release is the Toxics Release Inventory (TRI) required under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act of 1990. Section 313 of EPCRA requires that persons who manufacture or process certain listed chemical substances in excess of 25,000 pounds per year or otherwise use chemical substances in

excess of 10,000 pounds per year report releases of listed chemicals to EPA. Because the TRI encompasses only a limited number of chemical substances and categories, and because companies only report once they meet an applicable threshold, TRI does not represent the entire universe of chemicals or releases of chemicals. Nevertheless, EPA has found that only 37 percent of chemicals reported on TRI have releases in excess of 1 million pounds per year. Thus, EPA believes it to be a reasonable interpretation of TSCA section 4(a)(1)(B)(i) to consider releases in excess of 1 million pounds per year to constitute "substantial environmental release." Applying these criteria, a finding of substantial release can be made for chloroethane. According to the TRI, 4.86 million pounds of chloroethane were released to the environment in 1989 (Ref. 11). The quantity of 1,1,2,2-tetrachloroethane released to the environment in 1989 according to TRI was only 41,131 pounds (Ref. 11). There were no TRI data available on 1,1-dichloroethane, n-propylbenzene, or 1,3,5-trimethylbenzene, and additional information on the extent of their release to the environment was not submitted.

CMA (Ref. 1) commented that EPA cannot rely on TRI data alone to support a finding for substantial environmental release, but must combine these data with monitoring and environmental fate data. EPA disagrees with CMA that monitoring and chemical fate data must be considered to make the substantial release finding, and this position was supported by the cumene ruling in *CMA et al. vs. EPA*, 899 F.2d 344 (5th Cir. 1990) (Ref. 39). The TRI data are estimates provided by industry about chemical release and therefore, EPA believes it is reasonable to rely on them. Furthermore, EPA does not interpret the term "enters the environment" to require it to demonstrate persistence or exposure.

Monsanto (Ref. 6) commented that the proposed test rule reported that over 4 million pounds of chloroethane were released to air, but that there was no information on the release to surface waters which, Monsanto believes, should be the primary information considered since surface waters are a source of drinking water. In 1989 4.86 million pounds of chloroethane were released to the environment; of which 71,749 pounds were discharged directly to water. Although a much greater quantity is released to air than is discharged to water, there is, nevertheless, widespread contamination of drinking water by chloroethane. EPA believes that knowledge of how a chemical enters the environment does not in itself predict the ultimate distribution of that chemical in the various environmental media (air, water, land) because a substance may migrate between environmental media. Therefore, EPA believes the total amount of a chemical released to the environment should be the primary consideration in making a finding for substantial release.

c. *Significant or substantial human exposure.* The Association of Metropolitan Water Agencies (AMWA) (Ref. 34) commented that the drinking water data are clearly sufficient to support a finding that there is substantial exposure to the five chemical substances. EPA agrees with this comment, as discussed below in this unit.

CMA (Ref. 1) commented that EPA has not complied with the cumene court ruling which requires EPA to articulate its definition of "substantial exposure" and that the proposed test rule for the OW chemicals did not cite the standards or criteria by which EPA defines the concept of 'substantial or significant' human exposure in section 4(a)(1)(B) of TSCA.

CMA submitted this comment before EPA proposed and finalized its policy statement which articulated its criteria for determining potential substantial exposure under section 4(a)(1)(B) of TSCA. In the final statement of policy published on May 14, 1993 (58 FR 28736), EPA established the criteria for substantial human exposure as 100,000 persons in the general population, 10,000 consumers, or 1,000 workers. EPA believes that the different numerical thresholds for workers, consumers, and the general population are necessary to reflect the inherent differences in each probable exposure scenario (e.g., workers generally are exposed on a more routine or direct basis than consumers, and consumers are generally exposed on a more direct basis than the general public).

Comments on the application of the policy to chloroethane and 1,1,2,2-tetrachloroethane were received from HSIA (Ref. 30). HSIA stated that the application of the proposed policy to these chemicals was generic, based upon total production volume and survey data of disposal sites, and that an attempt should have been made to identify and analyze source, production method, intensity, duration, and/or frequency of exposure. EPA agrees that knowledge of these factors is desirable; however, such knowledge is not required to make the substantial human exposure finding under TSCA section 4(a)(1)(B)(i). These types of data are not usually available and testing should not be rejected simply because these data are nonexistent. Even if detailed exposure data were available, in the absence of reliable health or environmental effects data, it is impossible to determine what exposures are acceptable. Indeed, if adequate health effects data were available, testing would not be necessary.

CMA (Ref. 1) commented that EPA did not cite any data which demonstrated that the OW chemicals have been found in drinking water, but instead relied on groundwater, soil, and surface water monitoring data. CMA indicated that the data presented did not provide the "substantial evidence" required by TSCA to support exposure findings because (1) EPA possesses an extensive database regarding the levels at which various contaminants have been detected in drinking water sources around the country and these have been reviewed in other exposure-based test rules, and (2) EPA should obtain the available monitoring data on these chemicals before it reaches any conclusions about the magnitude of human exposure.

EPA under TSCA must provide "substantial evidence" in the rulemaking record that there is or may be significant or substantial human exposure. The drinking water data which were not available when this test rule was proposed, have since been provided for comment (56 FR 32294, July 15, 1991 and 57 FR 14371, April 20, 1992). The data provided on July 15, 1991, show that all five of these chemicals have been found in drinking water in the United States. This includes community drinking water systems of America's large cities (e.g., Miami, Philadelphia, Cincinnati, Seattle, New Orleans, and Washington, DC), private drinking water wells, and finished drinking water from ground water. The presence of these chemicals in these water supplies alone will result in the exposure of millions of persons and supports the finding of substantial human exposure. The data provided on April 20, 1992, further demonstrated contamination of drinking water by the five chemicals in this rule.

HSIA (Ref. 30) commented that 1,1,2,2-tetrachloroethane is not a commercial product, but an intermediate to which there is no potential for human exposure. Also, HSIA commented that chloroethane is a gas at room temperature and that human exposure would likely be only by inhalation.

The information EPA provided for the two supplemental comment periods, on

which HSIA did not comment, showed that 1,1,2,2-tetrachloroethane and chloroethane have been found in drinking water in many cities and states in the United States (56 FR 32292, July 15, 1991 and 57 FR 14371, April 20, 1992).

CMA (Ref. 1) and Monsanto (Ref. 6) also commented that if EPA examined data concerning physical/chemical properties and environmental fate of these chemicals and evaluated such characteristics as volatility, mobility, and biodegradation, that EPA would conclude that the migration of the OW chemicals to public water supplies as a result of groundwater contamination or surface water spills is an unlikely exposure scenario.

Although EPA agrees with CMA that surface water spills (and other releases) will result in some volatilization of the chemicals, these chemicals have similar Henry's Law constants and volatilization half-lives, and chloroethane has been detected in drinking water taken from surface waters (Ref. 10). Therefore, it is reasonable to assume that all of them could contaminate drinking water if a surface spill or other release occurred. Furthermore, groundwater contamination or releases from hazardous waste or landfill sites also have potential for contaminating drinking water. These chemicals are stable, transportable in groundwater, and have been detected in drinking water obtained from surface and groundwaters (Ref. 10). Therefore, it is EPA's opinion that the physical/chemical properties and environmental fate of these chemicals would suggest that groundwater contamination and surface water spills or other releases could lead to exposure via drinking water.

CMA (Ref. 1) commented that EPA made no effort to link the presence of the OW chemicals in groundwater and surface water to activities conducted at manufacturing and processing sites, a shortcoming they concluded was similar to that which the Fifth Circuit identified in the cumene case. Thus, CMA commented, EPA cannot sustain its exposure finding for the OW chemicals without some evidence linking the activities of their manufacturers and processors with the groundwater and surface water samples on which the Agency relies.

EPA's exposure finding does not depend solely on the presence of these chemicals in ground and surface waters, but also on the positive drinking water monitoring data which EPA made available (56 FR 32229, July 15, 1991 and 57 FR 14371, April 20, 1992). In addition, an exposure finding based on distribution in commerce, use, or disposal, requires both manufacturers and processors to conduct testing under TSCA section 4(b)(3)(B)(iii). It is, therefore, not necessary to specify linkage to one group or another.

Nevertheless, EPA believes that there is little doubt that the presence of the three chlorinated OW chemicals (chloroethane, 1,1-dichloroethane, 1,1,2,2-tetrachloroethane) is a result of industrial activities. These chemicals are not naturally formed. It is well known, as mentioned by many of the commenters, that these chemicals were landfilled before RCRA requirements prevented such activities. The detection of these three chemicals at hazardous waste sites may certainly be due to these past disposal practices; but while the TRI data would suggest that small amounts are still being released to or injected in the ground (Ref. 11), these past and present disposal practices can nonetheless contribute to current and future exposures.

Concerning the other OW chemical, 1,3,5-trimethylbenzene, there is evidence that it is released from non-petroleum manufacturing and processing plants; 1,3,5-trimethylbenzene has been found in effluents from the manufacture of textiles and plastics (Ref. 10). EPA also considers 1,3,5-trimethylbenzene to be released to the environment from the manufacturing, use, and disposal of gasoline (Ref. 10) because it is present in the C9 hydrocarbon fraction in gasoline (50 FR 20662, May 17, 1985). In addition, all four chemicals may be accidentally spilled while in transit.

The Koch Chemical Company (Ref. 32) commented that EPA did not support a finding for substantial human exposure to 1,3,5-trimethylbenzene because the total population exposed to 1,3,5-trimethylbenzene in drinking water in three states (Alabama, Massachusetts, and Rhode Island) did not exceed 200,000 persons.

The drinking water data from these three states indicated that 199,000 persons in the general population were exposed to 1,3,5-trimethylbenzene in drinking water (Ref. 31). EPA's guiding criterion for finding general population exposure substantial under TSCA is 100,000 persons. EPA, therefore, has supported a finding for substantial exposure to 1,3,5-trimethylbenzene.

The Koch Chemical Company (Ref. 32) commented that it and its customers for 1,3,5-trimethylbenzene are in the states of Texas, Kansas, and South Carolina and that there were no drinking water data from these states demonstrating contamination by 1,3,5-trimethylbenzene. Koch, therefore, believes that it should not be required to share in the testing costs of 1,3,5-trimethylbenzene.

EPA did not present data from these three states because they were not available. EPA has made the necessary findings under TSCA section 4(a)(1)(B) to support testing of 1,3,5-trimethylbenzene. Koch, as the largest manufacturer of pure 1,3,5-trimethylbenzene, is subject to this test rule under TSCA section 4(b)(3)(B), and is therefore responsible for its share of the testing costs.

4. *Derive HAs from existing data—a. Use of other methods to derive HAs.* CMA (Ref. 1) and the Monsanto Company (Ref.6) recommended that, rather than requiring further data development, EPA consider other methods to derive HAs from existing data, e.g., oral LD50 values and subacute and subchronic inhalation toxicity studies. CMA and the Monsanto Company cited Weil and McCollister (Ref. 12), Weil et al. (Ref. 13), and McNamara (Ref. 14) as authorities for extrapolation of short-term data to long term no-effect levels. CMA and the Monsanto Company proposed the calculation of 1-day HAs using the LD50 divided by 10 as an estimated 1-day No-Observed-Effect-Level (NOEL) and 10-day HAs using the LD50 divided by 20 as an estimated 10-day NOEL. According to CMA and Monsanto, Weil et al. (Ref. 13) found that the LD50 divided by 20 would encompass the No-Observed-Adverse-Effect-Level (NOAEL) or NOEL for a 7-day dosing regimen for 95 percent of the chemicals they evaluated, and Weil et al. (Ref. 13) and McNamara (Ref. 14) found that the LD50 divided by 100 would encompass the NOAEL or NOEL from a 90-day study for 95 percent of the chemicals they evaluated.

While this statement is partially correct, it does not reflect the conclusions of the cited authors as to the usefulness of these relationships in predicting longer-term no-effect levels from LD50 data. In addition, it should be noted that neither Weil and McCollister (Ref. 12), nor Weil et al. (Ref. 13) nor McNamara (Ref. 14) presented any analysis of potential extrapolations from LD50 values to 1-day or 10-day NOELs. Weil et al. (Ref. 13), concluded from data obtained in their laboratory that the relationship between the oral LD50 values and the 90-day minimum effective values (MiEs) was poor and that the relationship between LD50 values and the 7-day MiEs was only somewhat better. Weil et al. (Ref. 13) did not recommend extrapolation from the

LD50 to either the 7 or the 90–day MiE because of the wide spread of LD50/MiE ratios (from 0.2 to >512 for LD50/7–day MiE and from <0.4 to >1,939 for LD50/90–day MiE). McNamara (Ref. 14), analyzing literature data on a greater number of chemicals, found an even greater variability in the relationship between LD50 values and 90–day no-effect levels and also did not recommend extrapolating from LD50 values to a 90–day no-effect level. Furthermore, neither the EPA, nor the National Academy of Science (NAS), has adopted such a method of extrapolation. Guidelines for derivation of EPA drinking water health advisories specifically state that lethality data are not to be used as a basis for these advisories (Ref. 37, page 14). Similarly, the NAS (Ref. 22) stated that it did not use LD50s as a basis for short-term (24–hour or 7–day) drinking water advisories. There may be a huge cost to society either to human health or from requiring expensive and unnecessary treatment or providing alternative drinking water sources if HAs are based on poor methodology.

Vulcan Chemicals (Ref. 9) commented that regulatory agencies have often used data from single-dose 14–day studies, primarily LD50 or LC50 values, but also "some estimate of a no-effect-level," to estimate NOAELs. While adequate dose-effect data from oral single-dose 14–day studies could be appropriate as the basis for a 1–day HA, EPA is not aware of any use of LD50 data to estimate NOAELs by regulatory agencies.

CMA (Ref. 1) and Monsanto (Ref. 6) presented a table of HAs calculated by the EPA as compared with "theoretical HAs" calculated from the LD50 by extrapolating to a NOEL using the above method, and then applying an uncertainty factor of 100. Of the 13 chemicals with 1–day HAs calculated by EPA, the LD50-based HA was lower for 11, and was higher by a factor less than 2 for the remaining two chemicals. Hence, the LD50-based value was usually as protective as the EPA value for the 1–day HA. Of the seven chemicals with 10–day HAs calculated by EPA, however, the LD50-based HA was higher than the EPA HA for four chemicals. For two of these chemicals, the LD50-based HA was higher by a factor of about 2 and for the other two chemicals, the LD50-based HA was higher by a factor of about 10. Hence, this method of estimation is not as protective for the 10–day HA as the EPA value.

CMA (Ref. 1) proposed that EPA establish theoretical HAs based on LD50s and allow manufacturers and processors the option of conducting short-term studies if they found the proposed HA levels unacceptable. In view of the diminished protectiveness of 10–day HAs by the LD50 method, as noted above, EPA concludes that this approach is not acceptable. CMA also suggested that EPA compare the NOAELs identified in 90–day studies to values based on LD50s. The work by Weil et al. (Ref. 13) and McNamara (Ref. 14) addressed this issue, as discussed previously, and concluded that the relationship between LD50 values and 90–day no-effect or minimal effect levels was too poor for the LD50 to be used as a basis for extrapolation to 90–day exposure. Hence, there would appear to be no justification for EPA to adopt this approach. CMA also noted that EPA has established shorter-term HAs based on NOAELs identified in 90–day and lifetime studies, and that EPA should consider doing so for these chemicals, and remove the requirement for the separate 14–day studies from the test rule. While EPA has used this suggested approach as a conservative measure in the absence of short-term exposure data, these HAs may be revised as new data become available.

b. *Chloroethane data.* CMA (Ref. 1), HSIA (Ref. 5) and the Dow Chemical Company (Ref. 2) commented that EPA should use the available short-term and subchronic inhalation toxicity studies (Refs. 15-17) on chloroethane to derive drinking water HAs or should support its apparent conclusion that these data are insufficient as the basis for HAs. To use these data EPA would have to extrapolate from inhalation to oral exposure, which can usually only be justified when adequate pharmacokinetic data for both routes are available and indicate that the fate of the chemical is not strongly route-specific, or when the available toxicity data indicate that toxicity by both routes is similar. For chloroethane, however, pharmacokinetic data for both routes are inadequate and toxicity data for oral exposure are lacking. In addition, the available short-term and subchronic studies do not fully conform to the 14–day repeated-dose and 90–day toxicity test guidelines.

The Dow Chemical Company (Refs. 2 and 3) and HSIA (Ref. 5) commented, based on calculations of theoretical retained inhaled dose and oral dose, that tissue concentrations of chloroethane and its metabolites attained at the high-dose in the inhalation studies would exceed those resulting from drinking water administration at the solubility limit of chloroethane. Because data regarding absorption, distribution, and elimination of chloroethane are not available, such theoretical calculations may have little validity in terms of actual tissue concentrations. EPA agrees with the statement by the Dow Chemical Company (Ref. 2) that "data obtained by routes other than the most relevant should be used with caution and on a case-by-case basis."

Both the Dow Chemical Company (Ref. 3) and HSIA (Ref. 5) mention that a single-exposure inhalation disposition study is being initiated at the Dow Chemical Company to clarify assumptions used in calculating the retained inhalation dose. EPA believes that this objective may be met by the study, but because this study looks only at disposition from inhalation exposure, it cannot be used to predict disposition from the oral route of exposure.

c. *1,1-dichloroethane data.* The Dow Chemical Company (Ref. 2) commented that an NCI gavage study (Ref. 18) and a drinking water study of 1,1-dichloroethene by Klaunig et al. (Ref. 19) were not mentioned in the proposed test rule and should be considered. EPA did evaluate and cite the NCI study (Ref. 18) in the proposed test rule (55 FR 21393 at 21395-6 and 21399, May 24, 1990). This study was considered inadequate for the derivation of 10–day, Longer-Term and Lifetime HAs because the subchronic portion of the study was only 6 weeks in duration and did not include histopathological examinations and because of the high, compound-related mortality in both low-dose and high-dose male rats in the chronic portion of the study. The study by Klaunig et al. (Ref. 19) provides limited information on the toxicity to male mice following 24– and 52–week exposures to 1,1-dichloroethane in drinking water. The protocol falls far short of the proposed subchronic oral toxicity guidelines or the chronic oral toxicity guidelines because only one species and [illegible] were used, only two dose levels [illegible] administered, and a limited number of [illegible]ological endpoints were evaluated.

d. *1,1,2,2-tetrachloroethane data.* The Dow Chemical Company (Ref. 2) commented that the two studies of tetrachloroethane by NCI (Ref. 20) and Gohlke et al., (Ref. 21) were rejected by EPA with no explanation of why they were considered inadequate, leaving the reader to infer that they were rejected because of apparent disagreement between the results. EPA pointed out in the proposed test rule that the NCI study (Ref. 20) was considered inadequate for estimating 10–day, Longer-term, and Lifetime HAs because the subchronic range-finding study was only 6 weeks long and did not include histopathological examinations and

because in the chronic study, high compound-related mortality that may have been associated with pneumonia occurred in the female rats at both treatment levels. The Gohlke et al. study (Ref. 21), conducted by gavage in male rats for 2, 4, or 10 days, 6 weeks, and 27 weeks is not consistent with the proposed 14–day oral toxicity test guideline or the subchronic test guideline in terms of number of species and sexes, dose levels, and toxicological endpoints. Furthermore, the reporting of methods and results was inadequate to support evaluation of dose-effect-duration relationships or meaningful comparison with the NCI study (Ref. 20).

e. *1,3,5-trimethylbenzene data.* The Dow Chemical Company (Ref. 2) and the Koch Chemical Company (Ref. 32) commented that EPA did not explain why the prior toxicity studies on commercial C9 solvents, conducted under a section 4 test rule, are inadequate for evaluating the toxicity of 1,3,5-trimethylbenzene. In the proposed test rule for the OW chemicals, EPA indicated that inhalation data on a mixture that may contain as little as 15 percent trimethylbenzenes (actual amount is 8 percent) is not appropriate for evaluating the oral toxicity of pure 1,3,5-trimethylbenzene. Evidence of toxicity from exposure to such a mixture could be due to components of the mixture other than 1,3,5-trimethylbenzene, or to additive or interactive effects of the various mixture components making it unlikely that effects could be attributed to 1,3,5-trimethylbenzene alone. Even if that were the case, extrapolation from inhalation to oral exposure would usually require additional supporting evidence as previously discussed for chloroethane.

5. *Coordination of testing needs with other branches and agencies.* CMA (Ref. 1) and Monsanto Company (Ref. 6) commented that three of the compounds included in the proposed test rule are also the subjects of the Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profiles. These three compounds are chloroethane, 1,1-dichloroethane, and 1,1,2,2-tetrachloroethane. Both CMA and the Monsanto Company recommended that EPA coordinate its testing proposal with ATSDR's data needs. The Monsanto Company further suggested that testing needs and priorities be coordinated through the Interagency Testing Committee (ITC). While the ITC provides one mechanism for coordination of testing, the Office of Pollution Prevention and Toxics (OPPT) can and does take testing recommendations from other branches of EPA or from other agencies and initiates action on these recommendations.

CMA further recommended that EPA defer further rulemaking under section 4 of TSCA until ATSDR completes its identification of priority data needs for the above three chemicals. EPA notes that ATSDR has issued a Toxicological Profile for each of these 3 chemicals in which data needs are identified (Refs. 25, 26, and 27). In addition, in October 1991, ATSDR identified priority data needs for chloroethane (56 FR 52178, October 17, 1991) to be oral toxicity studies with acute (14 days or less) and intermediate (15–365 days) duration exposure. Subsequent communication with ATSDR confirmed that these priority data needs for chloroethane will be satisfied by the testing required in this rule (Ref. 29). ATSDR has not identified priority data needs for 1,1-dichloroethane and 1,1,2,2-tetrachloroethane (Ref. 29), but the ATSDR Toxicological Profiles (Refs. 26 and 27) indicated that oral toxicity studies of intermediate duration are needed. The testing required by this final test rule should satisfy the data needs identified thus far by ATSDR for both these chemicals. ATSDR also lists testing needs in addition to what OW has requested, but it is uncertain when these testing programs will be initiated by ATSDR, NTP, or EPA. Because of this, EPA will not defer rulemaking to require testing which it needs now to develop HAs. Also, ATSDR is required to coordinate with EPA to avoid the conduct of duplicative research (55 FR 11566, March 28, 1990), and therefore, will be aware of EPA's action and will take it into consideration.

CMA (Ref. 1) commented that although the same set of concerns underlies OW's and ATSDR's research agendas with regar[illegible] the above three chemicals (i.e., co[illegible]ination of drinking water from chemicals hazardous waste sites), there is no indication that OW and ATSDR consulted with each other about the testing that would best meet their common needs. EPA and ATSDR are required to take note of each other's activities. In this case, both agencies simultaneously and independently proposed the same priority testing needs for chloroethane including oral toxicity studies in drinking water for short-term exposure and for subchronic/intermediate exposure (EPA: 55 FR 21393, May 24, 1990 and ATSDR: 56 FR 52178, October 17, 1991). EPA believes the agreement of ATSDR on the needed testing further supports EPA's decision to require these tests. EPA also believes that any duplication of effort which may have occurred will be minimized in the future by relying on the recently developed Master Testing List (Ref. 28) to coordinate testing with ATSDR. It should be noted, however, that the testing needs identified by ATSDR were not an exact duplication of the testing proposed by EPA. ATSDR's concerns extend beyond drinking water exposure to other pathways of oral exposure and to inhalation and dermal exposure, whereas OW's concerns are focused on the effects of these substances as a result of consuming contaminated drinking water.

6. *Proposed testing and test standards.* CMA (Ref. 1), Eastman Kodak (Ref. 4), HSIA (Ref. 5), and Vulcan (Ref. 9) commented that a separate 14–day study should not be conducted to determine a NOAEL or LOAEL that could be extrapolated from a 90–day study. The CMA (Ref. 1), the Monsanto Company (Ref. 6), Vulcan (Ref. 9), and Shell Oil Company (Ref. 7) also commented that 14–day studies are generally used only as range-finding studies for longer term studies and, along with Kodak (Ref. 4), commented that they have little value for regulatory use because of their short duration. In contrast, the Dow Chemical Company (Ref. 2) urged EPA to use results from a routine 2–week probe study to estimate the 10–day HA, and validate the value using data from the 90–day study. Dow further suggested that EPA give manufacturers or processors who find such a 10–day HA unacceptable the option of conducting a 14–day study using a protocol that they would submit for EPA approval.

EPA has attempted to base estimated 10–day HAs on routine probe studies, but uncertainties associated with the results from the usual probe study, even when interpreted in light of findings in an associated 90–day study, diminish the confidence that can be placed in the 10–day HA. Further, uncertainties in the studies would compel EPA to apply higher uncertainty factors, possibly resulting in lower HA values. NOAELs and LOAELs identified from studies suitable for use in determining a Longerterm or Lifetime HA are often lower than those determined in the 14–day study. Extrapolating the NOAEL and/or LOAEL from a 90–day study would likely result in a lower 10–day HA. Low HA values lead to higher clean-up costs and in some cases the use of alternative drinking water sources with additional costs and hardships to the consumer. These uncertainties would not be addressed in a consistent manner by giving the manufacturers/processors the option to perform a 14–

day test when they find an HA "unacceptable" (i.e., too low). Therefore, EPA believes the NOAEL and/or LOAEL from the 14–day study should be used to estimate 1– and 10–day HAs whenever possible.

CMA (Ref. 1) and the Monsanto Chemical Company (Ref. 6) suggested that if a 14–day study is believed necessary, the test animals should be subject only to gross necropsy. EPA believes that for the purposes contemplated by this rule, a 14–day study should be as comprehensive in its examination of endpoints as a 90–day study and should, therefore, histologically examine the same organs and tissues as required in the 90–day study. To do less might result in an important endpoint of toxicity being overlooked. EPA, however, has reconsidered the requirement to do histological analysis of the lungs, kidney and liver of all animals in both the 14–day and 90–day tests. This provision has been modified in this final rule at § 799.5075(c)(1)(i)(B)(*14*) and (2)(i)(B)(*2*) to require that only the lungs be examined in all animals, while the liver and kidney need to be examined in only the high dose animals, and in the lower dose animals only if effects are seen in those organs in the high dose group.

Vulcan Chemicals (Ref. 9) apparently believes that full histopathological examinations were proposed for the satellite group in the 14–day study, but both the proposed 14–day guideline (under § 795.257(e)(11)(vi)) and the final 14–day guideline (under § 798.2650(e)(11)(vi)) specify that only tissue or organs identified as showing effects in the treated groups would have to be examined histopathologically in the satellite groups. The same requirement exists for the 90–day test.

The Shell Chemical Company (Ref. 7) stated that measurements of clinical chemistry and hematology do not appear justified. EPA believes that such measurements are necessary for a complete assessment of potential toxicity. EPA has, however, deleted the requirement to analyze for ornithine decarboxylase and total bilirubin in the 14–day study at § 799.5075(c)(1)(i)(B)(*13*). EPA has also revised its requirement for clinical biochemistry determinations on blood in the 14–day study; these measurements are now recommended, instead of required, to be done twice in the 14–day study, thus making the requirement consistent with the 90–day test guideline.

The Dow Chemical Company (Ref. 2) believed that clarification of both the 14–day and the 90–day test guidelines is needed concerning the clinical chemistry and hematologic parameters to be evaluated in the satellite group. EPA believes that the guideline for the 14–day and 90–day studies is quite clear under § 798.2650(e)(9)(i) where it states that "examinations shall be made on all animals of each sex in each group for rodents [including the satellite groups required by the modifications under § 799.5075(c)(1)(i)(B)(*4*) and (2)(i)(B)(*1*)], and all animals when non-rodents are used as test animals" (i.e., there is no satellite group when non-rodents are used). In other words, clinical chemistry and hematological evaluations must be made on all animals in the studies including, when rodents are used, animals in the satellite groups.

Vulcan Chemicals (Ref. 9) suggested that EPA use the recent NTP protocol for 14–day studies, apparently to show that it is less extensive than the proposed test guideline. EPA observes that the purpose of the NTP 14–day study is limited to range finding, whereas the purpose of the test required by this rule is not only range finding, but also to provide data suitable as the basis for short-term HAs.

CMA (Ref. 1), Eastman Kodak (Ref. 4), and the Shell Oil Company (Ref. 7) objected to the proposed use of five dose levels (instead of three or four) in the 14–day test. CMA and Monsanto (Ref. 6) also objected to the proposed modification of the 90–day test guideline which would require five dose levels be used. Eastman Kodak, apparently unaware of the proposed modification which would require five dose levels in the 90–day study, argued that the 14–day study should have three dose levels to be consistent with the 90–day study. EPA has considered these comments and has decided to require that three dose levels be used in both the 14–day and 90–day tests.

CMA (Ref. 1), HSIA (Ref. 5), the Monsanto Company (Ref. 6), and the Eastman Kodak Company (Ref. 4) commented that if the 14–day repeated-dose oral toxicity guideline cannot be eliminated it should be modified so that it is identical to OECD's 14–day test (Ref. 23), or at a minimum, "consistent" with it. EPA notes that the 14–day guideline is similar to the OECD guideline, with the following exceptions: the TSCA 14–day repeated-dose oral toxicity guideline specifies a greater number of animals per dose level and an ophthalmological examination. EPA is requiring the ophthalmological examination as an additional means to observe the systemic effects of the test chemical and to make the 14–day test consistent with the 90–day test. EPA is also requiring that 20 animals instead of 10 be used at each dose level. The OECD guideline states that "at least 10 animals (5 female and 5 male) should be used at each dose level." Obviously this OECD requirement does not preclude using larger numbers of animals. Other than additional animals and the ophthalmological exam, the protocols, including endpoints of toxicity, are virtually the same.

Vulcan Chemicals (Ref. 9), the Eastman Kodak Company (Ref. 4) and the Dow Chemical Company (Ref. 2) expressed concern about the "excessive" number of animals required by the proposed 14–day guideline. CMA (Ref. 1) stated that EPA must justify the increase in the number of animals in the proposed 14–day guideline. EPA is requiring the 14–day test to satisfy the need for health effects data on which to base short-term HAs. EPA believes the additional animals are necessary to assure that short-term HAs can be based on test results whose statistical validity won't be compromised by a loss of animals during the test. EPA believes the number of animals per dose level is the lowest possible to achieve adequate and reliable results.

The Eastman Kodak Company (Ref. 4) stated that the exposure conditions should be consistent with the subchronic guideline which allows dosing 5 days/week even though the subchronic guideline states a preference for dosing on 7 days/week. Eastman Kodak recommended consistency in the dosing schedule so that the 14–day study can be used to set subchronic dose levels. EPA believes that daily dosing, because it is uninterrupted exposure, is more relevant to drinking water exposure. EPA also believes that dosing for 14 days is useful in setting dose levels for longer duration studies, including studies with a 5 day/week dosing regimen. If Eastman Kodak believes that consistency in dosing is vital to the integrity of these two studies, then the option is available and preferable that dose administration in the subchronic study be conducted 7 days/week instead of 5 days/week.

Vulcan Chemicals (Ref. 9) claimed that when the highest dose in the 14–day protocol is sufficiently high to cause observable toxicity, the lower doses may be too high to allow the determination of a NOAEL. EPA believes that this will not be a problem because the test rule requires that the doses be spaced appropriately so that the lowest dose level produces no evidence of toxicity.

The Eastman Kodak Company (Ref. 4) commented that the age and weight requirements for non-rodent species in the proposed 14–day guideline may be too rigid because of limitations on the

availability of these species and greater variability in their ages and weights. EPA believes that animals will be available and points out that these age and weight requirements are consistent with those already established for the 90–day and chronic oral toxicity studies.

The Eastman Kodak Company (Ref. 4) expressed concern that the specification of drinking water as the preferred route of exposure may not be appropriate for a general 14–day study guideline. EPA notes that the proposed 14–day guideline provided for gavage, dietary or capsule administration in the event that drinking water administration is not feasible.

CMA (Ref. 1) and the Monsanto Company (Ref. 6) claimed that to attain the limit value of 1,000 mg/kg/day as specified for the limit tests in the 90–day and the 14–day test guidelines, a 400–g rat will have to consume 40 ml/day of drinking water containing 10 mg/ml (10,000 mg/L) of the test material. This concentration is above the limits of solubility in water for the selected chemicals.

EPA points out that the 14–day and 90–day test guidelines require that ideally the rats be almost 6 weeks of age or, in any case, no more than 8 weeks of age at the start of the test. Hence, the rats will be smaller than 400 g and will be consuming proportionately larger amounts of water. Nevertheless, the drinking water concentration required to deliver a dose of 1,000 mg/kg/day in the subchronic study would be somewhat higher than the limits of solubility for the most soluble chemicals (chloroethane and 1,1-dichloroethane), about twice as high for 1,1,2,2-tetrachloroethane, and orders of magnitude higher for the least soluble chemical, 1,3,5-trimethylbenzene. Therefore, the limit tests for all four compounds would likely have to be carried out by gavage, which is an alternative offered by the guidelines.

CMA (Ref. 1) and the Monsanto Company (Ref. 6) questioned the relevance of gavage testing to drinking water exposure scenarios. While EPA believes that gavage administration is less desirable, it also believes that results of gavage administration have relevance to assessment of human risk from drinking water exposure, based on considerable experience analyzing results from such studies. Depending on toxic potency, it may be possible to conduct the full three-dose 14–day and 90–day studies for the three more soluble compounds via drinking water. The test guidelines specify only that the highest dose should produce toxic effects, and do not specify the highest dose in mg/kg/day.

Eastman Kodak (Ref. 4) commented that the proposed 14–day guideline should not state a preference for one rodent and one non-rodent species, but rather should be consistent with the subchronic guideline, which allows a choice between a rodent and non-rodent species and does not require two species. EPA notes that the proposed 14–day guideline was consistent with the proposed 90–day subchronic guideline in that both specified testing in two species, preferably (but not required to be) a rodent and non-rodent.

CMA (Ref. 1), the Eastman Kodak Company (Ref. 4), and the Monsanto Company (Ref. 6) objected to the requirement for the use of two species in the 14–day test; Monsanto also objected to the requirement of two species in the 90–day test. CMA and Monsanto argued that the requirement for two species is not necessary to determine the most sensitive species because the most sensitive species can be determined by comparing LD50 values. EPA has reconsidered its proposal to conduct both tests in two species and has decided to require that both tests be conducted in one mammalian species, preferably a rodent, but a non-rodent may be used. EPA believes this decision brings these tests into conformity with similar tests required under TSCA. EPA has also clarified that the same species and strain of animal should be used in both tests. Concerning the most sensitive species, EPA is not aware of any validation of the use of a single-dose LD50 study as a predictor of species sensitivity for longer-term exposure.

The Eastman Kodak Company (Ref. 4) stated that a satellite group should not be required if the 14–day study is being conducted as a range-finding study, but rather should be optional as it is in the subchronic guideline. EPA points out that the 14–day study is not only intended to furnish range-finding information but also to provide a basis for short–term criteria for the protection of human health. Also, if rodents are selected as the test animal, the satellite group is required for the 90–day study (at § 799.5075(c)(2)(i)(B)(*1*)) as well as for the 14–day study to assess reversibility of effects.

CMA (Ref. 1) and the Shell Oil Company (Ref. 7) questioned how data on reversibility, persistence, and delayed occurrence of toxic effects from the satellite groups can be used to calculate HAs and CMA recommended that the requirements for the satellite groups be removed from the test guidelines. EPA uses this information, when available, to aid in deciding whether a given dose level constitutes a NOAEL, LOAEL, or Frank Effect Level (FEL). For example, a mild effect, which was not clearly adverse and which disappeared during the recovery period, would be judged evidence that the dose level was a NOAEL. Conversely, a mild effect, which was not clearly adverse as seen at the end of dosing but which progressed to a slight degenerative change during the post-exposure period, would be judged evidence that the dose level constituted a LOAEL.

CMA (Ref. 1) also suggested that for delayed toxic effects, information that a structurally related chemical produces such effects should be considered to justify a satellite group on a case-by-case basis. EPA believes that this approach would prevent detection of delayed toxicity for some chemicals and that it does not answer the need for information on reversibility and persistence of effects.

7. *Reporting requirements.* The Dow Chemical Company (Ref. 2) stated that EPA should clarify that submission of study plans may occur any time (rather than 45 days or more) prior to initiation of testing, consistent with changes to 40 CFR part 790 (55 FR 18881, May 7, 1990) that became effective June 21, 1990. EPA agrees and has provided clarification in Unit III.E. of this preamble.

8. *Keep the record open for additional data.* The Dow Chemical Company (Ref. 2) believes that additional data may be available now or under development now or in the future. Dow urged EPA to keep the record open for submission of studies that may become available before issuance of the final rule. EPA requested such additional data in the proposed test rule published on May 24, 1990. All additional studies that were submitted or cited were evaluated. The only study cited as in progress (Refs. 3 and 5) is an inhalation pharmacokinetic study of chloroethane, performed by Dow. Even when this study is complete, however, it will not obviate the need for the testing required by this rule because it will not predict or assist in evaluating the toxicity of chloroethane by the oral route.

9. *Economic analysis of proposed rule.* The Monsanto Company (Ref. 6) and CMA (Ref. 1) estimated that the 14–day repeated dose testing proposed by EPA will cost $250,000 for two rodent species or $300,000 for a rodent and a non-rodent species. They did not specify whether this estimate is the cost of the 14–day study for each chemical or for all the chemicals, but did comment that it considered the cost burdensome. In the proposed test rule,

EPA estimated the total testing cost per chemical for the 14– and 90–day studies at $396,130 to $579,590. The probability that this cost would cause an adverse economic impact was considered low (Ref. 35). Also, the cost of the testing program required by this final rule ($219,000 to $328,000) is considerably less than that of the proposed testing, mostly due to reducing the number of species to be tested from two to one, and reducing the number of doses from five to three.

The Koch Chemical Company (Ref. 32) commented that the proposed testing program for 1,3,5-trimethylbenzene would cause a substantial economic impact for its company which would most likely force it to discontinue sales of this chemical in the United States. EPA believes that the economic impact due to the testing of 1,3,5-trimethylbenzene will not be as great as Koch anticipates. First, the cost of the testing program required by this final rule is considerably less than that of the proposed testing as explained above. Second, Koch is mistaken in thinking it is the only manufacturer of 1,3,5-trimethylbenzene. There is another manufacturer of pure 1,3,5-trimethylbenzene and several manufacturers of C9 aromatic hydrocarbons, which contain 1,3,5-trimethylbenzene. The cost of testing 1,3,5-trimethylbenzene would be shared with these manufacturers.

III. Final Testing Requirements

A. Findings

EPA is basing the final health effects testing requirements for chloroethane, 1,1-dichloroethane, 1,1,2,2-tetrachloroethane, and 1,3,5-trimethylbenzene on the authority of section 4(a)(1)(B) of TSCA. EPA finds that: All four of the substances are produced in substantial quantities; chloroethane may enter the environment in substantial quantities; there may be substantial human exposure to all of these substances due to their presence in drinking water; there are insufficient data and experience to reasonably determine or predict the effects on human health from disposal and migration to drinking water resources of all of these substances; and testing is necessary to develop these data.

1. *The substances are produced in substantial quantities.* Production volumes submitted by manufacturers for all of the substances subject to this final test rule are listed on the TSCA section 8(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 volumes of the four substances are substantial according to the guidance of 1 million pounds per year established in the policy on 4(a)(1)(B) findings (58 FR 28736, May 14, 1993). These substances are chloroethane, 1,1-dichloroethane, 1,1,2,2-tetrachloroethane, and 1,3,5-trimethylbenzene.

2. *Chloroethane may enter the environment in substantial quantities.* EPA finds that chloroethane may 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. 11) lists releases of chloroethane during manufacturing, processing and use. The TRI reports that in 1989, 4.86 million pounds of chloroethane were released to the environment. The TRI data demonstrate that there is substantial release of chloroethane to the environment during manufacture, processing, use, and disposal.

3. *There may be substantial human exposure to the substances.* EPA believes there may be substantial human exposure to these chemical substances due to their presence in drinking water. All four substances have been found in drinking water in the United States (56 FR 32292, July 15, 1991). This includes community drinking water systems of America's large cities (e.g., Miami, Philadelphia, Cincinnati, Seattle, New Orleans, and Washington, DC), private drinking water wells, and finished drinking water from ground water. For the reasons articulated in the "B" policy, EPA has established criteria as guidance for finding human exposure substantial. For the general population, the criterion is a threshold of 100,000 persons who may be exposed to the chemical in question. The population of each of the cities whose drinking water contains the subject chemicals well exceeds 100,000. EPA, therefore, finds that there may be substantial human exposure to these chemicals. Further supporting this finding is monitoring data of public water systems from nine states (AL, FL, IN, MA, MI, NE, PA, RI, and WV) which EPA added to the docket for this rule and solicited comment on (57 FR 14371, April 20, 1992). These data showed that chloroethane was present in drinking water in four of the nine states; 1,1-dichloroethane in six of the nine states; 1,1,2,2-tetrachloroethane in five of the nine states; and 1,3,5-trimethylbenzene in three of the nine states (Ref. 31).

Further supporting this finding is the presence of these chemicals in ground and surface waters in or near hazardous waste disposal sites. Although monitoring data is available for only a portion of the hazardous waste sites in America, chloroethane has been found in or near hazardous waste sites in 17 states; 1,1-dichloroethane in 24 states; 1,1,2,2-tetrachloroethane in 25 states; and 1,3,5-trimethylbenzene in 7 states (Ref. 24). Many of the hazardous waste disposal sites in or near which these chemicals have been found have qualified for inclusion in the National Priorities List (NPL). As explained in the proposed rule, the NPL is a ranking of facilities nationally for remedial action based primarily on the migration score from the Hazardous Ranking System. A migration score is calculated for ground water, surface water and air by ranking the following factors: the population potentially affected, water use, distance to well or water intake, route characteristics that affect contaminant migration, and contaminant characteristics such as quantity, toxicity and persistence. EPA finds that potential for substantial human exposure exists since the subject chemicals are found at NPL and other hazardous waste sites and because 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 and could be the source of the documented drinking water contamination to which millions of people may be exposed.

4. *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 only 8 percent 1,3,5-trimethylbenzene. 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. EPA 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 four substances in this

final 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. 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. 18 and 20), 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. 21) 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. 20) 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, as discussed earlier, neither is considered adequate for risk assessment.

Therefore, under section 4(a)(1)(B)(ii) of TSCA, EPA has determined that there are insufficient data to reasonably predict or determine the effects on human health from the consumption of drinking water contaminated with each substance examined.

5. *Testing is necessary and relevant.* EPA believes that oral, repeated-dose subacute and subchronic testing of chloroethane, 1,1-dichloroethane, 1,1,2,2-tetrachloroethane, and 1,3,5-trimethylbenzene is necessary to determine or predict the effects these substances may have on human health as a result of drinking water exposures. Testing for other endpoints (e.g., mutagenicity, neurotoxicity, reproductive effects, developmental toxicity, and oncogenicity) might also be necessary, but to expedite this rulemaking and obtain the minimal data for establishing HAs, EPA has decided to defer consideration of these endpoints until receipt of data from these tests and monitoring data under section 1445 of the SDWA, or until ATSDR refers these chemicals to EPA for test rules and identifies additional testing needs.

EPA finds under section 4(a)(1)(B)(iii) of TSCA that the data generated from this testing will be relevant in determining whether the disposal and migration to drinking water resources of these substances does or does not present an unreasonable risk of injury to human health. EPA needs these subacute and subchronic data to develop HAs for each of the substances. EPA further believes that the testing of the substances included in this rule will develop the necessary information.

B. Test Standards

On the basis of the findings given in Unit III.A. of this preamble, EPA is requiring health effects testing for chloroethane; 1,1-dichloroethane; 1,1,2,2-tetrachloroethane, and 1,3,5-trimethylbenzene. A 14–day oral subacute and a 90–day oral subchronic study are required for each substance. The studies are to be conducted in accordance with EPA's TSCA Good Laboratory Practice Standards (GLPs) in 40 CFR part 792 and the specific TSCA test guideline in 40 CFR part 798.

EPA is requiring that these four substances undergo subacute and subchronic oral testing according to the TSCA test guideline at 40 CFR 798.2650, as modified by this rule. The studies shall be performed using drinking water as the route of exposure. If this route is not feasible, the substances may be administrated by gavage, in the diet, or in capsules. The tests will be performed with one mammalian species, preferably a rodent, but a non-rodent may be used. A variety of rodent species may be used, but the rat is preferred. The species and strain of animals used in the subacute and subchronic tests should be the same.

EPA is requiring that the above-referenced health effects test guideline, and any modifications to this guideline, be the test standards for testing these substances. Data generated from these tests will assist EPA in setting health standards, specifically Health Advisories. EPA believes that these test methods reflect the current state of the science for testing substances such as these for the specified endpoints.

C. Test Substance

EPA is requiring that each of the four 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.

D. 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 in commerce, or disposal.

Because EPA has found that there are insufficient data and experience upon which the health risks from the disposal and migration to drinking water resources of the substances subject to this test rule can reasonably be determined or predicted, EPA is requiring 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 for the particular substance as required by this 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.

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 has 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 790.45.

Processors subject to this rule, unless they are also manufacturers, are not 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 790.48.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for the substances subject to this test rule. As noted in Unit III.C. 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.

E. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with its TSCA GLPs, 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 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's reporting requirements for each of the test standards are specified 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 on each test shall be submitted 6 months after the effective date of the final test rule, and every 6 months thereafter until the final report is submitted to EPA.

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 each test shall be submitted 9 months from the effective date of the final test rule and every 6 months thereafter until the final report is submitted to EPA.

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(d).

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 make a one-time report to EPA upon the first export of the compound to any one country. EPA will notify the foreign country about the test rule for the substance.

F. Enforcement Provisions

EPA considers failure to comply with any aspect of a TSCA section 4 rule to be a violation of section 15 of TSCA. Section 15 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 TSCA 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 premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce ..." EPA 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 test rule. 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, interpretations and evaluations, and to determine compliance with TSCA GLPs and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. EPA maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing 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 790.28(b)).

Knowing or 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 TSCA 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. Section 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.

IV. Economic Analysis of Rule

To assess the potential economic impact of this rule, EPA has prepared an economic impact analysis 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 four 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.

The total testing cost for each of the four substances is estimated to range from $219,000 to $328,000. 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 $24,000 to $36,000. Given that these costs are less than one-tenth of one percent of the annual revenues from sales for each of these four substances, EPA believes that the potential for adverse economic impact resulting from the costs of testing is low.

Refer to the economic analysis contained in the public record for this rulemaking for a complete discussion of test cost estimation and potential for economic impact resulting from these costs (Ref. 36).

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

VI. Rulemaking Record

EPA has established a public record for this rulemaking proceeding [docket number OPPTS-42111C]. This record includes:

A. Supporting Documentation

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

(a) Notice of proposed rule on Office of Drinking Water chemicals (55 FR 21393, May 24, 1990).

(b) Notice of TSCA section 4(a)(1)(B) final statement of policy (58 FR 28736, May 14, 1993).

(c) Reopening of comment period for ODW chemicals. (56 FR 32292, July 15, 1991).

(d) Additional information supporting TSCA test rule on Office of Water chemicals. (57 FR 14371, April 20, 1992).

(e) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (54 FR 34034, August 17, 1989).

(f) Notice of interim final rule on consent agreement and test rule development and exemption procedures (51 FR 23706, June 30, 1986).

(g) Notice of final rule on testing consent agreements and test rules (55 FR 18881, May 7, 1990).

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

(i) Notice of priority data needs for 38 Priority Hazardous Substances (56 FR 52178, October 17, 1991).

(j) Notice of final test rule on ethyltoluenes, trimethylbenzenes, and the C9 aromatic hydrocarbon fraction (50 FR 20662, May 17, 1985).

(2) Support Documents: consisting of:

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

(b) TSCA test guideline § 798.2650, Oral Toxicity.

(3) Communications before proposal consisting of:

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

(b) Records of telephone conversations.

(c) Records or minutes of informal meetings.

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

B. References

(1) Chemical Manufacturers Association (CMA), Washington, DC. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to the Office of Pesticides and Toxic Substances (OPTS), U.S. Environmental Protection Agency (USEPA), Washington, DC 20460. (July 23, 1990).

(2) Dow Chemical Company, Midland, Michigan. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to OPTS, USEPA, Washington, DC. (July 23, 1990).

(3) Dow Chemical Company, Midland, Michigan. Comments of the Dow ChemicalCompany on Priority Data Needs for Chloroethane, Docket No. ATSDR-18. Submitted to OPTS, USEPA, Washington, DC. (July 23, 1990).

(4) Eastman Kodak Company, Rochester, New York. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to OPTS, USEPA, Washington, DC. (July 12, 1990).

(5) Halogenated Solvents Industry Alliance (HSIA), Washington, DC. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to OPTS, USEPA, Washington, DC. (July 23, 1990).

(6) Monsanto Company, St. Louis, Missouri. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to OPTS, USEPA, Washington, DC. (July 20, 1990).

(7) Shell Oil Company. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to OPTS, USEPA, Washington, DC. (July 13, 1990).

(8) Vista Chemical Company, Houston, Texas. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to OPTS, USEPA, Washington, DC. (July 20, 1990).

(9) Vulcan Chemicals, Birmingham, AL. Comments on proposed test rule for the Office of Drinking Water chemicals. Submitted to OPTS, USEPA, Washington, DC. (July 20, 1990).

(10) Syracuse Research Corporation, Syracuse, NY. Response to public comments, drinking water chemicals. (September 30, 1990).

(11) USEPA. 1989 Toxic Release Inventory. Printout for 1,1,2,2-tetrachloroethane and chloroethane. (April 22, 1991).

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(18) 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) 78–1316. (1978).

(19) Klaunig, J.E., Ruch, R.J., and Pereira, M.A. Carcinogenicity of chlorinated methane and ethane compounds administered in drinking water to mice. *Environmental Health Perspectives*. 69:89–95. (1986).

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

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(22) NAS (National Academy of Sciences). Drinking Water and Health. Volume 3. National Research Council. National Academy Press, Washington, DC. pp. 49–50, 68–69. (1980).

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(25) Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for chloroethane. ATSDR/TP–89/07. ATSDR, Atlanta, GA. (December, 1989).

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(27) ATSDR. Toxicological Profile for 1,1,2,2-tetrachloroethane. pp. 34–39. ATSDR/TP–89/22. ATSDR, Atlanta, GA. (December 1989).

(28) USEPA. Master Testing List. Office of Pollution Prevention and Toxics, USEPA, Washington, DC. (December 1, 1992).

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(30) HSIA, Washington, DC. Comments on TSCA Section 4(a)(1)(B) proposed statement of policy and reopening of comment period for ODW Chemicals. Submitted to OPTS, USEPA, Washington, DC. (September 13, 1991).

(31) USEPA. Memorandum from James Walasak, Water Supply Technology Branch, to Catherine Roman, Chemical Testing Branch. "Unregulated Contaminant Data." (August 26, 1991).

(32) Koch Chemical Company, Corpus Christi, Texas. Comments on the notice of data availability entitled "Additional information supporting TSCA test rule on Office of Water chemicals." Submitted to the Office of Pollution Prevention and Toxics (OPPT), USEPA, Washington, DC. (May 14, 1992).

(33) American Water Works Association, Washington, DC. Comments on the notice of data availability entitled "Additional information supporting TSCA test rule on Office of Water chemicals." Submitted to the Office of Pollution Prevention and Toxics (OPPT), USEPA, Washington, DC. (May 14, 1992).

(34) Association of Metropolitan Water Agencies, Washington, DC. Comments on the notice of data availability entitled "Additional information supporting TSCA test rule on Office of Water chemicals." Submitted to the Office of Pollution Prevention and Toxics (OPPT), USEPA, Washington, DC. (May 19, 1992).

(35) USEPA. Memorandum from Eileen Neely, Regulatory Impacts Branch, to Steve Ells, Test Rules Development Branch, (April 27, 1989), transmitting economic impact analysis of ODW chemicals proposed test rule. (April 26, 1989).

(36) USEPA. Economic impact analysis of OW chemicals final test rule. (June 10, 1992).

(37) USEPA. "Guidelines for authors of EPA Office of Water Health Advisories for drinking water contaminants." Office of Water. (March 1989).

(38) USEPA. "Ensuring safe drinking water." EPA Journal. pp. 11–13. (September 1985).

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Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the TSCA Nonconfidential Information Center (also known as the TSCA Public Docket Office), Rm. G–102, 401 M St. SW., Washington, DC, from 8 a.m. to 12 noon, and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays.

VII. Regulatory Assessment Requirements

A. Executive Order 12291

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

This 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., EPA is certifying that this test rule will not have significant impact on a substantial number of small businesses because: (1) They are not likely to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, if any, 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 OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to average 1,083 hours per respondent. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2131, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070–0033), Washington, DC 20503.

List of Subjects in 40 CFR Part 799

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

Dated: October 22, 1993.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR Chapter I, Part 799 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 § 799.5075 to subpart D to read as follows:

§ 799.5075 Drinking water contaminants subject to testing.

(a) *Identification of test substance.* (1) Chloroethane (CAS No. 75–00–3), 1,1-dichloroethane (CAS No. 75–34–3), 1,1,2,2-tetrachloroethane (CAS No. 79–34–5), and 1,3,5-trimethylbenzene (CAS No. 108–67–8) shall be tested in accordance with this section.

(2) Chloroethane, 1,1-dichloroethane, 1,1,2,2-tetrachloroethane, 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, or who intend to manufacture or process, the substances listed in paragraph (a) of this section after the effective date of this section 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 single-phase rulemaking, for the substances they manufacture subject to exclusions contained in § 790.42(a)(2), (a)(4) and (a)(5). These sections provide that processors, persons who manufacture less than 500 kg (1,100 lbs) annually, or persons who manufacture small quantities of the chemical solely for research and development as defined in § 790.42(a)(5) shall not be required to submit study plans, conduct tests and submit data, or submit exemption applications as specified in this section unless directed to do so in a subsequent notice as set forth in § 790.48(b).

(c) *Health effects testing*—(1) *Subacute toxicity*— (i) *Required testing.* (A) An oral 14–day repeated dose toxicity test shall be conducted with each of the substances designated in paragraph (a) of this section in accordance with § 798.2650 of this chapter except for the provisions in § 798.2650(a); (b)(1); (c); (e)(3), (4)(i), (5), (6), (7)(i), (iv), (v), (8)(vii), (9)(i)(A), (B), (11)(v); and (f)(2)(i). Each substance shall be tested in one mammalian species, preferably a rodent, but a non-rodent may be used. The species and strain of the animals used in this test should be the same as those used in the 90–day subchronic test required in paragraph (c)(2)(i) of this section. The tests shall 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 either oral gavage, in the diet, or in capsules.

(B) For the purpose of this section, the following provisions also apply:

(*1*) *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 safety criteria for short-term human exposure.

(*2*) *Definitions.* 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.

(*3*) *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.

(*4*) *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.

(*5*) *Dose levels and dose selection.* In subacute toxicity tests, it is desirable to have a dose response relationship as well as a NOAEL. Therefore, at least 3 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.

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

(*7*) *Observation period.* All animals shall be observed daily during the 14–day exposure period.

(*8*) *Observation period of satellite group.* 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.

(*9*) *Administration of test substance.* 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.

(*10*) *Time of administration of test substance.* 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 maintain a constant dose level in terms of animal body weight.

(*11*) *Observation of animals.* 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.

(*12*) *Hematology determinations.* 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.

(13) *Clinical biochemical determinations.* Certain clinical biochemistry determinations on blood should 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 are: 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 are: Calcium, phosphorus, chloride, sodium, potassium, fasting glucose (with the period of fasting appropriate to the species), serum alanine aminotransferase, serum aspartate aminotransferase, gamma glutamyl transpeptidase, urea nitrogen, albumin, blood creatinine, 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.

(14) *Histopathology.* Histopathology of the lungs of all animals shall be performed. 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.

(15) *Evaluation of the study results.* 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) *Reporting requirements.* (A) Each subacute test shall be completed and the final report submitted to EPA within 12 months of the date specified in paragraph (d)(1) of this section.

(B) For each test, a progress report shall be submitted to EPA beginning 6 months after the date specified in paragraph (d)(1) of this section and at 6-month intervals thereafter until the final report is submitted to EPA.

(2) *Subchronic toxicity*—(i) *Required testing.* (A) An oral 90-day subchronic toxicity test shall be conducted with each of the substances designated in paragraph (a) of this section in accordance with § 798.2650 of this chapter except for the provisions in § 798.2650(e)(3), (7)(i), and (11)(v). The tests shall 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 either by oral gavage, in the diet, or in capsules.

(B) For the purpose of this section, the following provisions also apply:

(1) *Satellite group (Rodent only).* A satellite group of 20 animals (10 animals per sex) shall be treated with the high dose level for 90 days and observed for reversibility, persistence, and delayed occurrence of toxic effects for a post-treatment period of appropriate length, normally not less than 28 days.

(2) *Histopathology.* Histopathology of the lungs of all animals shall be performed. 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.

(ii) *Reporting requirements.* (A) Each subchronic test shall be completed and the final report submitted to EPA within 15 months of the date specified in paragraph (d)(1) of this section.

(B) For each test, a progress report shall be submitted to EPA beginning 9 months after the date specified in paragraph (d)(1) of this section and at 6-month intervals thereafter until the final report is submitted to EPA.

(d) *Effective date.* (1) This section is effective on December 24, 1993.

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

[FR Doc. 93-27610 Filed 11-9-93; 8:45 am]
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DEPARTMENT OF ENERGY

48 CFR Parts 904, 925, 952, and 970

RIN 1991-AB06

Acquisition Regulation; Restrictions on Awards to Foreign Controlled Contractors

AGENCY: Department of Energy (DOE).

ACTION: Interim final rule.

SUMMARY: The Department is amending the Department of Energy Acquisition Regulation (DEAR) to implement section 836 of the Fiscal Year 1993, Defense Authorization Act. That section prohibits award of a contract under a national security program to a company owned by an entity controlled by a foreign government if that company requires access to a proscribed category of information to perform the contract.

DATES: *Effective Date:* This rule will be effective January 10, 1994.

Comments: Written comments must be received by January 10, 1994.

ADDRESSES:

Richard B. Langston, Office of Procurement and Assistance Management (PR-121), Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-8247.

Judith A. Sukol, Office of the Assistant General Counsel for Procurement and Finance (GC-34), Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-1526.

FOR FURTHER INFORMATION CONTACT: Richard B. Langston at the address above.

SUPPLEMENTARY INFORMATION:

I. Background
II. Public Comments
III. Detailed Changes
IV. Procedural Requirements
A. Regulatory Review
B. Review Under Executive Order 12778
C. Review Under the Regulatory Flexibility Act
D. Review Under the Paperwork Reduction Act
E. Review Under Executive Order 12612
F. National Environmental Policy Act

I. Background

Section 836 of Public Law 102-484 prohibits the award of any DOE contract under a national security program to a company owned by an entity controlled by a foreign government if it is necessary for that company to have access to proscribed information in order to perform the contract.

II. Public Comments

The Department has decided to issue this interpretative rule as an interim