standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

**Environment**

We have analyzed this proposed rule under Commandant Instruction M16475.1D and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, we believe that this rule should be categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation as this action relates to the promulgation of operating regulations or procedures for drawbridges. Under figure 2–1, paragraph (32)(e) of the Instruction, an ''Environmental Analysis Checklist'' is not required for this rule. Comments on this section will be considered before we make the final decision on whether to categorically exclude this rule from further environmental review.

**List of Subjects in 33 CFR Part 117**

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

## PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

**Authority:** 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. From January 1, 2007 through March 31, 2007, § 117.709 is amended by suspending paragraph (b) and adding a temporary paragraph (c) to read as follows:

**§ 117.709 Cheesequake Creek.**

* * * * *

(c) The draw of the New Jersey Transit Rail Operations railroad bridge at mile 0.2, need not open for the passage of vessel traffic from January 1, 2007 through March 31, 2007.

Dated: October 3, 2006.

**Timothy S. Sullivan,**

*Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.*

[FR Doc. E6–17578 Filed 10–19–06; 8:45 am]

**BILLING CODE 4910–15–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 799

**[EPA–HQ–OPPT–2002–0073; FRL–8081–3]**

**RIN 2070–AB79**

### Proposed Test Rule for Certain Chemicals on the ATSDR/EPA CERCLA Priority List of Hazardous Substances

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

**ACTION:** Proposed rule.

**SUMMARY:** In this action, EPA is proposing to require testing for certain chemicals on the Agency for Toxic Substances and Disease Registry (ATSDR)/EPA Priority List of Hazardous Substances which is compiled under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), and is soliciting proposals for enforceable consent agreements (ECAs). EPA is proposing a test rule under section 4(a) of the Toxic Substances Control Act (TSCA) that would require manufacturers (including importers) and processors of four chemical substances (chloroethane, hydrogen cyanide, methylene chloride, and sodium cyanide) to conduct testing for certain health effects relating to the manufacture, distribution in commerce, processing, use, or disposal of these substances. The data that would be obtained under the testing program will be used to address health effects data needs identified by ATSDR and EPA for these substances, which are among the hazardous substances most commonly found at sites listed on the CERCLA National Priorities List (NPL) and which are also hazardous air pollutants (HAPs) under section 112 of the Clean Air Act (CAA). EPA is soliciting proposals for ECAs involving the conduct of physiologically based pharmacokinetics (PBPK) studies as an alternative to the testing proposed in this rule, as appropriate. Alternatively, if ECA proposals involving the conduct of PBPK studies are not received, or if received, are not considered by the Agency to be adequate, EPA may consider ECA proposals which cover some or all of the testing identified for a given chemical in this proposed rule.

**DATES:** Comments must be received on or before December 19, 2006. Your request to present oral comments must be in writing and must be received by EPA on or before December 19, 2006.

**ADDRESSES:** Submit your comments, identified by docket (ID) number EPA–HQ–OPPT–2002–0073, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2002–0073. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions*: Direct your comments to docket ID number EPA–HQ–OPPT–2002–0073. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access''system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket*: All documents in the docket are listed in the regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket, EPA Docket Center (EPA/DC). The EPA/DC suffered structural damage due to flooding in June 2006. Although the EPA/DC is continuing operations, there will be temporary changes to the EPA/DC during the clean-up. The EPA/DC Public Reading Room, which was temporarily closed due to flooding, has been relocated in the EPA Headquarters Library, Infoterra Room (Room Number 3334) in EPA West, located at 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. EPA visitors are required to show photographic identification and sign the EPA visitor log. Visitors to the EPA/DC Public Reading Room will be provided with an EPA/DC badge that must be visible at all times while in the EPA Building and returned to the guard upon departure. In addition, security personnel will escort visitors to and from the new EPA/DC Public Reading Room location. Up-to-date information about the EPA/DC is on the EPA website at *http://www.epa.gov/epahome/dockets.htm*.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

*For technical information contact*: Robert Jones, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8161; e-mail address: *jones.robert@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

You may potentially be affected by this action if you manufacture (defined by the statute to include import) or process, or intend to manufacture or process, any of the chemical substances that are listed in § 799.5100(j) of the regulatory text. Any use of the term ''manufacture'' in this document will encompass ''import,'' unless otherwise stated. In addition, as described in Unit V., any person who exports or intends to export, any of the chemical substances in the final rule is subject to the export notification requirements in 40 CFR part 707, subpart D. Persons that could be subject to the requirements in this proposed rule may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of one or more of the four subject chemical sustances (NAICS code 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

- Processors of one or more of the four subject chemical substances (NAICS code 325, 32411), *e.g.,* chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding persons likely to be affected by this action. Other types of persons not listed in this Unit could also be affected. The North American Industry Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain types of businesses. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit IV.F. entitled *Would I Be Required to Test Under This Rule?* and consult the regulatory text at 40 CFR 799.5100(b). If you have any questions regarding the applicability of this action to a particular person, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

If you are a person identified in this unit, you would be subject to the requirements contained in the final rule only if you manufacture (including import) or process, or intend to manufacture or process, any of the four chemical substances that are listed in § 799.5100(b) of the regulatory text.

### *B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI that you mail to EPA as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

### *C. Can I Request an Opportunity to Present Oral Comments to the Agency?*

You may submit a request for an opportunity to present oral comments. This request must be in writing. If such a request is received on or before December 19, 2006, EPA will hold a public meeting on this proposed rule in Washington, DC. This written request must be submitted to the mailing or hand delivery addresses provided under **ADDRESSES**. If such a request is received, EPA will announce the scheduling of

the public meeting in a subsequent **Federal Register** document. If a public meeting is announced, and if you are interested in attending or presenting oral and/or written comments at the public meeting, you should follow the instructions provided in the subsequent **Federal Register** document announcing the public meeting.

## II. Background

### *A. What Action is the Agency Taking?*

EPA is proposing to issue a rule that would require manufacturers and processors to test certain chemical substances on the ATSDR/EPA CERCLA Priority List of Hazardous Substances. EPA is proposing this test rule to address data needs identified by ATSDR to enable ATSDR to conduct comprehensive health assessments for populations living near sites identified on the CERCLA NPL that may be exposed to any of the four chemical substances. The four chemicals included in this proposed rule were selected and the respective data needs were identified after a lengthy review process. As detailed in this unit, the process began with the listing of contaminated sites on the NPL, and the identification of hazardous substances most commonly found at sites on the NPL. Toxicological profiles and priority data needs were developed for a number of these chemicals according to the ATSDR ''Decision Guide for Identifying Substance-Specific Data Needs Related to Toxicological Profiles'' (54 FR 37618, September 11, 1989) (Decision Guide), and the priority data needs were reviewed by a number of Federal agencies (e.g., ATSDR, EPA (Office of Air and Radiation (OAR), OPPT, Office of Solid Waste and Emergency Response (OSWER), Office of Water (OW), and Office of Research and Development (ORD)), Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH), and the National Toxicology Program (NTP) at the National Institute for Environmental Health and Science (NIEHS)), as well as the public.

ATSDR is required under CERCLA section 104(i)(3) to perform extensive reviews of the scientific literature in order to develop and update toxicological profiles for the hazardous substances which are most commonly found at sites on the NPL. The toxicological profiles are developed by ATSDR in collaboration with EPA and NTP, independent peer reviewers, and the public. When developing the toxicological profiles, ATSDR identifies any available data that would be necessary for a complete understanding of the chemicals. See CERCLA section 104(i)(3). ATSDR then determines, by applying certain criteria, whether an existing ''data gap'' constitutes a ''data need'' that is critical to its ability to meet its statutory mandates under CERCLA section 104(i), such as the performance of health assessments for NPL and certain other facilities, or whether the missing data would only be useful to ATSDR in conducting a thorough review of a chemical. The criteria used in making this distinction are described in ATSDR's Decision Guide.

Chemical-specific Priority Data Needs (PDN) documents are then compiled by ATSDR to describe the data needs identified for each hazardous substance commonly found at sites on the NPL. PDN documents undergo several reviews, including public review, peer review by an external peer review panel, and review by scientists at the NTP and the Centers for Disease Control (CDC). ATSDR also coordinates its identification of PDNs with EPA and NIEHS through the Tri-Agency Superfund Applied Research Committee (TASARC). On October 17, 1991, ATSDR announced PDNs for 38 chemical substances commonly found at NPL sites, and allowed the public to comment on the needs identified (56 FR 52178, October 17, 1991). ATSDR received comments from academic institutions, industry groups, law firms, health groups, environmental groups, and government agencies. Manufacturers and processors were encouraged to volunteer to conduct research to fill specific priority data needs. ATSDR proposed procedures for conducting the needed research voluntarily as part of the ATSDR Substance-Specific Applied Research Program (SSARP) (57 FR 4758, February 7, 1992). A public meeting was held on April 29, 1992, to discuss voluntary testing agreements associated with any of the chemical substances. ATSDR announced final priority data needs for the 38 chemical substances and offered the public an opportunity to participate in a voluntary testing program to fill these data needs (57 FR 54160, November 16, 1992).

On October 27, 1992, ATSDR referred 60 data needs for the 38 chemical substances to EPA, and requested that EPA use its authority under TSCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136 to 136y, to obtain the needed data (Ref. 3). ATSDR's request was evaluated within EPA by OPPT, OAR, OW, OSWER, and ORD. Other Federal agencies, including OSHA, NIOSH, CPSC, and the Mine Safety and Health Administration (MSHA) also reviewed the referral. In addition, ATSDR's request was discussed at a TASARC meeting held in 1993.

EPA responded in part in December, 1992 (Ref. 4) and in April, 1993 (Ref. 5). These responses noted that, for a variety of reasons, 18 of the 38 chemical substances were more suitable for consideration by EPA for inclusion in potential future testing actions under TSCA and/or FIFRA, and that these substances and information needs would be prioritized based on various factors including, but not limited to, the appropriateness of using TSCA authority to require testing and the needs of other EPA offices and agencies for the test data.

On November 9, 1993, EPA agreed to consider the development of testing actions for most of the PDNs for 12 of the chemical substances referred by ATSDR (Ref. 6). The 12 chemicals included mercury, vinyl chloride, benzene, trichloroethylene, chromium, tetrachloroethylene, cyanide, beryllium, toluene, methylene chloride, di(2-ethylhexyl) phthalate (DEHP), and chloroethane. Arsenic, chloroform, carbon tetrachloride, nickel, zinc, and selenium were determined to be lower priority candidates for testing under TSCA section 4 authority at that time.

For testing purposes, sodium cyanide was deemed most relevant for testing by ATSDR. Sodium cyanide is prevalent at hazardous waste sites and is suitable for testing by the oral route, the major route of concern identified by ATSDR. Hydrogen cyanide is the most prevalent form of cyanide found in air, and is suitable for testing by inhalation, the major route of concern identified by EPA's OAR (Ref. 12). Simple cyanides, such as sodium cyanide and hydrogen cyanide dissociate completely yielding the cyanide ion that is the object of concern. Complex cyanides are less bioavailable and therefore less toxic. Complex cyanides are not good cyanide species for testing free cyanide toxicity (Ref. 13).

On September 30, 1994 (59 FR 49934) (FRL–4756–5), EPA invited manufacturers and processors to voluntarily develop and submit testing program proposals to EPA for consideration in the development of ECAs. The notice described testing needs for vinyl chloride, benzene, trichloroethylene, tetrachloroethylene, hydrogen cyanide, sodium cyanide, toluene, methylene chloride, chloroethane, mercury, chromium, and beryllium. The metals (mercury, chromium, and beryllium) were included, but the specific tests for these

substances were not described in the solicitation.

EPA received no proposals for testing through the solicitation, but the American Chemistry Council, rather than entering into an ECA with EPA, agreed to test vinyl chloride under a voluntary agreement with ATSDR (Ref. 11). That testing has been completed and accepted by ATSDR.

EPA, at this point, has determined that it would propose testing for the following substances under a TSCA section 4 test rule: Chloroethane (Chemical Abstract Service Registry Number (CAS No.) 75–00–3), hydrogen and sodium cyanide (CAS Nos. 74–90–8 and 143–33–9, respectively), and methylene chloride (CAS No. 75–09–2). Testing on DEHP is being deferred until EPA further defines its testing objectives and approach. At ATSDR's recommendation, and with TASARC's concurrence, testing for the metals will be considered for inclusion under separate TSCA section 4 testing actions, to the extent that the TSCA section 4 findings can be made, because these metals present unique issues related to fate, transport, speciation, bioavailability, and metabolism under different environmental conditions, and other issues specific to metals (Ref. 8).

Benzene, tetrachloroethylene, toluene, and trichloroethylene are among the 20 chemicals sponsored under Tier 1 of the pilot phase of EPA's Voluntary Children's Chemical Evaluation Program (VCCEP). The VCCEP is intended to provide data to help the public understand the potential health risks to children associated with certain chemicals. As explained in the December 26, 2000 **Federal Register** notice that announced the VCCEP (65 FR 81699) (FRL–6758–5), companies that manufacture or import certain chemicals may volunteer to sponsor an evaluation of these chemical substances in Tier 1 of the VCCEP pilot. As part of their sponsorship, companies collect and/or develop health effects and exposure information on their chemical(s). The VCCEP consists of three tiers to which a sponsor can commit to separately. Tier 1 includes an assessment of acute toxicity, repeated dose toxicity with reproductive and developmental toxicity screens, and genotoxicity, as well as an assessment of readily available exposure information. As part of the VCCEP Tier 1 sponsorship commitment, sponsors also assess the need for additional toxicity and exposure data, which could be provided by the next tier, to more fully characterize the risks the chemical may pose to children. After the submission of Tier 1 information and its evaluation by a Peer Consultation Group, EPA will review the sponsor's submission and the Peer Consultation report and then announce the Agency's decision as to whether additional information (i.e., toxicity testing and/or exposure information) is needed to adequately characterize the chemical's risk to children. If additional information is needed, companies may sponsor chemicals at a higher Tier under VCCEP. Additional information about the VCCEP, including the framework document and archives of public meetings, is available at the website *http://www.epa.gov/chemrtk/vccep/childhlt.htm*.

EPA has decided not to include benzene, tetrachloroethylene, toluene, and trichloroethylene in this proposed TSCA section 4 test rule. Instead, EPA has decided to continue evaluation and review of the data needs for these four substances within the context of previous commitments made by the sponsors of these substances under VCCEP. EPA expects that one of the outcomes of this evaluation will be an Agency decision on whether to pursue one or more TSCA section 4 testing action(s) for these chemicals.

ATSDR has developed criteria for evaluating the status of the PDNs as new information becomes available (67 FR 4836, January 31, 2002) and ATSDR provides updates on the status of the PDNs in the SSARP approximately every 3 years. Based on these criteria and the review of the current literature, ATSDR determines whether a PDN has been filled or is unchanged. A PDN is considered by ATSDR to be filled if information (i.e., new peer-reviewed and publicly available studies) to address the PDN has been identified and accepted by ATSDR. In addition, ATSDR considers a PDN to be filled if a study to generate the needed information has been initiated. In this latter case, even though the study has not yet been completed, ATSDR no longer considers it a priority to initiate additional studies at this time. During the literature review by ATSDR, new studies may be identified suggesting other effects of concern which were not included in the original list of PDNs. In such cases, additional PDNs may be added to the SSARP. This proposed TSCA section 4 test rule incorporates the PDNs listed in the latest update of the SSARP (70 FR 73749, December 13, 2005).

In addition to its proposal to require the testing of four chemical substances, EPA is soliciting proposals for ECAs as an alternative to the testing proposed in this document, as appropriate (see Unit IV.E.).

*B. How Would the Data Developed Under this Test Rule Be Used?*

ATSDR and EPA's OAR have asked that OPPT obtain specific data for these chemicals through its authority under TSCA to assist ATSDR and EPA in fulfilling their responsibilities under various statutes. For example, EPA is proposing to use its TSCA section 4 authority to obtain data supporting ATSDR's Substance-Specific Applied Research Program, a program for collecting the data and other information needed for developing health assessments for populations located near ''Superfund sites,'' i.e., sites that are included on the NPL under CERCLA, 42 U.S.C. 9601 *et seq*. ATSDR referred the chemicals subject to this action to EPA under the authority of section 104(i) of CERCLA, 42 U.S.C. 9604(i).

Section 104(i)(2) of CERCLA requires ATSDR and EPA to prepare and revise a list of hazardous substances which are most commonly found at sites listed on the CERCLA NPL and which ATSDR and EPA, in their sole discretion, determine are posing the most significant potential threat to human health.

Section 104(i)(3) of CERCLA directs ATSDR to prepare toxicological profiles for each substance included on the ATSDR/EPA list of chemicals most commonly found at NPL sites and it prescribes the profiles' contents. Each profile includes an examination, summary, and interpretation of available toxicological information and epidemiological evaluations on a hazardous substance to ascertain levels of human exposure and the associated human health effects. The adequacy of data currently available and under development are also evaluated in the toxicological profiles. ATSDR will update the toxicological profiles with the data obtained under the testing program proposed in this rule. If ATSDR determines that adequate information on a chemical substance is not available or is under development, ATSDR is required to assure the initiation of a program of research on the substance to determine its health effects including using toxicological testing. See CERCLA section 104(i)(5)(A) and (C).

Section 104(i)(5)(C) of CERCLA requires ATSDR to coordinate with EPA and NTP to avoid duplicative research being conducted in other programs and under other authorities. Section 104(i)(5)(D) of CERCLA states ''it is the sense of Congress that the costs of research programs'' initiated by ATSDR ''be borne by the manufacturers and processors of the hazardous substance

in question as required in programs of toxicological testing under the Toxic Substances Control Act.''

For purposes of the chemicals included in this proposed rule, ATSDR has determined that adequate information on the health effects of these chemical substances for certain endpoints is not available (70 FR 73749, December 13, 2005) (Ref. 3). Testing under TSCA would ensure that these substances are tested at the earliest practicable date.

EPA is often in a position of making decisions in the face of uncertainty. Requiring these additional data will allow EPA to refine risk assessments and reduce uncertainty. Nevertheless, EPA will continue to make decisions as the state-of-the-science evolves and data are being generated. The data that would be developed under the rule, as proposed, would provide a stronger scientific basis for risk assessments developed by EPA, other Federal agencies, State, and local governments, and the general public. Assessments affect decisions for listing/delisting the chemicals from regulatory lists of chemicals including, for example, the CERCLA section 104(i)(2)(A) list of hazardous substances most commonly found at sites on the NPL, and the list of HAPs under section 112 of CAA. The data would also be expected to influence other regulatory decisions such as how much of the chemical should be removed from Superfund sites, and what concentrations can safely be allowed in the air and water. The data would improve decisions setting protective standards and guidelines, and they could affect decisions for regulating the manufacturing, processing, distribution in commerce, use, and disposal of these chemical substances.

EPA would also use the data provided by this proposed TSCA test rule in various chemical evaluations EPA performs to meet the requirements under CAA, 42 U.S.C. 7401 *et seq.* For example, section 112(f) of CAA, 42 U.S.C. 7412(f), requires EPA to assess risks of HAPs remaining (i.e., residual risks) after maximum achievable control technology (MACT) standards have been imposed. MACT standards are technology-based air emission standards required under section 112(d) of CAA, 42 U.S.C. 7412(d). Studies included in this proposed rule would generate data useful for determining the nature and magnitude of residual risks. Based on these and other available data, EPA must decide whether additional standards (post-MACT standards) will be necessary for protecting the public health with an ample margin of safety.

In addition, the chemical substances identified in this proposed test rule are all included on the list of HAPs in section 112(b)(1) of CAA, 42 U.S.C. 7412(b)(1). Pursuant to section 112(b)(4) of CAA, 42 U.S.C. 7412(b)(4), ''if the Administrator determines that information on health or environmental effects of a substance is not sufficient to make a determination [that the list of HAPs should be modified], the [Agency] may use any authority available to the Administrator to acquire such information.'' If the data collected under the final TSCA test rule show that a chemical substance is not a concern to human health, this information may be helpful in making decisions concerning the potential delisting of any substance from the CAA HAPs list.

The data that would be developed under the final TSCA test rule may also be used to support assessments and other Agency actions, such as those related to the accidental release prevention program under section 112(r) of CAA, 42 U.S.C. 7412(r). The development of data under the final rule may also be used in conjunction with EPA's efforts to fulfill the Agency's statutory obligation under section 103(d) of CAA, 42 U.S.C. 7403(d), to conduct a research program on the health effects of air pollutants. For a more detailed discussion about how testing generally relates to requirements under the CAA, refer to the proposed TSCA section 4 test rule for HAPs at 61 FR 33178, June 26, 1996 (FRL–4869–1) and amended at 62 FR 67466, December 24, 1997 (FRL–5742–2) and at 63 FR 19694, April 21, 1998 (FRL–5780–6).

In developing this proposed rule, EPA and ATSDR have made maximum use of scientifically adequate existing test data to avoid unnecessary, duplicative testing, thereby avoiding the excessive use of animal testing. If at any time, including after this rule is finalized, the Agency receives adequate existing data that fulfill a specific data need for one of these chemicals, EPA will ensure that unnecessary testing is not required. In addition, EPA is particularly interested in receiving ECA proposals for PBPK studies as an alternative to the testing specified in this proposed rule, as appropriate (see Unit IV.E.).

All of the chemicals included in this proposed rule are of broad programmatic interest, and are included in the Agency's Integrated Risk Information System (IRIS). The health effects data that would be generated by the final rule may result in improvement of the health effects database and increased confidence in the reference doses (RfDs) and reference concentrations (RfCs) developed by EPA that are contained in IRIS. Improvements to the quality of IRIS data can result in considerable benefits to the public, because IRIS is publicly available and is used by a wide variety of governmental and non-governmental entities for assessing the safety of chemicals.

### *C. What is the Agency's Authority for Taking this Action?*

EPA is proposing a test rule under TSCA section 4(a), 15 U.S.C. 2603(a), that would require certain health effects testing for four chemical substances for which the ATSDR has PDNs. In addition, EPA's OAR may use the submitted data to implement section 112 of CAA. With this data, OAR will be able to characterize risks associated with both acute and longer term exposures.

Section 2(b)(1) of TSCA, 15 U.S.C. 2601(b)(1), states that it is the policy of the United States that ''adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [which is defined by statute to include import] and those who process such chemical substances and mixtures[.]'' To implement this policy, TSCA section 4(a) mandates that EPA require by rule that manufacturers and processors of chemical substances and mixtures conduct testing if the Administrator finds that:

(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data[.]

If EPA makes these findings for a chemical substance or mixture, the Administrator must require that testing be conducted on that chemical substance or mixture. The purpose of the testing would be to develop data about the substance's or mixture's health and environmental effects for which there is an insufficiency of data and experience, and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of the substance or mixture, or any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

Once the Administrator has made a finding under TSCA section 4(a)(1)(A)(i) (*i.e.,* a finding that a chemical substance may present an unreasonable risk of injury to health or the environment) or a finding under TSCA section 4(a)(1)(B)(i) (*i.e.,* a finding that a chemical substance is or will be produced in substantial quantities and it may either enter the environment in substantial quantities or there may be significant or substantial human exposure to the chemical substance), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance. EPA need not limit the scope of testing required to the factual basis for TSCA section 4(a)(1)(A)(i) or (B)(i) findings as long as EPA also finds that there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and that testing is necessary to develop such data. This approach is explained in more detail in EPA's TSCA section 4(a)(1)(B) Final Statement of Policy published in the **Federal Register** issue of May 14, 1993 (58 FR 28736, 28738–28739) (''B'' Policy).

## III. Findings

### *A. What is the Basis for EPA's Proposal to Test These Chemical Substances?*

As indicated in Unit II.C., in order to issue a rule under TSCA section 4(a) requiring the testing of chemical substances or mixtures, EPA must make certain findings for those chemicals regarding:

1. Risk (TSCA section 4(a)(1)(A)(i)); or
2. Production and either substantial release or significant or substantial human exposure (TSCA section 4(a)(1)(B)(i)); and
3. That the available data and experience are insufficient for EPA to determine or predict the health or environmental effects of the manufacture, distribution in commerce, processing, use, or disposal of the chemicals or mixtures subject to the rule or of any combination of such activities; and
4. That testing is necessary to develop the data.

### *B. What are EPA's Preliminary Findings Regarding the Chemical Substances in This Proposed Rule?*

EPA is proposing to require the testing of the chemical substances included in this test rule based on its preliminary findings under both TSCA section 4(a)(1)(A)(i) relating to risk to health or the environment and TSCA section 4(a)(1)(B)(i) relating to ''substantial'' production, and ''substantial'' release into the environment, and/or ''significant'' and/or ''substantial'' human exposure, as well as findings under TSCA sections 4(a)(1)(A)(ii) and (iii) and TSCA sections 4(a)(1)(B)(ii) and (iii), regarding the insufficiency of the available data and experience and whether testing is necessary to develop the data.

EPA has made preliminary findings under TSCA section 4(a)(1)(A)(i) that the chemical substances identified in this proposal may present an unreasonable risk of injury to health or the environment. Consistent with criteria discussed in its ''B'' Policy, EPA has also made preliminary findings under TSCA section 4(a)(1)(B)(i) that the chemical substances are produced in substantial quantities, and that they enter or may reasonably be anticipated to enter the environment in substantial quantities, and/or that there is or may be significant and/or substantial human exposure to these chemicals. EPA is making preliminary findings that the available data and experience are inadequate for determining or predicting the effects of manufacture, distribution in commerce, processing, use, or disposal of each of these substances on health or the environment or of any combination of such activities, (TSCA sections 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii)), and EPA is making preliminary findings that testing is necessary to develop the needed data (TSCA sections 4(a)(1)(A)(iii) and 4(a)(1)(B)(iii)).

In EPA's ''B'' Policy, discussed in Unit II.C., EPA explained that it generally considers ''substantial'' production of a chemical substance or mixture to be aggregate production (including import) volume equaling or exceeding one million pounds (lbs) per year (58 FR 28736, 28746, May 14, 1993). The ''B'' Policy also provides guidelines that are generally considered in evaluating whether there is ''substantial release,'' and/or ''substantial human exposure'' of workers, consumers, and the general population to a chemical substance or mixture. Refer to EPA's ''B'' Policy for further discussion on how EPA generally evaluates chemicals or mixtures under TSCA section 4(a)(1)(B)(i). For the reasons set out in the ''B'' Policy, EPA believes that the guidance included in the ''B'' Policy is appropriate for consideration in this proposed rule and EPA sees no reason not to act consistently with the guidelines with respect to the chemicals included in this proposed rule.

A detailed discussion of EPA's preliminary findings for each chemical substance included in this proposed rule is contained in a separate document entitled *TSCA Section 4(a) Preliminary Findings: Supporting Document for the Proposed Test Rule for Certain Chemical Substances on the ATSDR/EPA CERCLA Priority List of Hazardous Substances* that is available in the docket (Ref. 1). Table 1 of this unit (Summary, TSCA Section 4(a) Preliminary Statutory Findings) provides a summary of the preliminary findings EPA has made for the four chemicals that are the subject of this proposed rule.

TABLE 1.— SUMMARY, TSCA SECTION 4(A) PRELIMINARY STATUTORY FINDINGS

| Chemical substance CAS No. | Health effects used in making the TSCA section 4(a)(1)(A)(i) findings | Basis for the TSCA section 4(a)(1)(B)(i) findings | Testing endpoints [1] (reference to TSCA test guidelines) |
|---|---|---|---|
| Chloroethane CAS No. 75–00–3 | Lung, liver, and heart toxicity<br>Neurological effects<br>Gastrointestinal effects | Substantial production: ≥1,000,000 lbs/year<br>Substantial human exposure: ≥1,000 workers | § 799.9110 acute oral toxicity<br>§ 799.9310 90–day oral toxicity in rodents<br>§ 799.9370 prenatal developmental Toxicity—inhalation<br>§ 799.9380 reproduction and fertility effects—oral and inhalation<br>§ 799.9430 combined chronic toxicity/carcinogenicity—inhalation<br>§ 799.9620 neurotoxicity screening battery—oral and inhalation<br>§ 799.9630 developmental neurotoxicity—inhalation<br>§ 799.9780 immunotoxicity—oral and inhalation |
| Hydrogen cyanide CAS No. 74–90–8 | Acute toxicity<br>Neurotoxicity<br>Thyroid toxicity | Substantial production: ≥1,000,000 lbs/year<br>Substantial environmental release: ≥1,000,000 lbs/year<br>Substantial human exposure: ≥1,000 workers | § 799.9135 acute inhalation toxicity with histopathology<br>§ 799.9346 90–day inhalation toxicity<br>§ 799.9370 prenatal developmental Toxicity—inhalation<br>§ 799.9380 reproduction and fertility effects—inhalation<br>§ 799.9620 neurotoxicity screening battery—inhalation<br>§ 798.6500 schedule-controlled operant behavior—inhalation |
| Sodium cyanide CAS No. 143–33–9 | Acute toxicity<br>Neurotoxicity<br>Thyroid toxicity | Substantial production: ≥1,000,000 lbs/year<br>Substantial human exposure: ≥1,000 workers | § 799.9370 Prenatal Developmental Toxicity—oral |
| Methylene chloride CAS No. 75–09–2 | Neurotoxicity<br>Liver toxicity<br>Developmental toxicity<br>Oncogenicity<br>Teratogenicity | Substantial production: ≥1,000,000 lbs/year<br>Substantial environmental release: ≥1,000,000 lbs/year<br>Substantial human exposure: ≥1,000 workers, ≥10,000 consumers, ≥100,000 general population | § 799.9370 prenatal developmental toxicity—inhalation<br>§ 798.6500 schedule-controlled operant behavior—oral<br>§ 799.9630 developmental neurotoxicity—inhalation |

[1] Support for the preliminary finding that the available data are insufficient to determine or predict the human health effects of a chemical substance for these particular endpoints and for the finding that testing is necessary to develop the necessary data can be found in ''TSCA Section 4(a) Preliminary Findings: Supporting Document for the Proposed Test Rule for Certain Chemical Substances on the ATSDR/EPA CERCLA Priority List of Hazardous Substances'' (Ref. 1).

## IV. Proposed Testing

### *A. How Would the Studies Proposed Under This Test Rule Be Conducted?*

EPA is proposing specific testing and reporting requirements for each of the chemical substances specified in Table 2 of § 799.5100(j) of the proposed regulatory text, according to the test standards set forth at § 799.5100(j) of the proposed regulatory text. Testing under this proposed rule would be conducted in accordance with TSCA Good Laboratory Practice Standards (GLPS) (40 CFR part 792).

### *B. What Substances Would Be Tested Under This Rule?*

EPA is proposing that, with the exception of hydrogen cyanide and sodium cyanide, the chemical substances listed in Table 2 of § 799.5100(j) of the proposed regulatory text be tested at a purity of at least 99%. EPA is proposing that hydrogen cyanide and sodium cyanide be tested at a purity of at least 95%. Using data on relatively pure chemicals, EPA avoids the possible confounding effects of impurities that might be found in technical grade substances. EPA believes that the specified purities of 95% and 99% are available or readily achievable for all substances covered by this rule based on a search of on-line information from catalogs of chemical suppliers (*http://chemacx.cambridgesoft.com/chemacx/index.asp*) and chemical safety information provided on-line by the International Programme on Chemical Safety (IPCS) (*http://www.inchem.org*).

### *C. When Would Any Testing Imposed by This Rule Begin?*

The proposed testing requirements contained in this proposed rule are not effective until and unless the Agency issues a subsequent final rule. Based on the effective date of the final rule, which is typically 30 days after the publication of a final rule in the **Federal Register**, the test sponsor would need to plan the initiation of the required testing at a time sufficient to allow the final report to be submitted by the deadline indicated in § 799.5100(j) of the proposed regulatory text.

### *D . May I Submit Data From Studies in Which the Test Substance was Administered by a Route of Administration Other Than the Route Specified for Testing Under This Proposed Rule?*

EPA may accept data from studies in which the test substance was administered by a route of administration other than the route specified in the test under this proposed rule. Such data could result in a decision by EPA not to include the related testing under the proposed rule

in the final rule or in EPA's withdrawal of the related testing following promulgation of the final rule. These data, however, must be accompanied by an appropriate analysis that includes a scientifically sound route-to-route extrapolation of the quantitative dose-response relationship to meet the testing requirements from this rulemaking. Route-to-route extrapolations are generally conducted with the use of a PBPK model. A PBPK model simulates the kinetics (i.e., absorption, distribution, metabolism, and elimination) of a chemical substance, and can be used to derive an internal dose at a target site (or an internal dose that can be used as a surrogate for the dose at a target site) that would result from a given exposure scenario. The internal dose can then be related to the response to develop a more robust and biologically relevant characterization of the dose-response relationship. For example, a PBPK model would first be used to estimate an internal dose (e.g., average blood level) that would occur in a test species from an exposure at a given level to the chemical in drinking water. The model can then be used to estimate what the level of chemical in air would need to be to yield a comparable average blood level for the test species assuming a continuous inhalation exposure. This prediction then forms the basis for the route-to-route extrapolation.

There is no prescriptive formula or generic PBPK model that can be used to conduct a route-to-route extrapolation. EPA realizes that PBPK modeling expertise is often required, and that the approach and supporting arguments must be developed and evaluated on a case-by-case basis. Increasingly, however, route-to-route extrapolation using a PBPK model has been shown to be a useful and less expensive alternative to conducting studies via different routes of exposure. By potentially reducing the number of toxicity tests that are performed to fill the data needs, use of PBPK approaches can also reduce the number of test animals that otherwise would have been required.

Some of the main factors to consider in presenting a scientifically supportable route-to-route extrapolation include:

1. The nature of the adverse effect,

2. The adequacy of the kinetic and physiology data used to develop the PBPK model for the test species of interest, and

3. Sufficient understanding of the chemical-specific toxicokinetic processes that might result in a difference in the internal dose depending upon the route of exposure. The nature of the adverse effect is a key determinant of whether a route-to-route extrapolation is feasible. If an adverse effect is observed at a target site following delivery of the chemical or a metabolite via the systemic circulation, then, regardless of the route of exposure, a given internal concentration in the blood should reproducibly yield a comparable response. If, however, the adverse effect of interest occurs from direct action with barrier tissues at the portal-of-entry (*e.g.,* epithelial damage in the nasal region or the gastrointestinal (GI) tract), then one would not expect similar toxicity to occur from a different route of exposure. Secondly, the PBPK model must be calibrated and tested with sufficient data in the test species of interest to support a credible estimate of the internal dose. Third, the kinetics of the chemical must be sufficiently understood with respect to differences in internal disposition that may occur following different routes of exposure. For example, if the chemical is extensively metabolized in the liver, then the initial level of parent compound in the systemic circulation will depend upon whether the chemical is orally absorbed, and immediately enters the liver from the portal circulation where some portion will be metabolized before being systemically distributed, or is absorbed through the lungs and is immediately available for systemic distribution.

### *E. May I Submit Proposals for Enforceable Consent Agreements (ECAs)?*

Yes. EPA encourages the submission of such proposals, which could lead to the development of ECAs. EPA is particularly interested in receiving proposals for ECAs involving the conduct of PBPK studies as an alternative to the testing specified in this proposed rule, as appropriate. Route-to-route extrapolation using a PBPK model is a potentially useful and less expensive alternative to conducting studies via different routes of exposure. PBPK approaches can additionally reduce the number of test animals that would otherwise have been needed in order to conduct the toxicity tests specified in the rule. Alternatively, if ECA proposals involving the conduct of PBPK studies are not received, or if received, are not considered by the Agency to be adequate, EPA may consider ECA proposals received which cover some or all of the testing identified for a given chemical in this proposed rule.

Each ECA proposal submitted to EPA in response to this proposed rule should include the name of the chemical(s), a detailed description of the proposed study(ies), and, in the case of ECAs involving the conduct of PBPK studies, a discussion of how the proposed studies would support the application of the pharmacokinetics data in performing route-to-route extrapolations. Such discussions should reflect an understanding of the factors involved in developing a scientifically supportable route-to-route extrapolation (see Unit IV.D.), the existing database on the chemical, and the testing specified in this proposed test rule.

Each study proposal should be labeled: ''Proposal for Study of (name of chemical),'' identified by docket ID number EPA–HQ–OPPT–2002–0073, and sent according to the instructions under **ADDRESSES**.

EPA would review the proposals and decide whether to proceed with the ECA process under the procedures in 40 CFR 790.22. To initiate the ECA procedures, EPA would publish a notice in the **Federal Register** soliciting persons interested in participating in or monitoring negotiations for the development of an ECA to send EPA a written notice of their interest.

### *F. Would I Be Required to Test Under This Rule?*

Under TSCA sections 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA has made preliminary findings that there are insufficient data and experience to reasonably determine or predict health effects resulting from the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substances listed in this proposed rule or of any combination of such activities. As a result, under TSCA section 4(b)(3)(B), manufacturers and processors of these substances, and those who intend to manufacture or process them, would be subject to the rule with regard to those listed chemicals which they manufacture or process.

1. *Would I be subject to this rule?* You would be subject to the final rule and may be required to test if you manufacture (which is defined by statute to include import) or process, or intend to manufacture or process, one or more of the chemical substances listed in Table 2 of § 799.5100(j) in the proposed regulatory text during the time period discussed in Unit IV.F.2. However, if you do not know or cannot reasonably ascertain that you manufacture or process a listed test rule substance (based on all information in your possession or control, as well as all

information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you would not be subject to the final rule for that listed substance.

2. *When would my manufacture or processing (or my intent to do so) cause me to be subject to this rule?* You would be subject to the final rule if you manufacture or process, or intend to manufacture or process, a substance listed in Table 2 of § 799.5100(j) of the proposed regulatory text at any time from the effective date of the final test rule to the end of the test cost reimbursement period. The term ''reimbursement period'' is defined at 40 CFR 791.3(h) and may vary in length for each substance to be tested under a final TSCA section 4(a) test rule, depending on when testing is completed. See Unit IV.F.4.

3. *Would I be required to test if I were subject to the rule?* It depends on the nature of your activities. All persons who would be subject to the final TSCA section 4(a) test rule, which unless otherwise noted in the regulatory text would incorporate EPA's generic procedures applicable to TSCA section 4(a) test rules (contained within 40 CFR part 790), would fall into one of two groups, designated here as Tier 1 and Tier 2. Persons in Tier 1 (those who would have to initially comply with the final rule) would either: Submit to EPA letters of intent to conduct testing, conduct this testing, and submit the test data to EPA; or apply to and obtain from EPA exemptions from testing.

Persons in Tier 2 (those who would not have to initially comply with the final rule) would not need to take any action unless they are notified by EPA that they are required to do so, as described in Unit IV.F.3.b. Note that persons in Tier 1 who obtain exemptions and persons in Tier 2 would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit IV.F.4.

a. *Who would be in Tier 1 and Tier 2?* All persons subject to the final rule would be considered to be in Tier 1 unless they fall within Tier 2. The table in this unit describes who is in Tier 1 and Tier 2.

TABLE 2.—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2

| Tier 1 (Persons initially required to comply) | Tier 2 (Persons not initially required to comply) |
|---|---|
| Persons who manufacture (as defined at TSCA section 3(7)), or intend to manufacture, a test rule subtance, and who are not listed under Tier 2 | A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a test rule substance solely as one or more of the following:<br>–As a byproduct (as defined at 40 CFR 791.3(c));<br>–As an impurity (as defined at 40 CFR 790.3);<br>–As a naturally occurring substance (as defined at 40 CFR 710.4(b));<br>–As a non-isolated intermediate (as defined at 40 CFR 704.3);<br>–As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i));<br>–In amounts of less than 500 kilogram (kg) (1,100 lbs) annually (as described at 40 CFR 790.42(a)(4)); or<br>–In small quantities solely for research and development (as described at 40 CFR 790.42(a)(5)).<br>B. Persons who process (as defined at TSCA section 3(10)) or intend to process a test rule substance (see 40 CFR 790.42(a)(2)). |

Under 40 CFR 790.2, EPA may establish procedures applying to specific test rules that differ from the generic procedures governing TSCA section 4(a) test rules in 40 CFR part 790. For purposes of this proposed rule, EPA is proposing to establish certain requirements that differ from those under 40 CFR part 790.

In this proposed test rule, EPA has reconfigured the tiers in 40 CFR 790.42. In addition to processors, manufacturers of less than 500 kg (1,100 lbs) per year (''small-volume manufacturers''), and manufacturers of small quantities for research and development (''R&D manufacturers''), EPA has added the following persons to Tier 2: Byproduct manufacturers, impurity manufacturers, manufacturers of naturally occurring substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 substances. The Agency took administrative burden and complexity into account in determining who was to be in Tier 1 in this proposed rule. EPA believes that those persons in Tier 1 who would conduct testing under this rule, when finalized, would generally be large chemical manufacturers who, in the experience of the Agency, have traditionally conducted testing or participated in testing consortia under previous TSCA section 4(a) test rules.

The Agency also believes that byproduct manufacturers, impurity manufacturers, manufacturers of naturally occurring substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 substances historically have not themselves participated in testing or contributed to reimbursement of those persons who have conducted testing. EPA understands that these manufacturers may include persons for whom the marginal transaction costs involved in negotiating and administering testing arrangements are deemed likely to raise the expense and burden of testing to a level that is disproportional to the additional benefits of including these persons in Tier 1. Therefore, EPA does not believe that the likelihood of the persons proposed to be added to Tier 2 actually conducting the testing is sufficiently high to justify burdening these persons with Tier 1 requirements (e.g., submitting requests for exemptions). Nevertheless, these persons, along with all other persons in Tier 2, would be subject to reimbursement obligations to persons who actually conduct the testing, as described in Unit IV.F.4.

TSCA section 4(b)(3)(B) requires all manufacturers and/or processors of a chemical substance to test that chemical substance if EPA has made findings under TSCA sections 4(a)(1)(A)(ii) or 4(a)(1)(B)(ii) for that chemical substance, and therefore issued a TSCA section 4(a) test rule requiring testing. However, practicality must be a factor in determining who is subject to a particular test rule. Thus, persons who do not know or cannot reasonably ascertain that they are manufacturing or processing a substance subject to this proposed rule, e.g., manufacturers or processors of a substance as a trace contaminant who are not aware of and cannot reasonably ascertain these activities, would not be subject to the rule. See Unit IV.F.1. and § 799.5100(b)(2) of the proposed regulatory text.

b. *Subdivision of Tier 2 entities.* The Agency is proposing to prioritize which persons in Tier 2 would be required to perform testing, if needed. Specifically, the Agency is proposing that Tier 2 entities be subdivided into:

i. *Tier 2A.* Tier 2 manufacturers, i.e., those who manufacture, or intend to manufacture, a test rule substance solely as one or more of the following: A byproduct, an impurity, a naturally occurring substance, a non-isolated intermediate, a component of a Class 2 substance, in amounts less than 1,100 lbs annually, or in small quantities solely for research and development.

ii. *Tier 2B.* Tier 2 processors, i.e. those who process, or intend to process, a test rule substance (in any form). The terms ''process'' and ''processor'' are defined by TSCA sections 3(10) and 3(11), respectively.

If the Agency needs testing from persons in Tier 2, EPA would seek testing from persons in Tier 2A before proceeding to Tier 2B. It is appropriate to require manufacturers in Tier 2A to submit letters of intent to test or exemption applications before processors are called upon because the Agency believes that testing costs are traditionally passed by manufacturers along to processors, enabling them to share in the costs of testing (Ref. 9). In addition, ''[t]here are [typically] so many processors [of a given test rule chemical] that it would be difficult to include them all in the technical decisions about the tests and in the financial decisions about how to allocate the costs'' (Ref. 10).

c. *When would it be appropriate for a person required to comply with the rule to apply for an exemption rather than to submit a letter of intent to conduct testing?* You may apply for an exemption if you believe that the required testing will be performed by another person (or a consortium of persons formed under TSCA section 4(b)(3)(A)). You can find procedures relating to exemptions in 40 CFR 790.80 through 790.99, and in the proposed regulatory text at § 799.5100(c)(2), (c)(5), (c)(7), and (c)(11). In this proposed rule, EPA would not require the submission of equivalence data (i.e., data demonstrating that your substance is equivalent to the substance actually being tested) as a condition for approval of your exemption. Therefore, 40 CFR 790.82(e)(1) and 40 CFR 790.85 would not apply to this test rule.

d. *What would happen if I submitted an exemption application?* EPA believes that requiring the collection of duplicative data is unnecessarily burdensome. As a result, if EPA has received a letter of intent to test from another source or has received (or expects to receive) the test data that would be required under the final rule, the Agency would conditionally approve your exemption application under 40 CFR 790.87.

The Agency would terminate a conditional exemption if a problem occurs with the initiation, conduct, or completion of the required testing, or the submission of the required data to EPA. EPA may then require you to submit a letter of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5100(c)(10) of the proposed regulatory text. In addition, the Agency would terminate a conditional exemption if no letter of intent to test has been received by persons required to comply with the rule. See, e.g., § 799.5100(c)(8) of the proposed regulatory text. (Note that the provisions at 40 CFR 790.48(b) have been incorporated into the regulatory text of this rule; thus, persons subject to this rule are not required to comply with 40 CFR 790.48 itself (see § § 799.5100(c)(4)–(c)(9) and 799.5100(d)(3) of the proposed regulatory text)).

Persons who obtain exemptions or who receive them automatically would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit IV.F.4.

e. *What would my obligations be if I were in Tier 2?* If you are in Tier 2, you would be subject to the rule and you would be responsible for providing reimbursement to persons in Tier 1, as described in Unit IV.F.4. You are considered to have an automatic conditional exemption. You would not need to submit a letter of intent to test or an exemption application unless you are notified by EPA that you are required to do so.

If a problem occurs with the initiation, conduct, or completion of the required testing, or the submission of the required data to EPA, the Agency may require you to submit a letter of intent to test or an exemption application. See 40 CFR 790.93 and the proposed regulatory text at § 799.5100(c)(10).

In addition, you would need to submit a letter of intent to test or an exemption application if:

i. No manufacturer in Tier 1 has notified EPA of its intent to conduct testing; and

ii. EPA has published a **Federal Register** document directing persons in Tier 2 to submit to EPA letters of intent to conduct testing or exemption applications. See the proposed regulatory text at § 799.5100(c)(4), (c)(5), (c)(6), and (c)(7).

The Agency would conditionally approve an exemption application under 40 CFR 790.87, if EPA has received a letter of intent to test or has received (or expects to receive) the test data that would be required under the final rule. EPA is not aware of any circumstances in which test rule Tier 1 entities have sought reimbursement from Tier 2 entities either through private agreements or by soliciting the involvement of the Agency under the reimbursement regulations at 40 CFR part 791.

f. *What would happen if no one submitted a letter of intent to conduct testing?* EPA anticipates that it will receive letters of intent to conduct testing for all of the tests specified and chemical substances included in the rule. However, in the event it does not receive a letter of intent for one or more of the tests required by the rule for any of the chemical substances in the rule within 30 days after the publication of a **Federal Register** document notifying Tier 2 processors of the obligation to submit a letter of intent to conduct testing or to apply for an exemption from testing, EPA would notify all manufacturers and processors of the chemical substance of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document would additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and would give them an opportunity to take corrective action. If no one has notified EPA of its intent to conduct the required testing of the chemical substance within 30 days after receipt of the certified letter or publication of the **Federal Register** document, all manufacturers and processors subject to the rule with respect to that chemical substance who are not already in violation of the rule would be in violation of the rule.

4. *How do the reimbursement procedures work?* In the past, persons subject to test rules have independently worked out among themselves their respective financial contributions to those persons who have actually conducted the testing. However, if persons are unable to agree privately on reimbursement, they may take advantage of EPA's reimbursement procedures at 40 CFR part 791, promulgated under the authority of TSCA section 4(c). These procedures include: The opportunity for a hearing with the American Arbitration

Association; publication by EPA of a **Federal Register** document concerning the request for a hearing; and the appointment of a hearing officer to propose an order for fair and equitable reimbursement. The hearing officer may base his or her proposed order on the production volume formula set out at 40 CFR 791.48, but is not obligated to do so. Under this proposed rule, amounts manufactured as impurities would be included in production volume (40 CFR 791.48(b)), subject to the discretion of the hearing officer (40 CFR 791.40(a)). The hearing officer's proposed order may become the Agency's final order, which is reviewable in Federal court (40 CFR 791.60).

*G. What Would I Need To Do If I Cannot Complete the Testing Required by the Rule?*

A company who submits a letter of intent to test under the final rule and that subsequently anticipates difficulties in completing the testing by the deadline set forth in the final rule may submit a modification request to the Agency, pursuant to 40 CFR 790.55. EPA will determine whether modification of the test schedule is appropriate, and may first seek public comment on the modification.

*H. What Reporting Requirements are Proposed Under This Test Rule?*

You would be required to submit interim progress reports for a specific test every 6 months, beginning 6 months after the effective date of the final rule. You would be required to submit a final report for a specific test by the deadline indicated as the number of months after the effective date which would be shown in Table 2 of § 799.5100(j) of the proposed regulatory text.

*I. Would There Be Sufficient Test Facilities and Personnel To Undertake the Testing in This Proposed Test Rule?*

EPA's most recent analysis of laboratory capacity (Ref. 7) indicates that available test facilities and personnel would adequately accommodate the majority of the testing proposed in this rule. However, the laboratory capacity for conducting certain tests appears to be constrained because there is a limited number of testing laboratories with the facilities to perform these tests. For example, the current demand for inhalation testing appears to be high. EPA is proposing a relatively small number of inhalation tests (14). Although EPA realizes that in some cases these tests may take longer than anticipated to complete, the Agency believes it will be possible to complete the testing proposed within the time frame specified in this proposed rule. As explained in Unit IV.D., EPA is encouraging the submission of existing data from studies conducted via a route of administration other than the route specified in this proposed rule along with PBPK information which, together, could result in a decision by EPA not to include the related proposed testing in the final rule. Submission of such existing data after promulgation of the final rule could result in a decision by EPA to withdraw the related testing requirements from the final rule. In addition, in Unit IV.E., EPA is encouraging test sponsors to submit ECA proposals for PBPK studies that could further reduce the number of studies, particularly inhalation studies, specified in the rule. See Unit IV.G. for information regarding obtaining a modification of the test schedule.

*J. Might EPA Seek Further Testing of the Chemicals in This Proposed Test Rule?*

If EPA determines that it needs additional data regarding any of the chemical substances included in this proposed rule, the Agency might seek further health and/or environmental effects testing for these chemical substances. Should the Agency decide to seek such additional testing, EPA would initiate a separate action for that purpose.

## V. Export Notification

Any person who exports, or intends to export, one of the chemical substances contained in a final TSCA section 4 action in any form (e.g., as byproducts, impurities, components of Class 2 substances, etc.) is subject to the export notification requirements in TSCA section 12(b)(1) and 40 CFR part 707, subpart D. This approach is consistent with the Agency's approach when the export notification regulations were originally promulgated in 1980 (45 FR 82844, December 16, 1980). Export notification is generally not required for articles, as provided by 40 CFR 707.60(b). Section 12(b) of TSCA states, in part, that any person who exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 must notify the EPA Administrator of such export or intent to export. The Administrator in turn will notify the government of the importing country of EPA's regulatory action with respect to the substance.

## VI. Economic Impacts

EPA has prepared an economic assessment entitled *Economic Assessment for the Proposed ATSDR Test Rule for Four Chemicals* (Ref. 2), a copy of which has been placed in the public docket. This economic assessment evaluates the potential for significant economic impacts as a result of the testing that is being proposed. The total cost of providing test information specified in this proposed rule is estimated to be $8.6 million for all four chemicals subject to the rule (Ref. 2).

While they would be legally subject to this test rule, Tier 2 manufacturers and all processors of a subject chemical would only be required to comply with the requirements of the rule if they are directed to do so by EPA as described in § 799.5085(c)(4) through (c)(10) of the proposed regulatory text. EPA would require Tier 2 manufacturers and/or processors to test only if no Tier 1 manufacturer has submitted a letter of its intent to conduct testing, or if, under 40 CFR 790.93, a problem occurs with the initiation, conduct, or completion of the required testing, or the submission of the required data to EPA. Because EPA has identified at least one manufacturer in Tier 1 for each subject chemical, the Agency expects that, for each chemical in this proposed rule, at least one such person would submit a letter of intent to conduct the required testing and that person would conduct such testing and would submit the test data to EPA. EPA believes that there would not be any costs to Tier 2 manufacturers or processors for conducting the testing required by the final rule because EPA is not aware of any circumstances in which Tier 1 entities have sought reimbursement from Tier 2 entities either through private agreements or by soliciting the involvement of the Agency under the reimbursement regulations at 40 CFR part 791. Given this consistent experience with previous test rules, EPA does not believe that there would be any administrative, negotiation, or any other costs associated with seeking reimbursement from Tier 2 entities.

To evaluate the potential for an adverse economic impact of testing on manufacturers of the chemical substances in this proposed rule, EPA employed a screening approach that compares the annual revenues from the sale of a chemical to the annualized testing costs for that chemical and expresses the testing costs as a percent of revenues generated from each chemical. Annualized testing costs divide testing expenditures into an equivalent, constant yearly expenditure over a longer period of time. To calculate the percent price impact, testing costs (including laboratory and administrative expenditures) are

annualized over 15 years (the expected life of a chemical) using a 7% discount rate. Annualized testing costs are then divided by the estimated total supply of the chemical to derive a unit test cost. The unit test costs are then divided by the chemical's sales price to determine the impact of testing requirements.

EPA estimates the annualized cost to industry of testing the 4 chemicals evaluated in the economic analysis to be $0.9 million with an average annualized cost of testing of approximately $237,000 per chemical (Ref. 2). In addition, the TSCA section 12(b) export notification that would be required only for the first export by a particular exporter to a particular country of each chemical subject to a final TSCA section 4 action, is estimated to average $67.33 for the first time that an exporter must comply with TSCA 12(b) export notification requirements, and $21.81 for each subsequent export notification submitted by an exporter (Ref. 2). The Agency's estimated total costs of testing (including both laboratory and administrative costs), annualized testing costs, price impacts, and public reporting burden hours for this proposed rule are presented in the economic assessment (Ref. 2).

Prices were estimated for each of the four chemicals. The price impact of the test costs is a function of the chemical's price and the production volume. For three of the four chemicals included in the proposed rule the price impact of the proposed requirements is estimated to be less than 1.0%. EPA concludes that for these chemicals the potential for adverse economic impacts is low.

For one of the four chemicals, chloroethane, the estimated price impact is in excess of 1.0%. EPA concludes that there is a potential for adverse economic impacts as a result of the test requirements for this chemical. For chemicals where the profit margins are low, the costs of testing may use a significant part of the profits generated by the chemical.

On the basis of these calculations, EPA believes that the proposed test rule presents a low potential for adverse economic impact for the majority of the chemicals subject to the proposed rule. Because the subject chemical substances have relatively large production volumes, the annualized unit costs of testing, relative to the price of the chemicals, would be very small for most chemicals. However, it cannot be shown that the price impact for chloroethane would be below 1.0%. For this chemical, companies may choose to use revenue sources other than profits from the individual chemicals to pay for testing.

EPA does not provide quantitative estimates of the benefits from these tests. Ideally, a discussion of benefits would focus on the additional benefits to be gained from new information relative to information that already exists. Such an approach could examine the value of new information over and above the value of the information described in the ATSDR toxicological profiles. Because of information constraints on the value of the new information, our evaluation of benefits is qualitative and does not address incremental benefits. We believe, however, that the net benefits of the new information are positive.

## VII. Materials in the Docket

As indicated under **ADDRESSES**, a docket was established for this rulemaking under docket ID number EPA–HQ–OPPT–2002–0073. The following is a listing of the documents that have been placed in the docket for this proposed rule. The docket includes information considered by EPA in developing this proposed rule, including the documents listed in this unit, which are physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these other documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Section 4(a) Preliminary Findings: Supporting Document for the Proposed Test Rule for Certain Chemical Substances on the ATSDR/EPA CERCLA Priority List of Hazardous Substances. Washington, DC. (October, 2005)

2. EPA. Economic Assessment for the Proposed ATSDR Test Rule for Four Chemicals. (July 12, 2006)

3. ATSDR. Letter from Barry Johnson, Assistant Surgeon General, ATSDR, Atlanta GA, to Linda Fisher, Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, EPA. Washington, DC. (October 27, 1992)

4. EPA. Letter to Barry Johnson, Assistant Surgeon-General, ATSDR, from Mark Greenwood, Director, Office of Pollution Prevention and Toxics. (December 30, 1992)

5. EPA. Letter to Barry Johnson, Assistant Surgeon-General, ATSDR, from Joseph Carra, Deputy Director, Office of Pollution Prevention and Toxics. (April 22, 1993)

6. EPA. Letter to Barry Johnson, Assistant Surgeon-General, ATSDR, from Lynn Goldman, Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances. (November 9, 1993)

7. EPA. Analysis of Laboratory Capacity to Support U.S. EPA Chemical Testing Program Initiatives. Economic and Policy Analysis Branch. Washington, DC. (August, 2004)

8. ATSDR. Letter from Christopher De Rosa, P.h. D., Director, Division of Toxicology, Agency for Toxic Substances and Disease Registry to Charles Auer, Director, Chemical Control Division, Office of Pollution Prevention and Toxic Substances. (July 3, 1996)

9. EPA. Toxic Substances; Test Rule Development and Exemption Procedures. Interim Final Rule. 40 CFR part 790. **Federal Register** (50 FR 20652, 20654, May 17, 1985).

10. EPA. Toxic Substances Control Act; Data Reimbursement. Final Rule. 40 CFR part 791. **Federal Register** (48 FR 31786, 31789, July 11, 1983).

11. Huntington Life Sciences. Vinyl Chloride Combined Inhalation Two-Generation Reproduction and Developmental Toxicity Study in CD Rats. Submitted to Chemical Manufacturers Association, Chemstar Department. 1300 Wilson Blvd., Arlington, VA 22209. (January 30, 1998)

12. ATSDR. Toxicological Profile for Cyanide, Draft for Public Comment. U.S. Department of Health and Human Services. Public Health Service. Agency for Toxic Substances and Disease Registry. Division of Toxicology/ Toxicology Information Branch. 1600 Clifton Rd., NE., MS F–32, Atlanta GA 30333. (September 2004)

13. EPA. National Primary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals. Final Rule. 40 CFR parts 141 and 142. **Federal Register** (57 FR 138, July 17, 1992)

## VIII. Statutory and Executive Order Reviews

### *A. Executive Order 12866*

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has designated this proposed rule as a ''significant regulatory action'' under section 3(f) of the Executive Order. Accordingly, EPA submitted this proposed rulemaking to OMB for review under Executive Order 12866 and any changes made in response to OMB comments have been documented in the public docket for this rulemaking as

required by section 6(a)(3)(E) of the Executive Order.

In addition, EPA has prepared an economic analysis of this proposed action, which is contained in a document entitled *Economic Assessment for the Proposed ATSDR Test Rule for Four Chemicals* (Ref. 2). A copy of the economic analysis is available in the docket for this proposed rule and is summarized in Unit VI.

*B. Paperwork Reduction Act*

The information collection requirements contained in TSCA section 4 test rules have already been approved by OMB under the provisions of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control number 2070–0033 (EPA ICR No. 1139). The information collection activities related to export notification under TSCA section 12(b)(1) are already approved under OMB control number 2070–0030 (EPA ICR No. 0795). This proposed rule would not impose any new or amended requirements that would require additional review and/or approval by OMB.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information that is subject to approval under the PRA, unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations codified in chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers incertain EPA regulations is consolidated in 40 CFR part 9.

The estimated paperwork burden and costs for this proposed TSCA section 4 rule are provided for public comment in this proposal. The final rule would present estimates which have been adjusted to reflect any changes made since the proposed rule to reflect public comment received and the content of the final rule.

The standard chemical testing program involves the submission of letters of intent to test (or exemption applications), study plans, semi-annual progress reports, test results, and some administrative costs. For this proposed rule, EPA estimates the public reporting burden for all four chemicals is 10,782 hours. The estimated burden increase for each chemical would on average be 2,695 hours, and the reporting burden per respondent would be 449 hours on average (Ref. 2). The estimated burden of the information collection activities related to export notification is estimated to average 1 burden hour for each chemical/country combination for an initial notification and .5 hours for each subsequent notification (Ref. 2). In estimating the total burden hours approved for the information collection activities related to export notification, the Agency has included sufficient burden hours to accommodate any export notifications that may be required by the Agency's issuance of final chemical test rules. As such, EPA does not expect to need to request an increase in the total burden hours approved by OMB for export notifications.

As defined by PRA and 5 CFR 1320.3(b), ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: Review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments to EPA as part of your overall comments on this proposed action in the manner specified under **ADDRESSES**. In developing the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposal.

*C. Regulatory Flexibility Act*

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, after considering the potential economic impacts of this proposed rule on small entities, the Agency hereby certifies that this proposed rule would not have a significant adverse economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the economic analysis for this proposed rule (Ref. 2), which is summarized in Unit VI., and a copy of which is available in the docket for this rulemaking. The following is a brief summary of the factual basis for this certification.

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined in accordance with the RFA as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201;

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Based on the industry profile that EPA prepared as part of the economic analysis for this rulemaking (Ref. 2), EPA has determined that this proposed rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency's analysis presents only the estimated potential impacts on small businesses. Using the size standards established under the SBA regulations at 13 CFR 121.201 for firms in the NAICS codes that would likely be subject to this proposed rule, EPA identified two small businesses that would be potentially impacted by the proposed test rule.

As summarized in Unit VI., EPA estimates that the annualized cost for testing in this proposed rule would be $0.9 million (Ref. 2). The impact on these two small companies is expected to be less than 1% of company sales, which is not expected to be a significant adverse impact. The estimated cost of a TSCA section 12(b)(1) export notification, which, as a result of the final rule, would be required for the first export to a particular country of a chemical subject to the rule, is estimated to be $67.33 and $21.81 for each subsequent export notification submitted by an exporter (Ref. 2). EPA has concluded that the costs of TSCA section 12(b)(1) export notification would have a negligible impact on exporters of the chemicals in the final rule, regardless of the size of the exporter.

The Agency has also examined the standard practices that the industry uses in carrying out chemical testing in response to test rules, such as this one.

Based on that examination, EPA believes that:

- Small businesses do not perform the testing themselves, nor do they participate in the organization of the testing effort, because health effects testing of chemical substances is generally carried out by consortia of the large manufacturers or importers of the chemical substances;
- A small business would experience only very minor costs, if any, in securing an exemption from testing requirements, because exemption request requirements, described generally at 40 CFR 790.80 through 790.99 and the proposed regulatory text at § 799.5100(c)(2), (c)(5), and (c)(7), are minimal and EPA does not charge a fee for filing such a request; and
- Small businesses are unlikely to be affected by the reimbursement requirements because manufacturers (including importers) with a significant share of production or importation are the entities that will likely pay the highest share of testing costs, and the marginal benefit of securing reimbursement from small contributors may not be worth the cost.

In addition, in analyzing potential impacts, the RFA recognizes that it may be appropriate at times for Federal agencies to use an alternate definition of small business. As such, RFA section 601(3) also provides that an agency may establish a different definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment. Even though the Agency has used the default SBA definition of small business to conduct its analysis of potential small entity impacts for this proposed rule, EPA does not believe that the SBA size standards are generally the best size standards to use in assessing potential small entity impacts with regard to TSCA section 4(a) test rules.

The SBA size standards, which are primarily intended to define whether a business entity is eligible for Federal Government programs and preferences reserved for small businesses (13 CFR 121.101), ''seek to ensure that a concern that meets a specific size standard is not dominant in its field of operation'' (13 CFR 121.102(b)). See section 632(a)(1) of the Small Business Act. The SBA size standard is generally based on the number of employees an entity in a particular industrial sector may have. For example, in the chemical manufacturing industrial sector (i.e., NAICS code 325), approximately 98% of the industries would be classified as small businesses under the default SBA definition. The SBA size standard for 47% of this industry sector is 500 employees, and the size standard for 21% of this industry sector is 750 employees and for 32% is 1,000 employees. As a result, when assessing the potential impacts of test rules on chemical manufacturers, EPA believes that a standard based on total annual sales may provide a more appropriate means to judge the ability of a chemical manufacturing firm to support chemical testing without significant costs or burdens.

EPA is currently determining what level of annual sales would provide the most appropriate size cutoff with regard to various segments of the chemical industry usually impacted by TSCA section 4(a) test rules, but has not yet reached a determination. As stated in this unit, therefore, the factual basis for the RFA determination for this proposed rule is based on an analysis using the default SBA size standards. Although EPA is not proposing to establish an alternate small business definition in the small entity impact analysis conducted for this proposed rule, EPA is interested in receiving comments on whether the Agency should consider establishing an alternate small business definition to use in the small entity impact analyses for future TSCA section 4(a) test rules, and what size cutoff may be appropriate.

Any comments regarding the impacts that this action may impose on small entities, or regarding whether the Agency should consider establishing an alternate definition of small business to be used for analytical purposes for future test rules and what size cutoff may be appropriate, should be submitted to the Agency in the manner specified under **ADDRESSES**.

### *D. Unfunded Mandates Reform Act*

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. It is estimated that the total one-time total cost of the rule, which is summarized in Unit VI., is $8.6 million, with an annualized cost estimated to be $0.9 million, and the estimated annual cost per chemical to be approximately $237,000. In addition, since EPA does not have any information to indicate that any State, local, or tribal government manufactures or processes the chemicals covered by this action such that this rule would apply directly to State, local, or tribal governments, EPA has determined that this proposed rule would not significantly or uniquely affect small governments. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, 204, or 205 of UMRA

### *E. Executive Order 13132*

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule does not have ''federalism implications,'' because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive Order. This proposed rule would establish testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemicals. Because EPA has no information to indicate that any State or local government manufactures or processes the chemical substances covered by this action, this rule does not apply directly to States and localities and will not affect State and local governments. Thus, Executive Order 13132 does not apply to this proposed rule.

### *F. Executive Order 13175*

Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has determined that this proposed rule does not have tribal implications because it will not have any affect on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in the Order. As indicated previously, EPA has no information to indicate that any tribal government manufactures or processes the chemical substances covered by this action. Thus, Executive Order 13175 does not apply to this rule.

### *G. Executive Order 13045*

This proposed rule does not require special consideration pursuant to the terms of Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because it will not have an annual effect on the economy of $100 million or more, nor does it establish an environmental standard, or otherwise have a disproportionate effect on children. This proposed rule would establish testing and record keeping requirements that apply to manufacturers (including importers)

and processors of certain chemicals, and would result in the production of information that will assist the Agency and others in determining whether the chemical substances in this proposed rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

*H. Executive Order 13211*

This proposed rule is not subject to Executive Order 13211, entitled *Actions concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866, nor is it likely to have any significant adverse effect on the supply, distribution, or use of energy.

*I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule involves technical standards because it proposes to require the use of particular test methods. If the Agency makes findings under TSCA section 4, EPA is required by TSCA section 4(b) to identify the specific standards or test methods that are to be used for the development of the data required in the test rules issued under TSCA section 4. If finalized as proposed, the testing that would be required under this action would be conducted according to the test standards proposed for use in this action, i.e., 40 CFR 799.9110 (acute oral toxicity), 40 CFR 799.9135 (acute inhalation toxicity with histopathology), 40 CFR 799.9310 (90–day oral toxicity in rodents), 40 CFR 799.9346 (90–day inhalation toxicity), 40 CFR 799.9430 (combined chronic toxicity/carcinogenicity), 40 CFR 799.9370 (prenatal developmental toxicity), 40 CFR 799.9630 (developmental neurotoxicity), 40 CFR 799.9380 (reproduction and fertility effects), 40 CFR 799.9620 (neurotoxicity screening battery), 40 CFR 798.6500 (schedule-controlled operant behavior), and 40 CFR 799.9780 (immunotoxicity).

The test standards identified in this proposed rule are based on the harmonized guidelines that are available at *http://www.epa.gov/opptsfrs/home/guidelin.htm*. EPA established a unified library for test guidelines that have been issued by OPPTS for use in testing chemical substances to develop data for submission to EPA under TSCA, the Federal Food, Drug and Cosmetic Act (FFDCA), or FIFRA. This unified library of test guidelines represents an Agency effort that began in 1991 to harmonize the test guidelines within OPPTS, as well as to harmonize the OPPTS test guidelines with those used internationally, such as those of the Organization for Economic Cooperation and Development (OECD) of the European Community. The purpose for harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the Agency's identified data needs under FIFRA, FFDCA, and TSCA. The process for developing and amending the OPPTS harmonized test guidelines includes several opportunities for public participation and the extensive involvement of the scientific community, including external peer review by the FIFRA Scientific Advisory Panel (SAP), EPA's Science Advisory Board (SAB), and other expert scientific organizations, as appropriate. By identifying the test guidelines in its proposed TSCA test rules, EPA is providing the public another opportunity to review and comment on a particular test guideline before it is promulgated for use in a TSCA test rule.

In developing this proposed rule, EPA conducted a search to identify potentially applicable voluntary consensus standards. No such standards were identified for certain of the endpoints that the Agency is proposing to test based on the preliminary findings under TSCA section 4 that are discussed in Unit III. Specifically, EPA could not identify any applicable voluntary consensus standards involving test methods for acute inhalation toxicity with histopathology, developmental neurotoxicity, neurotoxicity screening battery, immunotoxicity, and combined chronic toxicity/carcinogenicity.

The Agency did, however, identify potentially applicable voluntary consensus standards involving test methods for acute oral toxicity, 90–day oral toxicity in rodents, 90–day inhalation toxicity, and prenatal developmental toxicity. After careful consideration, the Agency has determined that the potentially applicable voluntary consensus standards that were identified are generally impractical for this rulemaking because they are not designed to provide the specific data that is proposed to be required in this test rule. As discussed in Unit II., the Agency is proposing to require the development of specific data in order to satisfy the identified data needs for each chemical in this proposed rule. The following paragraphs explain why each potentially applicable voluntary consensus standard is impractical and fails to satisfy the identified priority data need discussed in Unit II.

1. *Acute oral toxicity*. The standard proposed for use in this rulemaking (40 CFR 799.9110) requires evaluation of both sexes and has an observation period twice as long as the similar standard test for acute oral toxicity, ASTM E 1163. Evaluating both sexes allows for evaluation of possible differences in sensitivity to substances based on gender. The longer observation period provides time for an adverse response to develop and to be observed. These differences make the use of ASTM E 1163 impractical for this rulemaking because the proposed standard is more useful and more effectual in providing the data that addresses the identified Agency need.

2. *90–day oral toxicity in rodents*. The standard proposed for use in this rulemaking (40 CFR 799.9310) requires more frequent evaluation of animals for clinical signs, clinical pathology of all animals, and evaluation of more organs and tissues than the similar standard test for 90–day oral toxicity in rodents, ASTM E 1372–95. The additional procedures found in the TSCA guideline provide closer monitoring of the animals for adverse effects, a thorough examination of all animals that may discover effects overlooked by examining only a few selected animals, and may find effects in organs and tissues that would not be examined under ASTM E 1372–95. These differences make the use of ASTM E 1372–95 impractical for this rulemaking because the proposed standard is more useful and more effectual in providing the data that addresses the identified Agency need.

3. *90–day inhalation toxicity*. The standard proposed for use in this rulemaking (40 CFR 799.9346) requires more frequent evaluation of animals for clinical signs and clinical pathology of more (all) animals than the similar standard test for 90–day inhalation

toxicity in rodents, ASTM E 1373–01. The additional procedures found in the TSCA guideline provide closer monitoring of the animals for adverse effects. Performing histopathology on all animals under the TSCA guideline is more likely to observe effects that could be overlooked after examining only a sample of animals under ASTM E 1373–01. These differences make the use of ASTM E 1373–01 impractical for this rulemaking because the proposed standard is more useful and effectual in providing the data that addresses the identified Agency need.

4. *Prenatal developmental toxicity*. The standard proposed for use in this rulemaking (40 CFR 799.9370) would require the use of a greater number of test subjects, which increases the power of the test to detect adverse effects, as compared to the similar standard test method for assessing developmental toxicity in rats and rabbits, ASTM E 1483–92. The standard proposed for use in this rulemaking would also require a longer dosing period (beyond organogenesis through late gestational development) which reduces the possibility of maternal and/or fetal recovery from treatment related effects that may otherwise not be observed from shorter dosing periods. Extending the dosing period also increases the sensitivity of the test to detect developmental effects of chemicals which exert their effect during late gestation. Finally, the proposed test guideline periodically adjusts dose based on the increasing body weight of the pregnant animal so that the dose in milligram (mg)/kg is constant rather than declining. These differences make the use of ASTM E 1483–92 impractical for this rulemaking because the proposed standard is more useful and effectual in providing the data that addresses the identified Agency need.

EPA found no other potentially applicable voluntary consensus standards that it believes could provide a possible substitute for the TSCA test guidelines being proposed. The Agency invites comment on its determination regarding the potentially applicable voluntary consensus standards considered for this proposed rule, and specifically invites the public to identify potentially applicable voluntary consensus standard(s) and to explain why such standard(s) should be used in the final rule.

*J. Executive Order 12898*

This proposed rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency does not need to consider environmental justice-related issues.

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

Environmental protection, Chemicals, Hazardous substances, Laboratories, Reporting and recordkeeping requirements.

Dated: October 6, 2006.

**James B. Gulliford,**

*Assistant Administrator, Office of Prevention, Pesticides and Toxics Substances.*

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

## PART 799—[AMENDED]

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

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

2. By adding § 799.5100 to subpart D to read as follows:

**§ 799.5100 Chemical testing requirements for certain chemicals on the ATSDR/EPA CERCLA Priority List of Hazardous Substances.**

(a) *What substances will be tested under this section?* Table 2 in paragraph (j) of this section identifies the chemical substances that must be tested under this section. The purity of each chemical substance to be tested except sodium cyanide and hydrogen cyanide must be 99% or greater. The purity of sodium cyanide and hydrogen cyanide must be 95% or greater.

(b) *Am I subject to this section?* (1) If you manufacture (including import) or intend to manufacture, or process or intend to process, any chemical substance listed in Table 2 in paragraph (j) of this section at any time from [*insert date 30 days after date of publication of the final rule in the* **Federal Register**] to the end of the test data reimbursement period as defined in 40 CFR 791.3(h), you are subject to this section with respect to that chemical substance.

(2) If you do not know or cannot reasonably ascertain that you manufacture or process a chemical substance listed in Table 2 in paragraph (j) of this section during the time period described in paragraph (b)(1) of this section (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without an unreasonable burden), you are not subject to this section with respect to that chemical substance.

(c) *If I am subject to this section, when must I comply with it?* (1)(i) Persons subject to this section are divided into two groups as set forth in Table 1 of this paragraph: Tier 1 (persons initially required to comply) and Tier 2 (persons not initially required to comply). If you are subject to this section, you must determine if you fall within Tier 1 or Tier 2, based on Table 1 of this paragraph.

TABLE 1.—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2

| Persons initially required to comply with this section (Tier 1) | Persons not initially required to comply with this section (Tier 2) |
|---|---|
| Persons not otherwise specified in column 2 of this table that manufacture (as defined at TSCA section 3(7)), or intend to manufacture, a chemical substance included in this section. | A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a chemical substance included in this section solely as one or more of the following:<br>–As a byproduct (as defined at 40 CFR 791.3(c));<br>–As an impurity (as defined at 40 CFR 790.3);<br>–As a naturally occurring substance (as defined at 40 CFR 710.4(b));<br>–As a non-isolated intermediate (as defined at 40 CFR 704.3);<br>–As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i));<br>–In amounts of less than 500 kilogram (kg) (1,100 lbs) annually (as described at 40 CFR 790.42(a)(4)); or<br>–For research and development (as described at 40 CFR 790.42(a)(5)). |

TABLE 1.—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2—Continued

| Persons initially required to comply with this section (Tier 1) | Persons not initially required to comply with this section (Tier 2) |
|---|---|
| | B. Persons who process (as defined at TSCA section 3(10)) or intend to process a chemical substance included in this section (see 40 CFR 790.42(a)(2)). |

(ii) Table 1 of paragraph (c)(1)(i) of this section expands the list of persons specified in § 790.42(a)(2), (a)(4), and (a)(5) of this chapter, who, while legally subject to this section, must comply with the requirements of this section only if directed to do so by EPA under the circumstances set forth in paragraphs (c)(4) through (c)(7) and (c)(10) of this section.

(2) If you are in Tier 1 with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, you must, for each test required under this section for that chemical substance, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than [*insert date 60 days after date of publication of the final rule in the* **Federal Register**].

(3) If you are in Tier 2 with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, you are considered to have an automatic conditional exemption and you will be required to comply with this section with regard to that chemical substance only if directed to do so by EPA under paragraphs (c)(5), (c)(7), or (c)(10) of this section.

(4) If no person in Tier 1 has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2 in paragraph (j) of this section by [*insert date 60 days after date of publication of the final rule in the* **Federal Register**], EPA will publish a **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter of intent has been submitted, and notify manufacturers in Tier 2A of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(5) If you are in Tier 2A with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, and if you manufacture, or intend to manufacture, this chemical substance as of [*insert date 30 days after date of publication of the final rule in the* **Federal Register**], or within 30 days after publication of the **Federal Register** document described in paragraph (c)(4) of this section, you must, for each test specified for that chemical substance in the document described in paragraph (c)(4) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the document described in paragraph (c)(4) of this section.

(6) If no manufacturer in Tier 1 or Tier 2A has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2 in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(4) of this section, EPA will publish another **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter of intent has been submitted, and notify processors in Tier 2B of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(7) If you are in Tier 2B with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, and if you process, or intend to process, this chemical substance as of [*insert date 30 days after date of publication of the final rule in the* **Federal Register**], or within 30 days after publication of the **Federal Register** document described in paragraph (c)(6) of this section, you must, for each test specified for that chemical substance in the document described in paragraph (c)(6) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the document described in paragraph (c)(6) of this section.

(8) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the chemical substances listed in Table 2 in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(6) of this section, EPA will notify all manufacturers and processors of those chemical substances of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document will additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and will give the manufacturers and processors of the chemical substance(s) an opportunity to take corrective action.

(9) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the chemical substances listed in Table 2 in paragraph (j) of this section within 30 days after receipt of the certified letter or publication of the **Federal Register** document described in paragraph (c)(8) of this section, all manufacturers and processors subject to this section with respect to that chemical substance who are not already in violation of this section will be in violation of this section.

(10) If a problem occurs with the initiation, conduct, or completion of the required testing or the submission of the required data with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, under the procedures in § § 790.93 and 790.97 of this chapter, EPA may initiate termination proceedings for all testing exemptions with respect to that chemical substance and may notify persons in Tier 1 and Tier 2 that they are required to submit letters of intent to test or exemption applications within a specified period of time.

(11) If you are required to comply with this section, but your manufacturing or processing of, or intent to manufacture or process, a chemical substance listed in Table 2 in paragraph (j) of this section begins after the applicable compliance date referred to in paragraphs (c)(2), (c)(5), or (c)(7) of this section, you must either submit a letter of intent to test or apply to EPA for an exemption. The letter of intent to test or the exemption application must be received by EPA no later than the day you begin manufacturing or processing.

(d) *What must I do to comply with this section?* (1) To comply with this section you must either submit to EPA a letter of intent to test, or apply to and obtain from EPA an exemption from testing.

(2) For each test with respect to which you submit to EPA a letter of intent to test, you must conduct the testing specified in paragraph (h) of this section and submit the test data to EPA.

(3) You must also comply with the procedures governing test rule requirements in part 790 of this chapter, as modified by this section, including the submission of letters of intent to test or exemption applications, the conduct of testing, and the submission of data; Part 792—Good Laboratory Practice Standards of this chapter; and this section. The following provisions of 40 CFR part 790 do not apply to this section: Paragraphs (a), (d), (e), and (f) of § 790.45; paragraph (a)(2) and (b) of § 790.80; and paragraph (e)(1) of § § 790.82, 790.85, and 790.48.

(e) *If I do not comply with this section, when will I be considered in violation of it?* You will be considered in violation of this section as of one day after the date by which you are required to comply with this section.

(f) *How are EPA's data reimbursement procedures affected for purposes of this section?* If persons subject to this section are unable to agree on the amount or method of reimbursement for test data development for one or more chemical substances included in this section, any person may request a hearing as described in 40 CFR part 791. In the determination of fair reimbursement shares under this section, if the hearing officer chooses to use a formula based on production volume, the total production volume amount will include amounts of a chemical substance produced as an impurity.

(g) *Who must comply with the export notification requirements?* Any person who exports, or intends to export, a chemical substance listed in Table 2 in paragraph (j) of this section is subject to part 707, subpart D, of this chapter.

(h) *How must I conduct my testing?* The chemical substances identified by Chemical Abstract Service Registry Number (CAS No.) and chemical name in Table 2 in paragraph (j) of this section must be tested as follows:

(1) *Testing standards.* Testing must be conducted in accordance with test standards specified in Table 2 in paragraph (j) of this section. The test standards cited in Table 2 in paragraph (j) of this section apply as they exist on the effective date indicated in paragraph (k) of this section.

(2) *Required tests.* In Table 2 in paragraph (j) of this section, the column ''Required Tests'' references the applicable test guideline on which the test standard is based.

(3) *Testing specifications.* The following limitations apply when specified for a particular chemical substance in Table 2 in paragraph (j) of this section under ''Testing specifications.''

(i) *Test species.* The test animal must be:

(A) The rat or the mouse.

(B) The mouse.

(C) The rat.

(D) The rabbit.

(ii) *Route of exposure.* Animals must be exposed via:

(A) Oral.

(B) Inhalation.

(C) Gavage.

(iii) *Duration and frequency of exposure.* (A) The substance must be administered by both acute and subchronic exposures.

(B) Animals must be exposed for a 4–hour period in an acute study.

(C) Animals must be exposed for 6 hours per day, 5 days per week for a 90–day period in a 90–day study.

(D) A multiple fixed-interval fixed-ratio schedule shall be used. Fixed-ratio and fixed-interval contingencies shall alternate throughout daily test sessions of at least 60 minutes duration.

(iv) *Specific organ gross pathology and histopathology.* (A) The thyroid glands shall be subjected to gross pathologic examination and shall be trimmed and weighed wet as soon as possible after dissection to avoid drying.

(B) The thyroid glands from all animals in the control and high dose groups shall undergo full histopathological examination; in the event that there are excessive early deaths or other problems that occur within the high dose group that could compromise the significance of the data, full histopathology shall be performed on the thyroid glands from all animals from the next highest exposure group.

(v) *Specific hormone level determinations.* T3 and T4 hormone levels shall be measured at terminal sacrifice.

(i) *Reporting requirements.* Interim progress reports for each test must be submitted every 6 months, beginning 6 months after the effective date of this rule as specified in paragraph (k) of this section. The number of interim progress reports that must be submitted for each test is listed in Table 2 in paragraph (j) of this section. A final report for each test for each subject chemical substance must be received by EPA by the deadline indicated in that table as the number of months after the effective date of this rule as specified in paragraph (k) of this section.

(j) *Designation of specific chemical substances and testing requirements.* The chemical substances identified by name and CAS No. in Table 2 of this paragraph must be tested in accordance with the testing requirements and limitations designated in this section, and the requirements described in Part 792—Good Laboratory Practice Standards of this chapter.

TABLE 2.—TEST REQUIREMENTS AND REPORTING DATES

| CAS No. | Chemical name and type of testing | Required tests | Testing specifications (all references are to § 799.5100(h)(3) | Number of interim 6-month reports required per test | Final report per test (months after effective date) |
|---|---|---|---|---|---|
| 75–00–3 | Chloroethane: | | | | |
| | Acute oral toxicity | § 799.9110 | (i)(C) | 0 | 6 |
| | 90–day oral toxicity in rodents | § 799.9310 | (i)(A) | 2 | 18 |
| | Prenatal developmental toxicity | § 799.9370 | (i)(B), (i)(D), (ii)(B) | 2 | 15 |
| | Reproduction and fertility effects | § 799.9380 | (i)(C), (ii)(A), (ii)(B) | 4 | 29 |
| | Combined chronic toxicity/carcinogenicity | § 799.9430 | (i)(B), (ii)(B) | 9 | 60 |
| | Neurotoxicity screening battery | § 799.9620 | (i)(C), (ii)(A), (ii)(B), (iii)(A), (iii)(B), (iii)(C). | 3 | 21 |
| | Developmental neurotoxicity | § 799.9630 | (i)(C), (ii)(B) | 3 | 21 |
| | Immunotoxicity | § 799.9780 | (i)(A), (ii)(A), (ii)(B) | 2 | 18 |
| 74–90–8 | Hydrogen cyanide: | | | | |
| | Acute inhalation toxicity with histopathology | § 799.9135 | (i)(C), (iv)(A), (iv)(B) | 1 | 9 |
| | 90–day inhalation toxicity | § 799.9346 | (i)(A), (iv)(A), (iv)(B), (v) | 2 | 18 |
| | Prenatal developmental toxicity | § 799.9370 | (i)(C), (i)(D), (ii)(B) | 2 | 15 |

TABLE 2.—TEST REQUIREMENTS AND REPORTING DATES—Continued

| CAS No. | Chemical name and type of testing | Required tests | Testing specifications (all references are to § 799.5100(h)(3) | Number of interim 6-month reports required per test | Final report per test (months after effective date) |
|---|---|---|---|---|---|
| | Reproduction and fertility effects | § 799.9380 | (i)(C), (ii)(B) | 4 | 29 |
| | Neurotoxicity screening battery | § 799.9620 | (i)(C), (ii)(B), (iii)(A), (iii)(B), (iii)(C). | 3 | 21 |
| | Schedule-controlled operant behavior | § 798.6500 | (i)(C), (ii)(B), (iii)(C), (iii)(D) | 6 | 36 |
| 143–33–9 | Cyanide: Sodium cyanide | | | | |
| | Prenatal developmental toxicity | § 799.9370 | (i)(C), (i)(D), (ii)(A) | 1 | 12 |
| 75–09–2 | Methylene chloride: | | | | |
| | Prenatal developmental toxicity | § 799.9370 | (i)(C), (i)(D), (ii)(B) | 2 | 15 |
| | Schedule-controlled operant behavior | § 798.6500 | (i)(C), (ii)(A), (iii)(C), (iii)(D) | 6 | 36 |
| | Developmental neurotoxicity | § 799.9630 | (i)(C), (ii)(B) | 3 | 21 |

(k) *Effective date*. This section is effective on [*insert date 30 days after date of publication of the final rule in the* **Federal Register**].

[FR Doc. E6–17569 Filed 10–19–06; 8:45 am]

**BILLING CODE 6560–50–S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 660

**[Docket NO. 061003253–6253–01; I.D. 092606A]**

**RIN 0648–AU27**

## Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule.

**SUMMARY:** NMFS proposes a regulation to implement the annual harvest guideline for Pacific mackerel in the U.S. exclusive economic zone off the Pacific coast for the fishing season of July 1, 2006, through June 30, 2007. This harvest guideline has been calculated according to the regulations implementing the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP) and establishes allowable harvest levels for Pacific mackerel off the Pacific coast.

**DATES:** Comments must be received by November 20, 2006.

**ADDRESSES:** You may submit comments on this proposed rule, identified by [092606A] by any of the following methods:

- E-mail: *0648–AU27.SWR@noaa.gov* Include the I.D. number in the subject line of the message.
- Federal e-Rulemaking portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Rodney R. McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213.
- Fax: (562) 980–4047.

Copies of the report *Pacific Mackerel (Scomber japonicus) Stock Assessment for U.S. Management in the 2006–2007 Fishing Year* may be obtained from the Southwest Regional Office (see **ADDRESSES**).

**FOR FURTHER INFORMATION CONTACT:** Joshua B. Lindsay, Southwest Region, NMFS, (562) 980–4034.

**SUPPLEMENTARY INFORMATION:** The CPS FMP, which was implemented by publication of the final rule in the **Federal Register** on December 15, 1999 (64 FR 69888), divides management unit species into two categories: actively managed and monitored. Harvest guidelines for actively managed species (Pacific sardine and Pacific mackerel) are based on formulas applied to current biomass estimates. Biomass estimates are not calculated for species that are only monitored (jack mackerel, northern anchovy, and market squid).

At a public meeting each year, the biomass for each actively managed species is reviewed by the Pacific Fishery Management Council's (Council) CPS Management Team (Team). The biomass, harvest guideline, and status of the fisheries are then reviewed at a public meeting of the Council's CPS Advisory Subpanel (Subpanel). This information is also reviewed by the Council's Scientific and Statistical Committee (SSC). The Council reviews the reports from the Team, Subpanel, and SSC, provides time for public comment, and then makes its recommendation to NMFS. The annual harvest guideline and season structure are then written and published by NMFS in the **Federal Register**. The Pacific mackerel season begins on July 1 and ends on June 30 of each year.

Public meetings of the Team and Subpanel, as well as a subcommittee of the SSC, were held at NMFS Southwest Fisheries Science Center (SWFSC), in La Jolla, CA on May 16, 17, and 18, 2006 (71 FR 25152). During these meetings the current stock assessment update for Pacific mackerel, which included a preliminary biomass estimate and harvest guideline, were reviewed in accordance with the procedures of the FMP. These meetings are designed to allow a review of the biomass and harvest guideline, and are required by the FMP.

The Team supported the conclusions from the Pacific mackerel stock assessment and recommended to the Council at its June 2006 Council meeting that based on the total stock biomass estimate of 112,700 mt, the Council adopt a harvest guideline (HG) for the 2006/2007 management season (i.e., July 1, 2006, through June 30, 2007) of 19,845 mt. The Council adopted this HG, as well as the Subpanel's guideline on the management of the fishery by dividing the harvest guideline into a directed fishery with a guideline of 13,845 metric tons and set-aside of 6,000 metric tons to accommodate incidental landings of Pacific mackerel in other CPS fisheries. The set-aside is intended to prevent a reoccurrence of the 2000/ 2001 Pacific mackerel season where early attainment of the entire harvest guideline in the directed fishery curtailed the Pacific sardine fishery which incidentally lands mackerel.

The proposed incidental fishery would be constrained to a 40–percent