Federal Register

Thursday,
July 24, 2008

Part III

Environmental Protection Agency

40 CFR Part 799

Testing of Certain High Production Volume Chemicals; Second Group of Chemicals; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA–HQ–OPPT–2007–0531; FRL–8373–9]

RIN 2070–AD16

Testing of Certain High Production Volume Chemicals; Second Group of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a test rule under section 4(a)(1)(B) of the Toxic Substances Control Act (TSCA) to require manufacturers, importers, and processors of certain high production volume (HPV) chemical substances to conduct testing to obtain screening level data for health and environmental effects and chemical fate. EPA has preliminarily determined that: Each of the 19 chemical substances included in this proposed rule is produced in substantial quantities and that there is or may be substantial human exposure to each of them; there are insufficient data to reasonably determine or predict the effects on health or the environment of the manufacture, distribution in commerce, processing, use, or disposal of the chemicals, or of any combination of these activities; and the testing program proposed here is necessary to develop such data. Data developed under this proposed rule will provide critical information about the environmental fate and potential hazards associated with these chemicals which, when combined with information about exposure and uses, will allow the Agency and others to evaluate potential health and environmental risks and to take appropriate follow-up action. Persons who export or intend to export any chemical substance included in the final rule would be subject to the export notification requirements in TSCA section 12(b)(1) and at 40 CFR part 707, subpart D. EPA has also taken steps, as described in this document, to consider animal welfare and to provide instructions on ways to reduce or in some cases eliminate animal testing, while at the same time ensuring that the public health is protected.

DATES: Comments must be received on or before October 22, 2008.

Written requests to present oral comments must be received on or before October 22, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2007–0531, 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 Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2007–0531. 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–2007–0531. EPA's policy is that all comments received will be included in the 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. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Follow the on-line instructions to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal 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. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

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., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Paul Campanella or John Schaeffer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone numbers: (202) 564–8091 or (202) 564–8173; e-mail addresses*: campanella.paul@epa.gov* or *schaeffer.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process any of the chemical substances that are listed in § 799.5087(j) of the proposed regulatory text. Any use of the term ''manufacture'' in this document will encompass ''import,'' unless otherwise stated. In addition, as described in Unit

V., once the Agency issues a final rule, any person who exports, or intends to export, any of the chemical substances included in the final rule will be subject to the export notification requirements in TSCA section 12(b)(1) and at 40 CFR part 707, subpart D. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of one or more of the 19 subject chemical substances (NAIC codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.
- Processors of one or more of the 19 subject chemical substances (NAIC codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit IV.E. and consult § 799.5087(b) of the proposed regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult either of the technical persons listed under **FOR FURTHER INFORMATION CONTACT**.

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 that you mail to EPA, mark the outside of the disk or CD-ROM 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 document 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 made in writing. If such a request is received on or before October 22, 2008, 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 document in the **Federal Register**. 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 test rule under TSCA section 4(a)(1)(B) (15 U.S.C. 2603(a)(1)(B)) that would require manufacturers and processors of 19 chemical substances to conduct testing for environmental fate (including five tests for physical/chemical properties and biodegradation), ecotoxicity (in fish, Daphnia, and algae), acute toxicity, genetic toxicity (gene mutations and chromosomal aberrations), repeat dose toxicity, and developmental and reproductive toxicity. The chemicals are HPV chemicals, i.e., chemicals with a production/import volume equal to or greater than 1 million pounds (lbs.) per year. A detailed discussion regarding efforts to enhance the availability of screening level hazard and environmental fate information about HPV chemicals can be found in a **Federal Register** notice which published on December 26, 2000 (Ref. 1).

The tests are screening level tests which are part of the Screening Information Data Set (SIDS) (see Unit II.D.). Some or all of these tests are being proposed as required tests for a particular chemical substance, depending upon what data are already available for that substance.

This action also follows an earlier testing action for certain HPV chemicals (see ''Testing of Certain High Production Volume Chemicals; Proposed Rule'' (Ref. 2) and ''Testing of Certain High Production Volume Chemicals; Final Rule'' (Ref. 3).

At a future date, EPA plans to propose testing for additional HPV chemicals as the Agency learns more about the chemicals with respect to human exposure, release, and sufficiency of data and experience available on the potential hazards.

B. What is the Agency's Authority for Taking this Action?

EPA is proposing this test rule under section 4(a)(1)(B) of TSCA (15 U.S.C. 2603(a)(1)(B)).

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)(1) mandates that EPA require by rule that manufacturers and/or 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 shall require by rule that testing be conducted on that chemical substance or mixture to develop data about health or 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 chemical substance or mixture, or any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment. TSCA section 4(a)(1).

Once the Administrator has made a finding under TSCA section 4(a)(1)(A) or 4(a)(1)(B), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance or mixture that are relevant to whether the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture, or any combination of such activities, presents an unreasonable risk of injury to health or the environment. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or (B)(i) findings. This approach is explained in more detail in EPA's TSCA section 4(a)(1)(B) Final Statement of Policy (''B'' policy) (Ref. 4, pp. 28738–28739).

In this proposed rule, EPA would use its broad TSCA section 4(a) authority to obtain data necessary to support the development of preliminary or ''screening level'' hazard and risk characterizations for certain HPV chemical substances specified in Table 2 in § 799.5087(j) of the proposed regulatory text. EPA has made preliminary findings for these chemical substances under TSCA section 4(a)(1)(B) that: They are produced in substantial quantities; there is or may be substantial human exposure to them; existing data are insufficient to determine or predict their health and environmental effects; and testing is necessary to develop such data.

C. Why is EPA Taking this Action?

On April 21, 1998, EPA initiated a national effort to empower citizens by providing them with knowledge about the most widespread chemicals in commerce. A major objective of this effort is to make certain basic information about the environmental fate and potential health and environmental hazards associated with HPV chemicals available to the public. Mechanisms to collect or, where necessary, develop needed data on U.S. HPV chemicals include the voluntary HPV Challenge Program, certain international efforts, and TSCA section 4 rules.

1. *Voluntary HPV Challenge Program.* The voluntary HPV Challenge Program, officially launched in late 1998, was created to ensure that a baseline set of data on approximately 2,800 HPV chemicals would be made available to EPA and the public. HPV chemicals are manufactured or imported in amounts equal to or greater than 1 million lbs. per year and were identified for this program through data reported under the TSCA Inventory Update Rule (IUR) during 1990.

The data set sought by the voluntary HPV Challenge Program is known as the Screening Information Data Set (SIDS) that was developed by the Organization for Economic Cooperation and Development (OECD), of which the United States is a member. SIDS provides an internationally agreed upon set of test data for screening high production volume chemicals for human and environmental hazards, and will assist the Agency and others to make an informed, preliminary judgment about the hazards of HPV chemicals.

Since the Program's inception in 1998, industry chemical manufacturers and importers have participated in the Challenge by sponsoring 2,250 chemicals. More than 350 companies and 100 consortia have sponsored chemicals directly in the Program while additional companies/consortia have sponsored chemicals indirectly in an international counterpart to the voluntary HPV Challenge Program, the International Council of Chemical Associations (ICCA) HPV Initiative. HPV chemicals that are not sponsored in the Program may be subject to a test rule under TSCA section 4 where, among other things, these chemicals lack needed testing. The voluntary HPV Challenge Program is further described in a **Federal Register** document which published on December 26, 2000 (Ref. 1) and on the voluntary HPV Challenge Program website (*http://www.epa.gov/chemrtk*).

Under the voluntary HPV Challenge Program, alternatives to the testing proposed under this proposed rule were available. For example, under the OECD HPV SIDS Program, some instances have been identified where, using chemical category approaches, less than a full set of SIDS tests for every chemical in the category has been judged sufficient for screening purposes. In addition, the OECD HPV SIDS Program allows some use of structure activity relationship (SAR) analysis for individual chemicals. These strategies have the potential to reduce the time required to complete the program, the number of tests actually conducted, and the number of test animals needed.

EPA advocated the use of categories or SAR approaches in the voluntary HPV Challenge Program and provided support for their use by developing guidance documents to assist industry and others in constructing scientifically defensible categories (Ref. 45) and SAR (Ref. 48). While EPA encouraged the use of scientifically appropriate categories of related chemicals and SAR under the voluntary HPV Challenge Program, these approaches are not included in this proposed rule. EPA has not identified any chemicals in this proposal for which category and SAR approaches would be appropriate. In addition, EPA believes that the incorporation of such elements in a test rule would require complex, time consuming, and intensive procedural steps, such as multi-phase rulemaking, without a corresponding benefit.

In the proposed test rule (Ref. 2) for the final HPV SIDS test rule (Ref. 3), EPA specifically solicited comments and suggestions on procedures that would allow inclusion of such approaches in TSCA section 4 HPV SIDS rulemaking. The procedures suggested by commenters on that proposed rule would have required complex, time consuming, and resource-intensive procedural steps, such as multi-phase rulemaking. As a result, EPA did not incorporate these suggestions into the final rule. In addition, EPA did not identify, nor did the commenters bring to EPA's attention, any possibilities that would have allowed inclusion of a category or SAR approach within the final test rule for any specific chemicals included in the final test rule (Ref. 19).

Although the Agency believes that none of the chemicals included in this proposed rule appear to be candidates for category or SAR approaches, persons who believe that a chemical under this

proposed rule can be dealt with using a category or SAR approach are encouraged to submit appropriate information, along with their rationale which substantiates this belief, during the comment period on this proposed rule. If, based on submitted information and other information available to EPA, the Agency determines that a chemical is appropriate for consideration under a category or SAR approach, and that practicable measures are available at the time to modify the proposed testing requirement, EPA will take such measures as are necessary to avoid unnecessary testing in the final rule.

2. *Certain international efforts*. The voluntary HPV Challenge Program is designed to make maximum use of scientifically adequate existing test data and to avoid unnecessary and duplicative testing of U.S. HPV chemicals. Therefore, EPA is continuing to participate in the voluntary international efforts, complementary to the voluntary HPV Challenge Program, that are being coordinated by the OECD to secure basic hazard information on HPV chemicals in use worldwide, including some of those on the U.S. (1990) HPV chemicals list (Ref. 5). This includes agreements to sponsor a U.S. HPV chemical under either the OECD HPV SIDS Program (Ref. 6), including sponsorship by OECD member countries beyond the United States, or the international HPV Initiative that is being organized by the ICCA (Ref. 7).

The OECD HPV SIDS Program seeks the development of test data, if such data are not already available, related to 6 health and environmental effects endpoints for international HPV chemicals (see Unit II.D.). The SIDS data set has been internationally agreed upon by the 29 member countries of the OECD as providing the minimum data set required to make an informed preliminary judgment about the hazards of a given HPV chemical.

The ICCA consists of representatives of chemical industry trade associations from the United States, Europe, Japan, Australia, Canada, Mexico, Brazil, New Zealand, and Argentina. The intended goal of the ICCA HPV Initiative was to complete screening-level hazard assessments on 1,000 ''high priority'' chemicals. Most of the chemicals on the ICCA working list (Ref. 7) are also U.S. HPV chemicals. The ICCA testing/assessment work is tied directly to that under the OECD HPV SIDS Program.

Any U.S. HPV chemicals that are handled under the OECD HPV SIDS Program or the ICCA HPV Initiative are considered by EPA to be ''sponsored'' and are not anticipated to be addressed in the voluntary HPV Challenge Program unless the international commitments are not met. Nor does EPA intend to evaluate these chemicals for possible TSCA section 4 HPV SIDS rulemaking unless the international commitments are not met.

The OECD HPV SIDS Program and the ICCA HPV Initiative are further described in the **Federal Register** document announcing the voluntary HPV Challenge Program (Ref. 1) and on the OECD website (Ref. 6) and ICCA website (Ref. 7).

3. *TSCA rulemaking*. U.S. data needs which remain unmet in the voluntary HPV Challenge Program or through international efforts may be addressed through TSCA section 4 rulemakings, such as the final test rule promulgated by EPA on March 16, 2006 (Ref. 3). This proposed rule is the second TSCA section 4 HPV SIDS rule, and addresses the unmet data needs of 19 chemicals.

Data collected and/or developed under a final rule based on this proposal and the voluntary HPV Challenge Program, when combined with information about exposure and uses, will allow the Agency and others to better assess the potential risk to health and the environment from these chemicals. EPA intends to make the information collected under the final rule available to the public, other Federal agencies, and any other interested parties on its website (*http://www.epa.gov/chemrtk*) and in the public docket for the final rule. As appropriate, this information will be used to ensure a scientifically sound basis for risk assessment/management actions. This effort will serve to further the Agency's goal of identifying and controlling human and environmental risks as well as providing greater protection and knowledge to the public. By using the same approach to testing as that of the OECD HPV SIDS Program, EPA is assuring that the data developed under this proposed rulemaking activity and the voluntary HPV Challenge Program will be comparable to the data being developed in other countries, thereby enabling an international sharing of data and the prevention of unnecessary and duplicative testing. See Refs.1 and 2, pp. 81662–81664, for further information about the voluntary HPV Challenge Program and international efforts.

D. Why is this Proposal Focusing on HPV Chemicals and SIDS Testing?

This proposal pertains to HPV chemicals, which are manufactured or imported in amounts equal to or greater than 1 million lbs. per year. Although those chemicals cover only about 11% of the chemical substances on the TSCA Inventory (see TSCA sections 8(a) and 8(b)), using TSCA Inventory information available in 1988 (Ref. 8, p. 32296), that small percentage of the TSCA Inventory accounted for 95% of total chemical production in the United States.

Testing under this proposal pertains to SIDS testing because SIDS is a battery of tests agreed upon by the international community through OECD, of which the United States is a member country, as appropriate for screening HPV chemical substances for toxicity and produces information relevant to understanding the basic health and environmental hazards and fate of HPV chemicals. The content of SIDS was agreed upon at the 13th Joint Meeting of the OECD Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals (Refs. 9 and 10). The United States believes these are the right tests for basic screening of U.S. HPV chemicals for health and environmental effects and environmental fate.

- SIDS testing evaluates the following six testing endpoints (Ref. 6):
- Acute toxicity.
- Repeat dose toxicity.
- Developmental and reproductive toxicity.
- Genetic toxicity (gene mutations and chromosomal aberrations).
- Ecotoxicity (studies in fish, Daphnia, and algae).
- Environmental fate (including physical/chemical properties (melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility), photolysis, hydrolysis, transport/distribution, and biodegradation).

While data on the six SIDS endpoints do not fully characterize a chemical's toxicity and fate, they provide a consistent minimum set of information that can be used to help assess the relative risks of chemicals and whether additional testing or assessment is necessary.

E. How Does EPA's HPV Work Relate to that of OECD?

As noted in Unit II.C.2., the OECD HPV SIDS Program is complementary to the voluntary HPV Challenge Program. However, EPA's definition of an HPV chemical differs from that of the OECD. EPA defines an HPV chemical as having an annual production or importation volume of 1 million lbs. or more. OECD defines an HPV chemical as having an annual production volume of 2.2 million lbs. (equivalent to 1 million kilograms (kg)) reported in any member country.

The presence of a chemical on the OECD's list of HPV chemicals was and

continues to be accepted by OECD member countries as providing a sufficient indicator of potential exposure to warrant testing at the SIDS level (Ref. 11). EPA, however, does not believe that a production volume threshold which is chosen for an international program on existing chemicals and which is the only trigger for entry into that program should be determinative of the threshold chosen for ''substantial production'' under TSCA section 4(a)(1)(B)(i). See EPA's ''B'' policy (Ref. 4). Among the reasons is that the TSCA section 4(a)(1)(B)(i) finding of substantial production is not the sole finding EPA must make to require testing based on TSCA section 4(a)(1)(B). EPA must also find that there is substantial release, or substantial or significant human exposure under TSCA sections 4(a)(1)(B)(i)(I) and (II). In addition, EPA must find that data are insufficient and testing is necessary under TSCA sections 4(a)(1)(B)(ii) and (iii). Accordingly, a finding that a chemical is produced in substantial quantities alone is not a sufficient basis to require testing under TSCA section 4.

In response to EPA's proposed ''B'' policy (Ref. 8), both the American Chemistry Council (ACC), formerly the Chemical Manufacturers Association (CMA) and the Society of the Plastics Industry, Inc., commented that EPA's proposed annual production-volume threshold of 1 million lbs. is a reasonable interpretation of ''substantial production'' under TSCA (Refs. 12 and 13). Additionally, they indicated that the OECD's 2.2 million lb. threshold would be preferable to achieve consistency between EPA's activities under TSCA section 4 and the OECD HPV SIDS Program. Although the United States and OECD differ in their definition of an HPV chemical and what should trigger basic screening tests of an HPV chemical, both the U.S. and OECD HPV SIDS Programs are alike in their information needs for an HPV chemical. Both the U.S. and OECD HPV SIDS Programs have identified the SIDS battery of tests as the basic screening tests needed to provide enough information to support a screening level assessment of the health and environmental effects of a chemical.

F. Why is EPA Pursuing Hazard Information on HPV Chemicals?

In 1998 EPA found that, of those non-polymeric organic substances produced or imported in amounts equal to or greater than 1 million lbs. per year based on 1990 IUR reporting, only 7% had a full set of publicly available and internationally recognized basic screening test data for health and environmental effects (Ref. 14). Of the over 2,800 U.S. HPV chemicals based on 1990 IUR data, 43% had no publicly available basic hazard data. For the remaining chemicals, limited amounts of the data were available. This lack of available hazard data compromises EPA's and others' ability to determine whether these HPV chemicals pose potential risks to human health or the environment, as well as the public's ability to know about the hazards of chemicals that may be found in their environment, their homes, their workplaces, and the products they buy.

G. What is the Role of this Proposed Rule and Any Future TSCA Section 4 HPV SIDS Rulemaking with Regard to the Voluntary HPV Challenge Program?

As indicated in the December 26, 2000 **Federal Register** document describing the voluntary HPV Challenge Program (Ref. 1), EPA intends to use rulemaking under TSCA, where appropriate, to help fill data gaps not addressed as part of the voluntary HPV Challenge Program or international efforts. EPA does not intend at this time to evaluate U.S. HPV chemicals that have been or are being handled through the OECD HPV SIDS Program or under a complementary program being coordinated by the ICCA (Ref. 7) for screening level testing under TSCA section 4 HPV SIDS rulemaking, although the Agency may revisit this question if commitments under those international programs are not met. See Unit III.G. of Ref. 1 for more information on these programs. EPA is evaluating the extent to which additional non-sponsored HPV chemicals meet the threshold criteria for rulemaking under TSCA section 4.

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

Hazard data are used in risk assessment and risk management, and ultimately to inform the public and promote the pollution prevention ethic. Activities to ensure the availability of basic hazard information on HPV chemicals support EPA's objectives.

EPA would use the data obtained from this proposed rule to support development of preliminary hazard and risk assessments for the 19 chemical substances subject to the rule. The data would also be used by EPA to set priorities for further testing that may produce hazard information on these chemical substances that may be needed by EPA, other Federal agencies, the public, industry, and others, to support adequate risk assessments. As appropriate, this information would be used to ensure a scientifically sound basis for risk characterizations and risk management actions. As such, this effort would serve to further the Agency's goal of identifying and controlling human and environmental risks as well as providing greater knowledge and protection to the public. In the past, EPA has used data from test rules to support such activities as the development of water quality criteria, Toxic Release Inventory (TRI) listings, chemical advisories, and reduction of workplace exposures.

Under the Security and Prosperity Partnership of North America (SPP), a trilateral effort to encourage greater cooperation and information sharing among the United States, Canada, and Mexico (*http://www.spp.gov*), the United States committed in August 2007 to assess and initiate needed action by the end of 2012 on the approximately 6,750 chemicals produced above 25,000 lbs. per year in the United States. (*http://www.spp.gov/pdf/spp_reg_coop_chemicals.pdf*). To fulfill these SPP commitments, EPA established the Chemical Assessment and Management Program (ChAMP). Under ChAMP, EPA is developing screening-level documents that summarize basic hazard and exposure information on HPV chemicals, identify potential risks, note scientific issues and uncertainties, and indicate the initial priority being assigned by the Agency for potential future appropriate action. These screening-level documents are based primarily on hazard, use, and exposure data available to the Agency through the voluntary HPV Challenge Program and on EPA's examination of chemical use and exposure information collected from the 2006 IUR as well as data from readily available sources of hazard and exposure information. Information on ChAMP and the risk-based prioritization process for HPV chemicals is available on the EPA's ChAMP website (*http://www.epa.gov/champ*) and on the related risk-based prioritization page (*http://www.epa.gov/hpv/hpvis/aboutrbd.htm*).

The data obtained from a final test rule based on this proposal would furnish the basic hazard information integral to this ChAMP process for the 19 chemical substances subject to the rule.

Finally, because the SIDS data would be comparable to the type of data agreed to as being appropriate and being developed by the OECD HPV SIDS Program, the development of these data would enable an international sharing of data. As conceived by the OECD, the SIDS battery of tests can be used by governments and others worldwide to conduct an initial assessment of the

hazards and risks posed by HPV chemicals and prioritize HPV chemicals to identify those in need of additional, more in-depth testing and assessment, as well as those of lesser concern. Not only could the data contribute to the international effort, but also international SIDS testing and assessments can be used to fill the data gaps identified as part of the voluntary HPV Challenge Program. Additional detailed information is available on the SIDS website (*http://cs3-hq.oecd.org/scripts/hpv*) and EPA's voluntary HPV Challenge Program website (*http://www.epa.gov/chemrtk*).

Data collected or developed for each sponsored chemical in the voluntary HPV Challenge Program are provided in the format of a ''robust'' (i.e., detailed) summary. A robust summary contains the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report, which can either be an experiment or in some cases an estimation or prediction method. (See Ref. 15; also at *http://www.epa.gov/HPV/pubs/general/robsumgd.htm*). A robust summary provides information that would assist a technically qualified person in making an independent assessment of a given study, and thereby facilitates the evaluation of existing data and the identification of additional data needs. EPA requests that existing data relevant to the testing in this proposed rule be submitted to the Agency in robust summary format. For any data developed under that final rule, EPA will request that a robust summary of the final report for each specific test be submitted in addition to the required final report itself (see § 799.5087(i) of the proposed regulatory text). Persons who respond to this request to submit robust summaries are also encouraged to submit the robust summary electronically via the High Production Volume Information System (HPVIS) to allow for its ready incorporation into HPVIS. Directions for electronic submission of robust summary information into HPVIS are provided at *https://iaspub.epa.gov/oppthpv/metadata.html*. This link will direct you to the ''HPVIS Quick Start and User's Guide.''

I. How are Animal Welfare Issues Being Considered in the HPV Initiative?

EPA recognizes the concerns that have been expressed about the use of test procedures that require the use of animals. As discussed in Unit II.E. of Ref. 1, EPA is making every effort to ensure that as the HPV Initiative is implemented (including TSCA section 4 HPV SIDS test rules), unnecessary or duplicative testing is avoided and the use of animals is minimized. As a general matter, EPA does not require that tests on animals be conducted if an alternative scientifically validated method is found acceptable and practically available for use. Where testing must be conducted to develop adequate data, the Agency is committed to reducing the number of animals used for testing, to replacing test methods requiring animals with alternative test methods when acceptable alternative methods are available, and to refining existing test methods to optimize animal use when there is no substitute for animal testing. EPA believes that these reduction, replacement, and refinement objectives are all important elements in the overall consideration of alternative testing methods.

The governmental and non-governmental scientific community is working to design, validate, and employ new methods of toxicity testing that are more accurate, less costly, and that reduce the need to use live animals. Over the years, significant research has been pursued to develop and validate non-animal test methods. U.S. scientists in academia, government, and industry have participated in both domestic and international efforts to develop alternative, non-animal tests. As part of the enterprise, the National Institute of Environmental Health Sciences (NIEHS) established a Federal Interagency Committee, the Interagency Coordinating Committee on Validation of Alternative Methods (ICCVAM), to review the status and validation of toxicological test methods including those that are performed *in vitro*. EPA scientists have contributed significantly to this body of knowledge and are continuing to play an important role in the development of alternative test methods for consideration.

In addition, as part of the voluntary HPV Challenge Program, EPA asked participants in that program to observe certain testing principles, which are laid out in an October 14, 1999 letter (Ref. 16). In this same letter, the Agency also indicated its intention that related TSCA rulemaking proceed in a manner consistent with these principles. This letter is available in the public docket for this proposed rulemaking, as well as on EPA's ChemRTK website. In the letter, EPA requested that participants conduct a thoughtful, qualitative analysis of existing data before testing. This proposed rule reflects many of the principles presented in the referenced voluntary HPV Challenge Program letter. Certain components of these principles, however, are not pertinent to this proposed rule. For example, this proposed rule does not require any dermal toxicity testing or any terrestrial toxicity testing.

III. EPA Proposed Findings

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

As indicated in Unit II.B., in order to develop a rulemaking under TSCA section 4(a) requiring the testing of chemical substances or mixtures, EPA must, among other things, make certain findings regarding either risk (TSCA section 4(a)(1)(A)(i)) or production combined with either chemical release or human exposure (TSCA section 4(a)(1)(B)(i)), with regard to those chemicals. EPA is proposing to require testing of the chemical substances included in this proposed test rule based on its preliminary findings under TSCA section 4(a)(1)(B)(i) relating to ''substantial'' production and ''substantial human exposure,'' as well as findings under TSCA sections 4(a)(1)(B)(ii) and (iii) relating to sufficient data and the need for testing. The chemical substances included in this proposed rule are listed in Table 2 in § 799.5087(j) of the proposed regulatory text along with their Chemical Abstract Service (CAS) registry numbers.

In EPA's ''B'' policy (see Unit II.E.), ''substantial production'' of a chemical substance or mixture is generally considered to be aggregate production (including import) volume equaling or exceeding 1 million lbs. per year of that chemical substance or mixture (Ref. 4, p. 28747). The ''B'' policy also provides guidelines that are generally considered by EPA in evaluating whether there is ''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.

EPA has found preliminarily that, under TSCA section 4(a)(1)(B)(i), each of the 19 chemical substances included in this proposed rule is produced in ''substantial'' quantities (see Unit III.B.) and that there is or may be ''substantial human exposure'' to each chemical substance (see Units III.C. and III.D.). Also, for one substance, EPA has found

preliminarily that, under TSCA section 4(a)(1)(B)(i), the substance enters or may reasonably be anticipated to enter the environment in substantial quantities (see Unit III.E.). In addition, under TSCA section 4(a)(1)(B)(ii), EPA has preliminarily determined that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, processing, or use of these chemical substances, or of any combination of such activities, on human health or the environment (see Unit III.F.). EPA has also found preliminarily that testing the 19 chemical substances identified in this proposed rule is necessary to develop such data (TSCA section 4(a)(1)(B)(iii)) (see Unit III.F.). EPA has not identified any ''additional factors'' as discussed in the ''B'' policy (Ref. 4, p. 28746) to cause the Agency to use decisionmaking criteria other than those described in the policy.

The chemical substances included in this proposed rule are listed in § 799.5087(j) of the proposed regulatory text along with their CAS numbers.

B. Are These Chemical Substances Produced and/or Imported in Substantial Quantities?

EPA has made preliminary findings that each of the chemical substances included in this proposal is produced and/or imported in an amount equal to or greater than 1 million lbs. per year (Ref. 18), based on information gathered pursuant to the 2006 IUR which is the most recently available compilation of TSCA Inventory data. EPA believes that these annual production and/or importation volumes are ''substantial'' as that term is used with reference to production in TSCA section 4(a)(1)(B)(i). (See also Ref. 4, p. 28746). A discussion of EPA's preliminary ''substantial production'' finding for each chemical substance included in this proposed rule is contained in a separate document (See Ref. 18).

C. Are a Substantial Number of Workers Exposed to These Chemicals?

EPA has made preliminary findings that the manufacture, processing, and use of the 19 chemical substances (Table 1.–Exposure Based Findings–Substantial Human Exposure, Unit III.D.) included in this action result or may result in exposure of a substantial number of workers to the chemical substances.

This finding is based, in large part, on information submitted in accordance with the 2006 IUR. For chemicals whose total production volume (manufactured and imported) exceeded 300,000 lbs. at a site during calendar year 2005, manufacturers and importers were required to report the number of potentially exposed workers during industrial processing and use to the extent the information was readily obtainable. In addition, the submitters are required to provide information regarding the commercial and consumer uses of the chemical substance.

EPA believes that an exposure of over 1,000 workers to a chemical substance is ''substantial'' as that term is used with reference to ''human exposure'' in TSCA section 4(a)(1)(B)(i). EPA believes, based on experience gained through case-by-case analysis of existing chemicals, that an exposure of 1,000 workers or more to a chemical substance is a reasonable interpretation of the phrase ''substantial human exposure'' in TSCA section 4(a)(1)(B)(i); see Ref. 4). Therefore, EPA's preliminary finding is that there is or may be substantial human exposure (workers) to these 19 chemical substances.

In addition to the 2006 IUR data, EPA also reviewed National Occupational Exposure Survey (NOES) data developed by the National Institute for Occupational Safety and Health (NIOSH). Based on the NOES data, EPA found that more than 1,000 workers were exposed to each of the 19 chemical substances that are the subject of this proposed rule. The NOES was a nationwide data gathering project conducted by NIOSH, which was designed to develop national estimates for the number of workers potentially exposed to various chemical, physical and biological agents and describe the distribution of these potential exposures. Begun in 1980 and completed in 1983, the survey involved a walk-through investigation by trained surveyors of 4,490 facilities in 523 different types of industries. Surveyors recorded potential exposures when a chemical agent was likely to enter or contact the worker's body for a minimum duration. These potential exposures could be observed or inferred. Information from these representative facilities was extrapolated to generate national estimates of potentially exposed workers for more than 10,000 different chemicals (Refs. 20, 57, and 58). EPA also compared production volumes from the 1986 IUR data collection to the production volumes for the 2006 IUR data collection. Of the 19 chemical substances in this proposed rule, only one chemical's production volume decreased from 1986 to 2006. The 2006 IUR production volume data are consistent with NOES results, as the production volumes for the remaining chemical substances either stayed the same or increased since 1986, thereby indicating that the usage of these chemical substances is no less than when NOES data were gathered.

EPA has performed a chemical-by-chemical analysis for all 19 chemical substances and carefully considered the industrial process and use information along with the commercial and consumer use information from the 2006 IUR submissions. Commercial uses are defined as ''The use of a chemical substance or mixture in a commercial enterprise providing saleable goods or services (e.g., dry cleaning establishment, painting contractor)''; 40 CFR 710.43. Detailed information from the IUR submissions can be found in ''Testing of Certain High Production Volume Chemicals; Second Group of Chemicals (Exposure Findings Supporting Information)'' (Ref. 18). Based on the nature of the IUR uses, EPA considers that chemicals with reported commercial uses may result in potential exposure to 1,000 workers or more. The total number of workers reported under the IUR is the sum of information on both industrial workers plus commercial use workers.

In 2003, EPA partially exempted certain petroleum process streams (including ''Hydrocarbons, C>4'' (CAS No. 68647–60–9) and ''Oils, reclaimed'' (CAS No. 69029–75–0)) from reporting certain processing and use data under the TSCA section 8(a) IUR. The exemption was not based on an assessment of the toxicity of the process streams but on the fact that the chemicals are frequently processed, transported, and stored in vessels that minimize the potential for releases and exposure to workers. (**Federal Register** issue of January 7, 2003 (68 FR 848) (FRL–6767–4) and **Federal Register** issue of December 19, 2005 (71 FR 75059) (FRL–7743–9); available on-line at: *http://www.epa.gov/fedrgstr*). Despite the fact that the degree of exposure is expected to be diminished to particular workers because of the chemical processing and handling practices used, available data indicate that more than 1,000 workers are potentially exposed to these chemicals, supporting the preliminary finding of substantial human exposure (Ref. 18).

D. Are a Substantial Number of Consumers Exposed to These Chemicals?

Based on 2006 IUR data, EPA has made preliminary findings that the uses of 13 of the chemical substances included in this action result or may result in exposure to a substantial number of consumers (Ref. 18). EPA reviewed the consumer use information reported for the 2006 IUR and carefully

considered the nature of those uses. Upon completion of the review, EPA concluded that the reported consumer uses for the chemicals in this action may result in at least 10,000 potentially exposed consumers, thus meeting the exposure based finding for consumers.

In addition to findings made based on the 2006 IUR data, EPA has also made consumer exposure based findings based on the National Library of Medicine (NLM) Household Products Database (Ref. 18). The chemical substances reported in the National Library of Medicine (NLM) Household Products Database are present in multiple household products subject to TSCA including hobby/craft products, personal care products, home cleaning products, home maintenance products, and automotive products. The NLM Household Products Database provides information on the chemical ingredients and their percentage in specific brands of household products. Information in the database is from a variety of publicly available sources including brand-specific labels and Material Safety Data Sheets when available from manufacturers and manufacturers' websites. Publicly available information from the database is available on-line at: *http://householdproducts.nlm.nih.gov*.

EPA believes that use of the consumer products identified in the NLM Household Products Database may expose a substantial number of consumers (i.e., greater than 10,000) to these chemical substances. EPA believes that an exposure of over 10,000 consumers to a chemical substance is ''substantial'' as that term is used with reference to ''human exposure'' in TSCA section 4(a)(1)(B)(i). EPA believes, based on experience gained through case-by-case analysis of existing chemicals, that an exposure of 10,000 consumers or more to a chemical substance is a reasonable interpretation of the phrase ''substantial human exposure'' in TSCA section 4(a)(1)(B)(i). (See Ref. 4.) Therefore, EPA's preliminary finding is that there is or may be substantial human exposure (consumers) to these chemical substances.

A discussion of EPA's preliminary ''substantial exposure'' finding for consumers is contained in a separate document (see Ref. 18). The Agency solicits comment regarding additional information pertaining to numbers of consumers potentially exposed to the chemical substances identified in this proposed rule.

TABLE 1.—EXPOSURE BASED FINDINGS—SUBSTANTIAL HUMAN EXPOSURE

CAS No.	2006 IUR Production Volume	Meet Exposure Based CriteriaFor Mfg & Industrial Workers	NOES (number of workers)	Meet Exposure Based Criteria for Commercial Workers	Meet Exposure Based Criteria for Consumers	Meet Substantial or Significant Release Criteria	NLM Household Chemicals Database
75–07–0	> 100 million (M)–500 M	X	216,533		X	X	X
78–11–5	> 1 M–10 M	X	2,650		X		
84–65–1	> 10 M–50 M	X	6,187	X	X		
89–32–7	> 1 M–10 M	X	1,926				
110–44–1	> 1 M–10 M	X	69,243	X	X		X
118–82–1	> 1 M–10 M	X	120,009	X	X		
119–61–9	> 1 M–10 M	X	41,516	X	X		X
144–62–7	> 1 M–10 M	X	142,000	X	X	X	X
149–44–0	> 1 M–10 M	X	239,465	X	X		
2524–04–1	> 10 M–50 M	X	1,088				
4719–04–4	> 10 M–50 M	X	225,251	X	X	X	X
6381–77–7	> 1 M–10 M	X	19,468				
31138–65–5	> 1 M–10 M	X	74,165	X	X		
66241–11–0	> 1 M–10 M	X	38,555	X	X		
68187–76–8	> 1 M–10 M	X	11,164	X	X		
68187–84–8	> 1 M–10 M	X	36,381	X	X		X
68479–98–1	> 10 M–50 M	X	4,121				
68527–02–6	> 1 M–10 M	X	84,192				
68647–60–9	> 1 Billion lbs.	X	1,257				

E. Are Substantial Quantities of These Chemicals Released to the Environment?

EPA does not have readily available data on environmental releases for most of the 19 chemical substances in this proposed rule. However, one substance, acetaldehyde (CAS No. 75–07–0) is included in TRI and has estimated environmental release in 2005 of 13,567,452 lbs. (Ref. 18). TRI contains information about releases of certain chemicals and management of wastes at a wide variety of sources, including manufacturing operations, certain service businesses, and Federal facilities. Publicly available information from the 2005 TRI reporting cycle is available on-line at: *http://www.epa.gov/triexplorer*. Two additional chemicals (ethanedioic acid and 1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol) also meet the substantial release criteria based on the environmental releases from their reported IUR uses.

EPA believes that an environmental release of a chemical substance in an amount equal to or greater than 1 million lbs. per year or greater than 10% of the reported production volume is ''substantial'' as that term is used with reference to ''enter the environment in substantial quantities'' in TSCA section 4(a)(1)(B)(i). (See Ref. 4).

The Agency solicits comment regarding additional information pertaining to the amount of environmental release of the chemical substances identified in this proposed rule.

F. Do Sufficient Data Exist for These Chemical Substances?

In developing the testing requirements for chemicals contained in this proposed rule, available information on chemical/physical properties, environmental fate, ecotoxicity, and human health effects was searched using the data sources outlined in the OECD guidelines found in section 3.1 (Reliability, Relevance and Adequacy) of the ''Manual for the Investigation of HPV Chemicals'' (Ref. 6) such as: Beilstein Database, CRC Handbook of Chemistry and Physics, Hawley's Condensed Chemical Dictionary, Illustrated Handbooks of Physical-Chemical Properties and Environmental Fate for Organic Chemicals, Merck Index, Hazardous Substances Data Bank (HSDB), Toxicology Literature Online (TOXLINE), and the National Technical Information Service (NTIS). EPA also searched for available data as summarized in its HPV Information System (Ref. 56). For one HPV chemical, data available from an EPA reassessment of its use as an inert in pesticides formulations were examined (Ref. 21). When appropriate, the Federal Research In Progress (FEDRIP) database was also searched. Any information that was obtained from these searches was evaluated for data acceptability using the guidelines described on EPA's voluntary HPV Challenge Program website (*http://www.epa.gov/chemrtk/pubs/general/guidocs.htm*): ''Guidance for Meeting the SIDS Requirements (The SIDS Guide)'' and ''Guidance for Assessing the Adequacy of Existing Data.'' Furthermore, data adequacy and reliability were evaluated using the OECD guidelines which can be found in section 3.1 of the OECD ''Manual for the Investigation of HPV Chemicals'' (Ref. 6).

It is worth noting that additional testing is being proposed for five chemicals that had been included in the final TSCA section 4 HPV SIDS rulemaking issued on March 16, 2006 (Ref. 3). EPA noted in the proposed (Ref. 2) and final rule (Ref. 3) for that first HPV SIDS rulemaking that, for chemicals for which some data were available on one or more SIDS endpoints, EPA was not requiring testing at that time for those endpoints. However, EPA stated at that time that no definitive determination had been made as to the adequacy of those existing data for an initial assessment of a chemical's hazards or risks to health or the environment. Consequently, in that final rule, EPA stated that if EPA determines that it needs additional data regarding any of the chemical substances included in the final rule, the Agency might seek further health and/or environmental effects testing for those chemical substances. EPA has now completed its assessment of the adequacy of the available data for those endpoints that were not included for these chemicals in the first HPV SIDS rulemaking. In some instances, EPA has made a preliminary finding that, for some of the SIDS endpoints, the existing data and experience are not sufficient to enable the effects of these substances on health or the environment to reasonably be determined or predicted. Therefore, EPA has also proposed testing for those endpoints in this proposed rule.

Section 799.5087(j) of the proposed regulatory text lists each chemical and the SIDS tests for which adequate data are not currently available to the Agency. The Agency preliminarily finds that the existing data for one or more of the SIDS testing endpoints for each of the chemical substances listed in Table 2 of the proposed regulatory text (including environmental fate (comprising five tests for physical/chemical properties [melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility] and biodegradation); ecotoxicity (tests in fish, Daphnia, and algae); acute toxicity; genetic toxicity (gene mutations and chromosomal aberrations); repeat dose toxicity; and developmental and reproductive toxicity) are insufficient to enable EPA to reasonably determine or predict the human health and environmental effects resulting from manufacture, processing, and use of these chemical substances.

EPA solicits comment concerning the availability of existing studies on the SIDS endpoints proposed in this document on these chemical substances. To the extent that additional studies relevant to the testing proposed in this rulemaking are known to exist, EPA strongly encourages the submission of this information as comments to the proposed rule, including full citations for publications and full copies of unpublished studies. If EPA judges such data to be sufficient, corresponding testing will not be included in the final rule. Commenters are also encouraged to prepare a robust summary (Ref. 15) for each such study to facilitate EPA's review of the full study report or publication. Persons who respond to this request to submit robust summaries are also encouraged to submit the robust summary electronically via the High Production Volume Information System (HPVIS) to allow for its ready incorporation into HPVIS. Directions for electronic submission of robust summary information into HPVIS are provided at *https://iaspub.epa.gov/oppthpv/metadata.html*. This link will direct you to the ''HPVIS Quick Start and User's Guide.''

As noted in Unit II.C.1., persons who believe that adequate information regarding a chemical subject to this proposed rule can be developed using a category or SAR approach are encouraged to submit appropriate information, along with their rationale which substantiates this belief, during the comment period on this proposed rule. If, based on submitted information and other information available to EPA, the Agency agrees; EPA will take such measures as are needed to avoid unnecessary testing in the final rule.

G. Is Testing Necessary for These Chemical Substances?

EPA would use the data obtained from this proposed testing to support development of preliminary hazard and risk characterizations for these HPV chemicals as part of the ChAMP process

fulfilling the U.S. commitments under the SPP to set initial priorities for potential future appropriate action, including possible further testing that would produce more definitive hazard information where needed on such chemical substances. Such additional information is needed by EPA, other Federal agencies, the public, industry, and others to ensure that adequate hazard and risk assessments can be conducted on these chemical substances. EPA has used data from test rules to support such activities as the development of water quality criteria, TRI listings, chemical advisories, and input for actions resulting in reduction of workplace exposures.

EPA preliminarily believes that conducting the needed SIDS testing identified for the 19 subject chemical substances is necessary to provide data relevant to a determination of whether the manufacture, processing, and use of the chemical substances does or does not present an unreasonable risk of injury to human health and the environment.

IV. Proposed Testing

A. What Testing is Being Proposed in this Action?

EPA is proposing specific testing and reporting requirements for the chemical substances specified in § 799.5087(j) of the proposed regulatory text.

All of the proposed testing requirements are listed in Table 2 in § 799.5087(j) of the proposed regulatory text and consist of a series of test methods covering many of the endpoints in the OECD HPV SIDS testing battery. EPA, however, requires that the American Society for Testing and Materials (ASTM) or the TSCA test guidelines at 40 CFR part 799 (TSCA 799 guidelines) be used because the language in the TSCA 799 guidelines makes clear which steps are mandatory and which steps are only recommended. EPA's TSCA 799 guidelines, however, have been harmonized with the OECD guidelines. Accordingly, in order to comply with this test rule, testing must be conducted in accordance with the specified mandatory and enforceable requirements in the ASTM or TSCA 799 guidelines. Most of the proposed testing requirements for a particular endpoint are specified in one test standard. In the case of certain endpoints, however, any of multiple listed methods could be used. For several of the proposed test standards, EPA has identified and is proposing certain ''Special Conditions'' as discussed in this unit. The following endpoints and proposed test standards would be required under this proposed rule.

1. *Physical/chemical properties.*

Melting Point: American Society for Testing and Materials (ASTM) E 324–99 (Capillary tube) (Ref. 22).

Boiling Point: ASTM E 1719–05 (Ebulliometry) (Ref. 23).

Vapor Pressure: ASTM E 1782–03 (Thermal analysis) (Ref. 24).

n-Octanol/Water Partition Coefficient:

Method A (40 CFR 799.6755—shake flask)

Method B (ASTM E 1147–92(2005)—liquid chromatography) (Ref. 25).

Method C (40 CFR 799.6756—generator column).

Water Solubility:

Method A: (ASTM E 1148–02—shake flask) (Ref. 26).

Method B (40 CFR 799.6784—shake flask).

Method C (40 CFR 799.6784—column elution).

Method D (40 CFR 799.6786—generator column).

EPA is proposing, for those chemicals for which melting points determinations are needed, that melting points be determined according to the method ASTM E 324–99. Although ASTM indicates on its website, *http://www.astm.org/cgi-bin/SoftCart.exe/STORE/filtrexx40.cgi?U+mystore+lien2117+-L+E324+/usr6/htdocs/astm.org/DATABASE.CART/WITHDRAWN/E324.htm* that ASTM E 324–99 has been withdrawn, ASTM has explained that ASTM E 324–99 was withdrawn because:

> The standard utilizes old, well-developed technology; it is highly unlikely that any additional [changes] and/or modifications will ever be pursued by the E15 [committee]. The time and effort needed to maintain these documents detract from the time available to develop new standards which use modern technology.
> (Ref. 27)

Withdrawal of the method by ASTM means only that ASTM no longer continues to develop and improve the method. It does not mean that ASTM no longer considers the method to be valid. ASTM still makes the method available for informational purposes and it can still be purchased from ASTM at the address listed in § 799.5087(h) of the proposed regulatory text. EPA concludes that ASTM's withdrawal of E 324–99 does not have negative implications on the validity of the method; therefore, EPA is proposing, for those chemicals for which melting points determinations are needed, that melting points be determined according to the method ASTM E 324–99.

For the *n*-octanol/water partition coefficient and water solubility endpoints, EPA is proposing that certain ''Special Conditions'' be considered by test sponsors in determining the appropriate test method that would be used from among those included for these endpoints in Table 3 in § 799.5087(j) of the proposed regulatory text.

For the ''*n*-Octanol/Water Partition Coefficient (log 10 basis)'' endpoint, also known as log K_{ow}, EPA proposes that an appropriate selection be made from among three alternative methods for measuring the substance's *n*-octanol/water partition coefficient. Prior to determining the appropriate standard to use, if any, to measure the *n*-octanol/water partition coefficient, EPA is recommending that the log K_{ow} be quantitatively estimated. EPA recommends that the method described in ''Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients'' (Ref. 28) be used in making such estimation. EPA is proposing that test sponsors must submit with the final study report the underlying rationale for the test standard selected for this endpoint. EPA is proposing this approach in recognition of the fact that depending on the chemical substance's log K_{ow}, one or more test methods may provide adequate information for determining the log K_{ow}, but that in some instances one particular test method may be more appropriate In general, EPA believes that the more hydrophobic a subject chemical is, the less well Method A (§ 799.6755—shake flask) will work and Method B (ASTM E 1147–92(2005)) and Method C (§ 799.6756—generator column) become more suitable, especially Method C. The proposed test methodologies have been developed to meet a wide variety of needs and, as such, are silent on experimental conditions related to pH. Therefore, EPA proposes that all required *n*-octanol/water partition coefficient tests be conducted at pH 7 to ensure environmental relevance. The proposed test standards and log K_{ow} ranges that would determine which tests must be conducted for this endpoint are shown in Table 2 of this unit.

TABLE 2.—TEST REQUIREMENTS FOR THE N-OCTANOL/WATER PARTITION COEFFICIENT ENDPOINT

Testing Category	Test Requirements and References	Special Conditions
Physical/chemical properties	*n*-Octanol/water partition coefficient (log 10 basis) or log K_{ow}: The appropriate log K_{ow} test, if any, would be selected from those listed in this column—see Special Conditions in the adjacent column. Method A: 40 CFR 799.6755 (shake flask) Method B: ASTM E 1147–92(2005) (liquid chromatography) Method C: 40 CFR 799.6756 (generator column)	*n*-Octanol/water partition coefficient or log K_{ow}: Which method is required, if any, is determined by the test substance's estimated log K_{ow} as follows: log K_{ow} < 0: no testing required. log K_{ow} range 0–1: Method A or B. log K_{ow} range > 1–4: Method A or B or C. log K_{ow} range > 4–6: Method B or C. log K_{ow} > 6: Method C. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7.

For the ''Water Solubility'' endpoint, EPA proposes an appropriate selection be made from among four alternative methods for measuring that endpoint. The test method used, if any, would be determined by first quantitatively estimating the test substance's water solubility. One recommended method for estimating water solubility is described in ''Improved Method for Estimating Water Solubility from Octanol/Water Partition Coefficient'' (Ref. 29). EPA is also proposing that test sponsors be required to submit in the final study report the underlying rationale for the test standard selected for this endpoint. The proposed test methodologies have been developed to meet a wide variety of needs and, as such, are silent on experimental conditions related to pH. Therefore, EPA proposes that all required water solubility tests be conducted starting at pH 7 to ensure environmental relevance. The estimated water solubility ranges that EPA is proposing for use in selecting an appropriate proposed test standard are shown in Table 3 of this unit.

TABLE 3.—TEST REQUIREMENTS FOR THE WATER SOLUBILITY ENDPOINT

Testing Category	Test Requirements and References	Special Conditions
Physical/chemical properties	Water solubility: The appropriate method to use, if any, to test for water solubility would be selected from those listed in this column—see Special Conditions in the adjacent column. Method A: ASTM E 1148–02 (shake flask) Method B: 40 CFR 799.6784 (shake flask) Method C: 40 CFR 799.6784 (column elution) Method D: 40 CFR 799.6786 (generator column)	Water solubility: Which method is required, if any, would be determined by the test substance's estimated water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7. > 5,000 milligram/Liter (mg/L): Method A or B. > 10 mg/L—5,000 mg/L: Method A, B, C, or D. > 0.001 mg/L—10 mg/L: Method C or D. ≤ 0.001 mg/L: No testing required.

2. *Environmental fate and pathways.*

Ready Biodegradation:

Method A: ASTM E1720–01 (Sealed vessel CO_2 production test) (Ref. 30).

Method B: ISO 14593 (CO_2 headspace test) (Ref. 31).

Method C: ISO 7827 (Method by analysis of dissolved organic carbon (DOC)) (Ref. 32).

Method D: ISO 9408 (Determination of oxygen demand in a closed respirometer) (Ref. 33).

Method E: ISO 9439 (Carbon dioxide evolution test) (Ref. 34).

Method F: ISO 10707 (Closed bottle test) (Ref 35).

Method G: ISO 10708 (Two-phase closed bottle test) (Ref. 36).

For the ''Ready Biodegradation'' endpoint, EPA proposes an appropriate selection be made from among seven alternative methods for measuring the substance's ready biodegradability. For most test substances, EPA considers Method A (ASTM E1720–01) and Method B (ISO 14593) to be generally applicable, cost effective, and widely accepted internationally. However, the test method used, if any, will depend on the physical and chemical properties of the test substance, including its water solubility. An additional document, ISO 10634 (Ref. 37), provides guidance for selection of an appropriate test method for a given test substance considering the substances physical and chemical properties. EPA is also proposing that test sponsors be required to submit in the final study report the underlying rationale for the test standard selected for this endpoint.

3. *Aquatic toxicity.*

Test Group 1:

Acute toxicity to fish (ASTM E 729–96(2002)) (Ref. 38).

Acute toxicity to Daphnia (ASTM E 729–96(2002)) (Ref. 38).

Toxicity to plants (algae) (ASTM E 1218–04e1) (Ref. 39).

Test Group 2:

Chronic toxicity to Daphnia (ASTM E 1193–97(2004)) (Ref. 40).

Toxicity to plants (algae) (ASTM E 1218–04e1) (Ref. 39).

For the ''Aquatic Toxicity'' endpoint, the OECD HPV SIDS Program recognizes that, for certain chemicals, acute toxicity studies are of limited value in assessing the substances' aquatic toxicity. This issue arises when considering chemical substances with high log K_{ow} values. In such cases, toxicity is unlikely to be observed over the duration of acute toxicity studies because of reduced uptake and the extended amount of time required for such substances to reach steady state or toxic concentrations in the test organism. For such situations, the OECD HPV SIDS Program recommends use of chronic toxicity testing in Daphnia in place of acute toxicity testing in fish and Daphnia. EPA is proposing that the aquatic toxicity testing requirement be

determined based on the test substance's measured log K_{ow} as determined by using the approach outlined in Unit IV.A.1., in the discussion of ''*n*-Octanol/Water Coefficient,'' and in Table 3 in § 799.5087(j) of the proposed regulatory text. For test substances determined to have a log K_{ow} of less than 4.2, one or more of the following tests (described as ''Test Group 1'' in Table 3 in § 799.5087(j) of the proposed regulatory text) are proposed: Acute toxicity to fish (ASTM E 729–96 (2002)); Acute toxicity to Daphnia (ASTM E 729–96(2002)); and Toxicity to plants (algae) (ASTM E 1218–04e1). For test substances determined to have a log K_{ow} that is greater than or equal to 4.2, one or both of the following tests (described as ''Test Group 2'' in Table 3 in § 799.5087(j) of the proposed regulatory text) are proposed: Chronic toxicity to Daphnia (ASTM E 1193–97(2004)) and Toxicity to plants (algae) (ASTM E 1218–04e1). As outlined in Table 3 in § 799.5087(j) of the proposed regulatory text, depending on the testing proposed in Test Group 1, the Test Group 2 chronic Daphnia test may substitute for either or both the acute fish toxicity test and the acute Daphnia test.

Using SAR, a log K_{ow} of 4.2 corresponds with a fish bioconcentration factor (BCF) of about 1,000 (Refs. 29, 41, and 42). A chemical substance with a fish BCF value of 1,000 or more is characterized as having a tendency to accumulate in living organisms relative to the concentration of the chemical in the surrounding environment (Ref. 42). For the purposes of this proposed rulemaking, EPA's use of a log K_{ow} equal to or greater than 4.2 (which corresponds with a fish BCF value of 1,000) is consistent with the approach taken in the Agency's Final Policy Statement under TSCA section 5 entitled *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (Ref. 43). EPA has also used a measured BCF that is equal to or greater than 1,000 or, in the absence of bioconcentration data, a log P [same as log K_{ow}] value equal to or greater than 4.3 to help define the potential of a new chemical substance to cause significant adverse environmental effects (Significant New Use Rules; General Provisions For New Chemical Follow-Up (Ref. 44) (See also 40 CFR 721.3.)). EPA considers the difference between the log K_{ow} of 4.3 cited in the 1989 **Federal Register** document and the log K_{ow} value of 4.2 cited in this proposed rule to be negligible.

EPA recognizes that in some circumstances, acute aquatic toxicity testing (Test Group 1) may be relevant for certain chemical substances having a log K_{ow} equal to or greater than 4.2. chemical substances that are dispersible in water (e.g., surfactants, detergents, aliphatic amines, and cationic dyes) may have log K_{ow} values greater than 4.2 and may still be acutely toxic to aquatic organisms. For any chemical substance listed in Table 3 in § 799.5087(j) of the proposed regulatory text for which a test sponsor believes that an alternative to the log K_{ow} threshold of 4.2 is appropriate, the test sponsor may request a modification of the test standard in the final rule as described in 40 CFR 790.55. Based upon the supporting rationale provided by the test sponsor, EPA may allow an alternative threshold or method to be used for determining whether acute or chronic aquatic toxicity testing must be performed for a specific substance. EPA is soliciting public comment on this approach as well as other alternative approaches in this area.

4. *Mammalian toxicity—acute.*

Acute Inhalation Toxicity (rat): Method A (40 CFR 799.9130).

Acute Oral Toxicity (rat): Method B (ASTM E 1163–98(2002) (Ref. 59) or 40 CFR 799.9110(d)(1)(i)(A)).

For the ''Mammalian Toxicity—Acute'' endpoint, EPA is proposing that certain ''Special Conditions'' in the form of the chemical substance's physical/chemical properties or physical state be considered in determining the appropriate test method that would be used from among those included for this endpoint in Table 3 in § 799.5087(j) of the proposed regulatory text. The OECD HPV SIDS Program recognizes that, for most chemical substances, the oral route of administration will suffice for this endpoint. However, consistent with the approach taken under the voluntary HPV Challenge Program, EPA is proposing that, for test substances that are gases at room temperature (25° C), the acute mammalian toxicity study be conducted using inhalation as the exposure route (described as Method A (40 CFR 799.9130) in Table 3 in § 799.5087(j) of the proposed regulatory text). In the case of a potentially explosive test substance, care must be taken to avoid the generation of explosive concentrations. For all other chemicals (i.e., those that are either liquids or solids at room temperature), EPA is proposing that the acute toxicity testing be conducted via oral administration using an ''Up/Down'' test method (described as Method B (ASTM E 1163–98(2002) or 40 CFR 799.9110(d)(1)(i)(A)) in Table 3 in § 799.5087(j) of the proposed regulatory text). Consistent with the voluntary HPV Challenge Program, EPA is proposing to allow the use of the Neutral Red Uptake (NRU) basal cytotoxicity assay to select the starting dose for the acute oral toxicity test. This test is included as a special condition in Table 3 of the proposed regulatory text. A document developed by NIH/NIEHS provides guidance on how to use the NRU assay to estimate a starting dose for an acute oral toxicity test (Ref. 50). Recent versions of the standardized protocols for the NRU assay are available at the NIEHS/ICCVAM website, *http://iccvam.niehs.nih.gov/methods/acutetox/invitrocyto/invcyt_proto.htm* (Refs. 51–53).

Dermal toxicity testing is not proposed in this rulemaking, and the Agency does not intend to include any dermal toxicity testing in any TSCA section 4 HPV SIDS rulemakings.

5. *Mammalian toxicity—genotoxicity.*

Gene mutations:

Bacterial Reverse Mutation Test (*in vitro*): 40 CFR 799.9510.

Chromosomal damage:

In Vitro Mammalian Chromosome Aberration Test (40 CFR 799.9537), or the *In Vivo* Mammalian Bone Marrow Chromosomal Aberration Test (rodents: mouse (preferred species), rat, or Chinese hamster) (40 CFR 799.9538), or the *In Vivo* Mammalian Erythrocyte Micronucleus Test (sampled in bone marrow) (rodents: mouse (preferred species), rat, or Chinese hamster) (40 CFR 799.9539).

Persons who would be required to conduct testing for chromosomal damage are encouraged to use *in vitro* genetic toxicity testing (i.e., the Mammalian Chromosome Aberration Test) to generate the needed genetic toxicity screening data, unless known chemical properties preclude its use. These could include, for example, physical chemical properties or chemical class characteristics. A primary focus of both the voluntary HPV Challenge Program and this proposed rule is to implement this program in a manner consistent with the OECD HPV SIDS Program and as part of a larger international activity with global involvement. This proposed approach provides the same degree of flexibility as that which currently exists under the OECD HPV SIDS testing program (Ref. 6). A subject person who uses one of the *in vivo* methods instead of the *in vitro* method to address this end-point would be required to submit to EPA a rationale for conducting that alternate test in the final study report.

6. *Mammalian toxicity—repeated dose/reproduction/developmental.*

Combined Repeated Dose Toxicity Study with the Reproduction/

Developmental Toxicity Screening Test: 40 CFR 799.9365.

Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355.

Repeated Dose 28–Day Oral Toxicity Study: 40 CFR 799.9305.

For the ''Mammalian Toxicity—Repeated Dose/Reproduction/Developmental'' endpoint, EPA recommends the use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365) as the test of choice. EPA recognizes, however, that there may be reasons to test a particular chemical substance using both the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9355) and the Repeated Dose 28–Day Oral Toxicity Study (40 CFR 799.9305) instead of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365). With regard to such cases, EPA is proposing that a subject person who uses the combination of the Reproduction/Developmental Toxicity Screening Test and the Repeated Dose 28–Day Oral Toxicity Study in place of the Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screen would be required to submit to EPA a rationale for conducting these alternate tests in the final study reports.

Certain of the chemical substances for which Mammalian Toxicity—Repeated Dose/Reproduction/Developmental testing is proposed may be used solely as ''closed system intermediates,'' as described in the EPA guidance document developed for the voluntary HPV Challenge Program (Ref. 46). As described in that guidance, such chemical substances may be eligible for a reduced testing battery which substitutes a developmental toxicity study for the SIDS requirement to address repeated dose (e.g., subchronic), reproductive, and developmental toxicity. In other words, since only the developmental toxicity study would be conducted for those chemical substances that qualify for a reduced testing battery, repeated dose (e.g., subchronic) and reproductive studies would not be conducted. At the present time, EPA does not have sufficient information to know with any degree of certainty which if any of the chemical substances that are listed in the proposed regulatory text are solely closed system intermediates as defined in the voluntary HPV Challenge Program guidance document (Ref. 46). Persons who believe that a chemical substance fully satisfies the terms outlined in the guidance document are encouraged to submit appropriate information along with their comments on this proposed rule which substantiate this belief. If, based on submitted information and other information available to EPA, the Agency believes that a chemical substance is considered likely to meet the requirements for use solely as a closed system intermediate, EPA would not address any developmental toxicity testing needs in this proposed rulemaking. In those cases in which the Agency can determine that chemicals are solely closed system intermediates, it plans to handle them in accordance with the existing OECD procedures.

B. When Would Any Testing Imposed by this Proposed Rulemaking Begin?

The testing requirements contained in this proposed rule are not effective until and unless the Agency issues a 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 may plan the initiation of any required testing as appropriate to submit the required final report by the deadline indicated as the number of months after the effective date that would be shown in § 799.5087(j) of the proposed regulatory text.

C. How Would the Studies Proposed Under this Test Rule be Conducted?

Persons required to comply with the final rule would have to conduct the necessary testing in accordance with the testing and reporting requirements established in the regulatory text of the final rule, and with the TSCA Good Laboratory Practice Standards (GLPS) (40 CFR part 792).

D. What Form of Test Substances Would be Tested Under this Rule?

EPA is proposing two distinct approaches for identifying the specific substances that would be tested under this proposed rule, the application of which would depend on whether the substance is considered to be a ''Class 1'' or a ''Class 2'' substance. First introduced when EPA compiled the TSCA Chemical Substance Inventory, the term Class 1 substance refers to a chemical substance having a chemical composition that consists of a single chemical species (not including impurities) that can be represented by a specific, complete structure diagram. By contrast, the term Class 2 substance refers to a chemical substance having a composition that cannot be represented by a specific, complete chemical structure diagram, because such a substance generally contains two or more different chemical species (not including impurities). Table 2 in § 799.5087(j) of the proposed regulatory text identifies the listed chemical substances as either Class 1 or Class 2 substances.

EPA is proposing that, for the Class 1 substances that are listed in the proposed rule, the test substance have a purity of 99% or greater. EPA has generally applied this standard of purity to the testing of Class 1 substances in the past under TSCA section 4(a) testing actions, except for substances where it has been shown that such purity is unattainable. EPA is soliciting comment on whether a purity level of 99% or greater cannot be attained for any of the Class 1 substances listed in this proposed rule. For the Class 2 substances that are listed in the proposed rule, EPA is proposing that the test substance be any representative form of the chemical substance, to be defined by the test sponsor(s).

In proposing a different approach for identifying the substance to be tested with regard to Class 2 substances, EPA recognizes two characteristics which further distinguish Class 1 from Class 2 substances. First, unlike for Class 1 substances, knowledge of the composition of commercial Class 2 substances can vary in quality and specificity from substance to substance.

The composition of the chemical species which comprise a Class 2 substance may be:

- Well-characterized in terms of molecular formulae, structural diagrams, and compositional percentages of all species present (for example, methyl phenol);
- Less well-characterized, for example, characterized only by molecular formulae, non-specific structural diagrams, and/or by incomplete or unknown compositional percentages of the species present (for example, C12–C14 tert-alkyl amines); or
- Poorly characterized because all that is known is the identity of only some of the chemical species present and their percentages of composition, or of only the feedstocks and method of manufacture used to manufacture the substance (for example, nut shell liquor of cashew).

Secondly, the composition of some Class 2 substances may vary from one manufacturer to another, or, for a single manufacturer, from production run to production run, because of small variations in feedstocks, manufacturing methods, or other production variables. A ''Class 2'' designation most frequently represents a group of chemical substances comprising substances that have similar combinations of different

chemical species and/or that were prepared from similar feedstocks using similar production methods. By contrast, Class 1 substances generally represent a much narrower group of substances for which the only variables are their impurities. EPA believes that, for purposes of this proposed rule, the testing of any representative form of a subject Class 2 substance would provide the data necessary to support the development of preliminary or screening level hazard and risk characterizations for the subject Class 2 substance. However, EPA would encourage the selection of representative forms of test substances that meet industry or consensus standards, where they exist. In accordance with TSCA GLPS at 40 CFR part 792, the final study report would be required to include test substance identification information, including name, CAS number, strength, purity, and composition, or other appropriate characteristics. (See 40 CFR 792.185).

As an alternative to requiring the testing of a representative form of a Class 2 substance designated by a person subject to the final rule, EPA is considering whether the Agency should specify the particular form of each chemical substance that must be tested, and, if so, what criteria EPA should use to identify the particular representative form that would be tested. EPA might specify, for example, a form of a substance that meets an industry or consensus specification, if one exists, or the form with the highest production volume, which could potentially be identified via information reported under a TSCA section 8(a) rule, or by other means.

Under both of the approaches described in this unit, manufacturers and processors of each chemical substance listed in this proposed rule would be jointly responsible for the testing of a representative form of each Class 2 substance.

To facilitate EPA's review of exemption applications under this alternative, the Agency would require the submission of certain chemical substance-identifying data, including characteristics and properties of the exemption applicant's substance, such as boiling point, melting point, chemical analysis, additives (if any), and spectral data information.

EPA solicits comment on the proposed alternative approaches to the testing of Class 2 substances included in this proposed rule.

E. Would I Be Required to Test Under this Rule?

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

1. *Would I be subject to this rule?* You would be subject to this 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 chemical substances listed in this proposed rule during the time period discussed in Unit IV.E.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 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 this rule if you manufacture or process, or intend to manufacture or process, a chemical substance listed in this proposed rule at any time from the effective date of the final test rule to the end of the test data 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 what testing is required and when testing is completed. See Unit IV.E.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 this TSCA section 4(a) test rule, which, unless otherwise noted in the regulatory text, incorporates 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 (because, for example, no person in Tier 1 had submitted a letter of intent to conduct testing), as described in Unit IV.E.3.d. Note that both persons in Tier 1 who obtain exemptions and persons in Tier 2 would nonetheless be subject to providing reimbursement to persons who actually conduct the testing, as described in Unit IV.E.4.

a. *Who would be in Tier 1 and Tier 2?* All persons who would be subject to the final rule are considered to be in Tier 1 unless they fall within Tier 2. Table 4 of this unit describes who is in Tier 1 and Tier 2.

TABLE 4.—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 substance, 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: —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring chemical substance (as defined at 40 CFR 710.4(b));—As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kg (1,100 lbs.) annually (as described at 40 CFR 790.42(a)(4)); or —In small quantities solely for research and development (R and D) (as described at 40 CFR 790.42(a)(5)). 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.E.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 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 chemical substance subject to this proposed rule, e.g., manufacturers or processors of a chemical 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.E.1. and § 799.5087(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. 54). 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. 55).

c. *When would it be appropriate for a person who would be 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 § 799.5087(c)(2), (c)(5), (c)(7), and (c)(11) of the proposed regulatory text. In this 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 this rule, the Agency would conditionally approve your exemption application under 40 CFR 790.87.

The Agency would terminate conditional exemptions if a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA. EPA may then require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5087(c)(8) 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., § 799.5087(c)(6) 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 § 799.5087(c)(4)–(c)(7) and § 799.5087(d)(3) of the proposed regulatory text). Note that persons who obtain exemptions or receive them automatically would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit IV.E.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.E.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 with the submission of the required data to EPA, the Agency may require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5087(c)(10) of the proposed regulatory text.

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

- No manufacturer in Tier 1 has notified EPA of its intent to conduct testing; and
- 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 § 799.5087(c)(4), (c)(5), (c)(6), and (c)(7) of the proposed regulatory text. 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 required under this 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 final rule. However, in the event it does not receive a letter of intent for one or more of the tests required by the final 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 document in the **Federal Register** 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).

F. What Reporting Requirements are Proposed Under this Test 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 of the final rule, which would be shown in § 799.5087(j) of the proposed regulatory text. A robust summary of the final report for each specific test should be submitted in addition to and at the same time as the final report. The term ''robust summary'' is used to describe the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report which can be either an experiment or in some cases an estimation or prediction method. Guidance for the compilation of robust summaries is described in a document entitled *Draft Guidance on Developing Robust Summaries* (Ref. 15) which is available at: *http://www.epa.gov/HPV/pubs/general/robsumgd.htm*. Persons who respond to this request to submit robust summaries are also encouraged to submit the robust summary electronically via the High Production Volume Information System (HPVIS) to allow for its ready incorporation into HPVIS. Directions for electronic submission of robust summary information into HPVIS are provided at *https://iaspub.epa.gov/oppthpv/metadata.html*. This link will direct you to the ''HPVIS Quick Start and User's Guide.''

G. What Would I Need to Do if I Cannot Complete the Testing Required by the Final Rule?

A company who submits a letter of intent to test under the final rule and who 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. Would There Be Sufficient Test Facilities and Personnel to Undertake the Testing Proposed Under this Test Rule?

EPA's most recent analysis of laboratory capacity (Ref. 47) indicates that available test facilities and personnel would adequately accommodate the testing proposed in this rule.

I. 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 would seek further health and/or environmental effects testing for these chemical substances. Should the Agency decide to seek such additional testing via a test rule, EPA would initiate a separate action for this purpose.

V. Export Notification

Any person who exports, or intends to export, one of the chemical substances contained in this proposed rule in any form (e.g., as byproducts, impurities, components of Class 2 substances, etc.) will be subject to the export notification requirements in TSCA section 12(b)(1) and at 40 CFR part 707, subpart D, but only after the final rule is issued and only if the chemical is contained in the final rule. 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 chemical substance.

VI. Economic Impacts

In addition, EPA has prepared an economic assessment entitled *Economic Analysis for the Proposed Section 4 Test Rule for High Production Volume Chemicals; Final Report* (Ref. 17), a copy of which has been placed in the public docket for this proposed rulemaking. This economic assessment evaluates the potential for significant economic impacts as a result of the testing that would be required by this proposal. The analysis covers 19 chemical substances. The total social cost of providing test data on the 19 chemical substances that were evaluated in this economic analysis is estimated to be $4.4 million (Ref. 17).

While legally subject to this test rule, processors of a subject chemical would be required to comply with the requirements of the rule only if they are directed to do so by EPA as described in § 799.5087(c)(5) and (c)(6) of the proposed regulatory text. EPA would only require processors to test if no person in Tier 1 has submitted a notice 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 assumes that, for each chemical substance in this proposed rule, at least one such person will submit a letter of intent to conduct the required testing and that person will conduct such testing and will submit the test data to EPA. Because processors would not need to comply with the proposed rule initially, the economic assessment does not address processors.

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 estimated the impact of testing requirements as a percentage of each chemical substance's sale price. This measure compares annual revenues from the sale of a chemical substance to the annualized compliance cost for that chemical to assess the percentage of testing costs that can be accommodated by the revenue stream generated by that chemical over a number of years. Compliance costs include costs of testing and administering the testing, as well as reporting costs. Annualized compliance 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 using a 7% discount rate. Annualized testing costs are then divided by the estimated annual revenue of the chemical substance to derive the cost-to-sales ratio. EPA estimates the total annualized compliance cost of testing for the 19 chemical substances evaluated in the economic analysis to be $1.68 million under the average cost scenario. In addition, the TSCA section 12(b) export notification requirements (included in the total and annualized cost estimates) that would be triggered by the final rule are expected to have a negligible impact on exporters. The estimated cost of the TSCA section 12(b) export notification requirements, which, under the final rule, would be required for the first export to a particular country of a chemical subject to the rule, is estimated to range from $25.56 per notice to $80.22 per notice (Ref.17). The Agency's estimated total costs of testing (including both laboratory and administrative costs) annualized testing cost, and public reporting burden hours for this proposed rule are presented in the economic assessment.

Under a least cost scenario, 16 out of the 19 chemical substances (84%) would have a price impact at less than the 1% level. Similarly, 15 out of the 19 chemical substances (79%) would be impacted at less than the 1% level under an average cost scenario. Thus, the potential for adverse economic impact due to the proposed test rule is low for at least 79% of the chemical substances in this proposed rule. Approximately 4 chemicals (21%) of the 19 chemical substances for which price data are available would have a price impact at a level greater than or equal to 1% under the least (average) cost scenario.

EPA believes, on the basis of these calculations, that the proposed testing of the chemical substances presents a low potential for adverse economic impact for the majority of the chemical substances. Because the subject chemical substances have relatively large production volumes, the annualized costs of testing, expressed as a percentage of annual revenue, are very small for most of the chemicals. There are, however, some chemical substances for which the price impact is expected to exceed 1% of the revenue from that chemical. The potential for adverse economic impact is expected to be higher for these chemical substances. In these cases, companies may choose to use revenue sources other than the profits from the individual chemicals to pay for testing. Smaller businesses are less likely to have additional revenue sources to cover the compliance costs in this situation. Therefore, the Agency also compared the costs of compliance to company sales for small businesses.

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 provided as a result of the test rule where such information has not been publicly available. Because of constraints on information on the value of 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. Public Comment

As discussed in Units III.D. and III.E., the Agency solicits comment regarding additional information pertaining to potential exposure of workers and consumers, respectively, to the chemical substances identified in this proposed rule. Also, as discussed in Units III.F., the Agency solicits comment regarding additional information pertaining to environmental releases of the chemical substances identified in this proposed rule.

As discussed in Unit III.F., EPA is soliciting comments which identify existing data that may meet the requirements of studies under this proposed rule. To the extent that data relevant to the testing specified in this proposed rule are known to exist, EPA strongly encourages the submission of this information as comments to the proposed rule. Data submitted to EPA to meet the requirements of testing under this proposed rule must be in the form of full copies of unpublished studies or full citations of published studies, and may be accompanied by a robust summary (Ref. 15). To the extent that studies required under this proposed rule are currently available, and the data are judged sufficient by EPA, testing for the endpoint/chemical combination will not be required in the final rule based on this proposed rule.

EPA also solicits public comment on the test methods proposed and the analysis detailing the burdens and costs for the regulatory impacts resulting from this rule.

In addition, EPA solicits comment on the proposed and alternative approaches to the testing of Class 2 substances, whether the proposed approach for testing Class 1 substances (i.e., that each Class 1 substance be tested at a purity of 99% or more) should be applied to any Class 2 substances, and whether the proposed or alternative approaches for the testing of Class 2 substances (i.e., that a representative sample of each Class 2 substance be tested) should be applied to any Class 1 substances.

VIII. Materials in the Docket

As indicated under **ADDRESSES**, a docket has been established for this proposed rulemaking under docket ID number EPA–HQ–OPPT–2007–0531. The following is a listing of the documents that have been placed in the public 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 public docket, regardless of whether these referenced documents are physically located in the public docket. For assistance in locating documents that are referenced in documents that EPA has placed in the public docket, but that are not physically located in the docket, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**. The public docket is available for review as specified under **ADDRESSES**.

1. EPA. Data Collection and Development on High Production Volume (HPV) Chemicals. Notice. **Federal Register** (65 FR 81686, December 26, 2000) (FRL–6754–6).

2. EPA. Proposed Test Rule for the Testing of Certain High Production Volume Chemicals. Proposed Rule. **Federal Register** (65 FR 81658, December 26, 2000) (FRL–6758–4).

3. EPA. Final Test Rule for the Testing of Certain High Production Volume Chemicals. Final Rule. 40 CFR part 799. **Federal Register** (71 FR 13708, March 16, 2006) (FRL–7335–2).

4. EPA. TSCA Section 4(a)(1)(B) Final Statement of Policy. Notice. **Federal Register** (58 FR 28736, May 14, 1993).

5. EPA, OPPT. HPV Challenge Program Chemical List. This list is updated periodically, and is available on-line at: *http://www.epa.gov/oppt/chemrtk/pubs/update/hpvchmlt.htm*.

6. OECD Secretariat. Manual for the Investigation of HPV Chemicals. OECD Programme on the Co-Operative Investigation of High Production Volume Chemicals. Paris, France. September 2004. Available on-line at: *http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.htm*.

7. International Council of Chemical Associations (ICCA). ICCA HPV Working List of Chemicals. October 2005. This list is updated periodically, and is available on-line at: *http://www.cefic.org/activities/hse/mgt/hpv/hpvinit.htm*.

8. EPA. TSCA section 4(a)(1)(B) Proposed Statement of Policy. Notice. **Federal Register** (56 FR 32294, July 15, 1991).

9. OECD Secretariat. Summary Record of the 13th Joint Meeting of the OECD Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals, November 8–10, 1989. ENV/CHEM/CM/89.2. February 1990.

10. OECD Secretariat. Proposal for Further Work on the Investigation of High Production Volume Chemicals. OECD Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals. ENV/CHEM/CM/89.14. October 1989.

11. OECD. Decision-Recommendation on the Co-Operative Investigation and Risk Reduction of Existing Chemicals–C(90)163/FINAL. January 31, 1991.

12. CMA (ACC). Comments on EPA's TSCA section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, EPA. September 13, 1991.

13. Epoxy Resin Systems Task Group of the Society of the Plastics Industry, Inc. Comments on EPA's TSCA section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, EPA. September 13, 1991.

14. EPA, Office of Pollution Prevention and Toxics (OPPT). Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? April 1998. Available on-line at: *http://www.epa.gov/chemrtk/pubs/general/hazchem.htm*.

15. EPA, OPPT. Draft Guidance on Developing Robust Summaries. October, 22, 1999. Available on-line at: *http://www.epa.gov/HPV/pubs/general/robsumgd.htm*.

16. EPA, Office of Prevention, Pesticides and Toxic Substances (OPPTS). Letter from Susan H. Wayland, Deputy Assistant Administrator, to participants in the voluntary HPV Challenge Program. October 14, 1999. Available on-line at *http://www.epa.gov/chemrtk/pubs/general/ceoltr2.htm*.

17. EPA, OPPT, Economics, Exposure and Technology Division (EETD), Economic and Policy Analysis Branch (EPAB). Economic Analysis for the Proposed Section 4 Test Rule for High Production Volume Chemicals; Final Report. February 2008.

18. EPA, OPPT, EETD. Testing of Certain High Production Volume Chemicals; Second Group of Chemicals (Exposure Findings Supporting Information). July 2008.

19. EPA. OPPT. Chemical Information and Testing Branch (CITB). Response to public comments regarding testing of certain high production volume chemicals. May 31, 2005.

20. NIOSH. National occupational exposure survey field guidelines. Vol. I. Seta JA, Sundin DS, Pedersen DH, eds. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 88–106. 1988. Available on-line at: *http://www.cdc.gov/niosh/88-106.html*.

21. EPA. Inert Reassessment—Oxalic Acid (CAS Reg. No. 144–62–7). Action Memorandum. From: Pauline Wagner, Chief, Inert Ingredient Assessment Branch, To: Lois A. Rossi, Director, Registration Division. September 6, 2005.

22. American Society for Testing and Materials International (ASTM International). Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals. ASTM. E 324–99. 1999.

23. ASTM International. Standard Test Method for Vapor Pressure of Liquids by Ebulliometry. ASTM. E 1719–05. 2005.

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25. ASTM International. Standard Test Method for Partition Coefficient (*n*-Octanol/Water) Estimation by Liquid Chromatography. ASTM. E 1147–92(2005). 2005.

26. ASTM International. Standard Test Method for Measurements of Aqueous Solubility. ASTM. E 1148–02. 2002.

27. 49. ASTM International. Question about ASTM E 324. E-mail from Diane Rehiel, ASTM, to Greg Schweer, CITB, CCD, OPPT, EPA. September 15, 2004.

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29. Meylan, W.M., Howard, P.H., and Boethling, R.S. Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient. *Environmental Toxicology and Chemistry*. 15(2):100–106. 1996.

30. ASTM International. Standard Test Method for Determining Ready, Ultimate, Biodegradability of Organic Chemicals in a Sealed Vessel CO_2 Production Test, ASTM E 1720–01. 2001.

31. International Organization for Standardization (ISO). Water quality—Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium—Method by analysis of inorganic carbon in sealed vessels (CO_2 headspace test). ISO 14593. 1999.

32. ISO. Water quality—Evaluation in an aqueous medium of the ''ultimate'' aerobic biodegradability of organic compounds—Method by analysis of dissolved organic carbon (DOC). ISO 7827. 1994.

33. ISO. Water quality—Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium by determination of oxygen demand in a closed respirometer. ISO 9408. 1999.

34. ISO. Water quality—Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium—Carbon dioxide evolution test. ISO 9439. 1999.

35. ISO. Water quality—Evaluation in an aqueous medium of the ''ultimate'' aerobic biodegradability of organic compounds—Method by analysis of biochemical oxygen demand (closed bottle test). ISO 10707. 1994.

36. ISO. Water quality—Evaluation in an aqueous medium of the ultimate aerobic biodegradability of organic compounds—Determination of biochemical oxygen demand in a two-phase closed bottle test (available in English only). ISO 10708. 1997.

37. ISO. Water quality—Guidance for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium. ISO 10634. 1995.

38. ASTM International. Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians. ASTM. E 729–96(2002). 2002.

39. ASTM International. Standard Guide for Conducting Static Toxicity Tests with Microalgae. ASTM. E 1218–04e1. 2004.

40. ASTM International. Standard Guide for Conducting Daphnia magna Life-Cycle Toxicity Tests. ASTM. E 1193–97(2004). 2004.

41. Veith, G.D. and Kosian, P. Estimating bioconcentration potential from octanol/water partition coefficients, in Physical Behavior of PCB's in the Great Lakes (MacKay, Paterson, Eisenreich, and Simmons, eds.), Ann Arbor Science, Ann Arbor, MI. 1982.

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43. EPA. Document containing EPA's Policy Statement under TSCA section 5 entitled *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances*. Notice. **Federal Register** (64 FR 60194, November 4, 1999) (FRL–6097–7). Available on-line at: *http://www.epa.gov/oppt/newchems/pubs/pbtpolcy.htm*.

44. EPA. Significant New Use Rules; General Provisions for New Chemical Follow-Up. Final Rule. **Federal Register** (54 FR 31307, July 27, 1989).

45. EPA, OPPT. Development of Chemical Categories in the HPV Challenge Program (Draft). August 25, 1999. Available on-line at: *http://www.epa.gov/chemrtk/pubs/general/categuid.htm*.

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48. EPA, OPPT. The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program. August 26, 1999. Available on-line at: *http://www.epa.gov/chemrtk/pubs/general/sarfinl1.htm*.

49. EPA, OPPT, EETD, EPAB. Economic Analysis in Support of the TSCA 12(b) Information Collection Request. October 30, 1998.

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51. NIEHS 2003a. Test Method Protocol for Solubility Determination, *in vitro* Cytotoxicity Validation Study—Phase III. National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). September 24, 2003. Available on-line at: *http://iccvam.niehs.nih.gov/methods/acutetox/invitrocyto/invcyt_proto.htm*.

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

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

56. EPA. OPPT. High Production Volume Chemical Data Information System (HPVIS). Data from HVPIS on 18 HPV chemicals. May 2008.

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IX. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this proposed rule is not a ''significant regulatory action'' subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, because it does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in section 3(f)(4) of the Executive Order. Accordingly, EPA did not submit this proposed rulemaking to OMB for review under Executive Order 12866.

EPA has prepared an economic analysis of this proposed action, which is contained in a document entitled *Economic Analysis for the Proposed Section 4 Test Rule for High Production Volume Chemicals; Final Report* (Ref. 17). 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

This proposed rule does not impose any new or amended paperwork collection requirements that would require additional review and/or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. Although the activities are approved, OMB has specified that the additional burden associated with a new test rule is not covered by the ICR until the final rule is effective. The information collection requirements contained in TSCA section 4 test rules have already been approved by OMB under PRA, and have been assigned OMB control number 2070–0033 (EPA ICR No. 1139). In the context of developing a new test rule, the Agency must determine whether the total annual burden covered by the approved ICR needs to be amended to accommodate the burden associated with the new test rule. If so the Agency must submit an Information Correction Worksheet (ICW) to OMB and obtain OMB approval of an increase in the total approved annual burden in the OMB inventory. The Agency's estimated burden for this test rule is provided in the economic analysis (Ref. 17).

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 rulemaking does not propose any new or changes to the export notification requirements, and is not expected to result in any substantive changes in the burden estimates for EPA ICR No. 0795 that would require additional review and/or approval by OMB.

Under 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 PRA, unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations codified in title 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 in certain EPA regulations is consolidated in 40 CFR part 9.

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 19 chemicals is 9,008 hours, with an estimated burden per chemical of 474 hours (Ref. 17). 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 0.5 hours for each subsequent notification (Ref. 17). 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. 17), which is summarized in Unit VI., and a copy of which is available in the docket for this proposed rulemaking. The following is a brief summary of the factual basis for this certification.

Under 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.

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 proposed rulemaking (Ref. 17), 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 business.

Two factors are examined in EPA's small entity impact analysis (Ref. 17) in order to characterize the potential small entity impacts of this proposed rule on small business:

1. The size of the adverse economic impact (measured as the ratio of the cost to sales or revenue).

2. The total number of small entities that experience the adverse economic impact.

Section 601(3) of RFA establishes as the default definition of ''small business'' the definition used in section 3 of the Small Business Act, 15 U.S.C. 632, under which SBA establishes small business size standards (13 CFR 121.201). For this proposed rulemaking, EPA has analyzed the potential small business impacts using the size standards established under this default definition. The SBA size standards, which are primarily intended to determine whether a business entity is eligible for 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. In analyzing potential impacts, RFA recognizes that it may be appropriate at times to use an alternate definition of small business. As such, section 601(3) of RFA 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 business 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 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 codes 325 and 324110), approximately 98% of the firms would be classified as small businesses under the default SBA definition. The SBA size standard for 75% of this industry sector is 500 employees, and the size standard for 23% of this industry sector is either 750; 1,000; or 1,500 employees. 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 RFA determination for this proposed rule is based on an analysis using the default SBA size standards. Although EPA is not currently proposing to establish an alternate definition for use in the analysis conducted for this proposed rule, the analysis for this proposed rule also presents the results of calculations using a standard based on total annual sales (40 CFR 704.3). EPA is interested in receiving comments on whether the Agency should consider establishing an alternate definition for small business to use in the small entity impact analyses for future TSCA section 4(a) test rules, and what size cutoff may be appropriate.

The SBA has developed 6 digit NAICS code-specific size standards based on employment thresholds. These size standards range from 500 to 1,500 employees for the various 6 digit NAICS codes that are potentially impacted (Ref. 17). For a conservative estimate of the number of small businesses affected by this proposed rule, the Agency chose an employment threshold of less than 1,500 employees for all businesses regardless of the NAICS-specific threshold to determine small business status.

For each manufacturer of the 19 chemicals covered by this proposed rule, the parent company (ultimate corporate entity, or UCE) was identified and sales and employment data were obtained for companies where data was publicly available. The search determined that there were 48 affected UCEs. Sales and employment data could be found for 45 and 46 of these UCEs (88%), respectively.

Parent company sales data were collected to identify companies that qualified as a ''small business'' for purposes of the RFA analysis. Based on the SBA size standard applied (1,500 employees or less), 20 companies were identified as small.

The potential significance of this proposed rule's impact on small businesses was analyzed by examining the number of small entities that experienced different levels of costs as a percentage of their sales. Small businesses were placed in the following categories on the basis of cost-to sales ratios: less than 1%, greater than 1%, and greater than 3%. This analysis was conducted under both a least and average cost scenario.

Of the 20 small businesses analyzed for small business impacts, one company had no sales data available. Another two companies could not be classified as small or large because there were no employment data available, but were still included in the small business impact analysis. Of the 19 designated as small businesses, none had cost-to-sales ratios of greater than 1% under both the least and average cost scenarios. For the chemicals where sales data were unavailable, EPA used the median sales value sales of all other small businesses equal to $15.4 million. The costs for the three companies were estimated to be well below 0.01% of this sales level. Given these results, the Agency has determined that there is not a significant economic impact on a substantial number of small entities as a result of this proposed rule, if finalized.

The estimated cost of the 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 $80.22 for the first time that an exporter must comply with TSCA section 12(b)(1) export notification requirements, and $25.56 for each subsequent export notification submitted by that exporter (Refs. 17, 48, and 49). 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.

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 rulemaking 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 aggregate costs of this proposed rule, which are summarized in Unit VI., would be $4.4 million. The total annualized costs of this proposed rule are estimated to be $1.68 million. 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, and 205 of UMRA.

E. Executive Order 13132

Under 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 proposed 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

Under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 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 Executive 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 proposed rule.

G. Executive Order 13045

This proposed rule is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because it does not establish an environmental standard intended to mitigate health or safety risks, will not have an annual effect on the economy of $100 million or more, nor does it otherwise have a disproportionate effect on children. This proposed rule would establish testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemicals, and would result in the development of data about those chemicals that can subsequently be used to assist the Agency and others in determining whether the chemicals 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 unlikely 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 standards 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(a), EPA is required by TSCA section 4(b) to include 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. For some of the testing that would be required by this rule, EPA is proposing the use of voluntary consensus standards issued by ASTM and ISO which evaluate the same type of toxicity as the TSCA and OECD test guidelines, where applicable. Copies of the 17 ASTM and ISO standards referenced in the proposed regulatory text at § 799.5087(h) have been placed in the docket for this proposed rulemaking. You may obtain copies of the ASTM standards from the American Society for Testing and Materials, 100 Bar Harbor Dr., West Conshohocken, PA 19428–2959, and copies of the ISO standards from the International Organization for Standardization, Case Postale, 56 CH-1211 Genève 20 Switzerland. In the final rule, EPA intends to seek approval from the Director of the **Federal Register** for the incorporation by reference of the ASTM and ISO standards used in the final rule in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

EPA is not aware of any potentially applicable voluntary consensus standards which evaluate partition coefficient (*n*-octanol/water) generator column, water solubility (column elution and generator column), acute inhalation toxicity, bacterial reverse mutations, *in vivo* mammalian bone marrow chromosomal aberrations,

combined repeated dose with reproductive/developmental toxicity screen, repeated dose 28–day oral toxicity screen, or the reproductive developmental toxicity screen which could be considered in lieu of the TSCA guidelines, 40 CFR 799.6756, 799.6784, 799.6786, 799.9130, 799.9510, 799.9538, 799.9365, 799.9305, and 799.9355, respectively, upon which the test standards in this proposed rule are based. The Agency invites comment on the potential use of voluntary consensus standards in this proposed rulemaking, and, specifically, invites the public to identify potentially applicable consensus standard(s) and to explain why such standard(s) should be used here.

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 that require special consideration by the Agency 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 believes that the information collected under this proposed rule, if finalized, will assist EPA and others in determining the potential hazards and risks associated with the chemicals covered by the rule. Although not directly impacting environmental justice-related concerns, this information will better enable the Agency to better protect human health and the environment, including in low-income and minority communities.

List of Subjects in 40 CFR Part 799

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

Dated: July 17, 2008.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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

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

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

2. By adding § 799.5087 to subpart D of part 799 that would read as follows:

§ 799.5087 Chemical testing requirements for certain high production volume chemicals; second group of chemicals.

(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. For the chemical substances identified as ''Class 1'' substances in Table 2 in paragraph (j) of this section, the purity of each substance must be 99% or greater, unless otherwise specified in this section. For the chemical substances identified as ''Class 2'' substances in Table 2 in paragraph (j), a representative form of each substance must be tested. The representative form selected for a given Class 2 substance should meet industry or consensus standards where they exist.

(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 the effective date of the final rule 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 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

Tier 1 (Persons initially required to comply with this section)	Tier 2 (Persons not initially required to comply with this section)
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.	Tier 2A. 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: —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring substance (as defined at 40 CFR 710.4(b)); —As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kilogram (kg) (1,100 lbs.) annually (as described at 40 CFR 790.42(a)(4)); or —For research and development (as described at 40 CFR 790.42(a)(5)). 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 in Tier 2, that is those 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), (c)(5), (c)(6), (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 30 days after the effective date of the final rule.

(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 within 30 days after the effective date of the final rule, 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 (as specified in Table 1 in paragraph (c) of this section) 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 [*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 intentto 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 (as specified in Table 1 in paragraph (c) of this section) 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 [*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 manufacture 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)(6) 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 manufacture 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 paragraph (b) of §§ 790.80, 790.82(e)(1), 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*? (1) The tests that are required for each chemical substance are indicated in

Table 2 in paragraph (j) of this section. The test methods that must be followed are provided in Table 3 in paragraph (j) of this section. You must proceed in accordance with these test methods as required according to Table 3 in paragraph (j) of this section, or as appropriate if more than one alternative is allowed according to Table 3 in paragraph (j) of this section.

(i) *Reporting requirements.* A final report for each specific test for each subject chemical substance must be received by EPA by [*date 13 months after the effective date of the final rule*] unless an extension is granted in writing pursuant to 40 CFR 790.55. A robust summary of the final report for each specific test should be submitted in addition to and at the same time as the final report. The term ''robust summary'' is used to describe the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report which can be either an experiment or in some cases an estimation or prediction method. Guidance for the compilation of robust summaries is described in a document entitled *Draft Guidance on Developing Robust Summaries* which is available at: *http://www.epa.gov/HPV/pubs/general/robsumgd.htm.*

(j) *Designation of specific chemical substances and testing requirements.* The chemical substances identified by chemical name, Chemical Abstract Service registry number (CAS No.), and class in Table 2 of this paragraph must be tested in accordance with the requirements designated in Tables 2 and 3 of this paragraph, and the requirements described in 40 CFR Part 792—Good Laboratory Practice Standards:

TABLE 2.—CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS

CAS No.	Chemical Name	Class	Required Tests/ (See Table 3 of this paragraph)
75–07–0	Acetaldehyde	1	C2, F2
78–11–5	1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester)	1	C4
84–65–1	9,10-Anthracenedione	1	C6
89–32–7	1H,3H-Benzo[1,2-c:4,5-c']difuran-1,3,5,7-tetrone	1	A3, A4, A5, B, C1, D, E1, F1
110–44–1	2,4-Hexadienoic acid, (E,E)-	1	C6, F2
118–82–1	Phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)-	1	C1
119–61–9	Methanone, diphenyl-	1	B, C2
144–62–7	Ethanedioic acid	1	A1, A2, A3, A5, B, C1, E2, F2
149–44–0	Methanesulfinic acid, hydroxy-, monosodium salt	1	E1
2524–04–1	Phosphorochloridothioic acid, O,O-diethyl ester	1	A1, A2, A3, A4, A5, B, C1, E1, E2, F2
4719–04–4	1,3,5-Triazine-1,3,5(2H,4H,6H)-triethanol	1	C6
6381–77–7	D-erythro-Hex-2-enonic acid, γ-lactone, monosodium salt	1	A4, B, C1
31138–65–5	D-gluco-Heptonic acid, monosodium salt, (2.xi.)-	1	A1, A2, A4, A5, B, C1, D, E1, E2, F1
66241–11–0	C.I. Leuco Sulphur Black 1	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68187–76–8	Castor oil, sulfated, sodium salt	2	A1, A2, A4, A5, C1, D, E1, E2, F1
68187–84–8	Castor oil, oxidized	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68479–98–1	Benzenediamine, ar,ar-diethyl-ar-methyl-	1	A1, A2, A3, A4, A5, C1, E1, E2, F1
68527–02–6	Alkenes, C12–24, chloro	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1
68647–60–9	Hydrocarbons, C > 4	2	A2, A3, A5, B, C1, D, E1, E2, F1

TABLE 3.—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2 OF THIS PARAGRAPH

Testing Category	Test	Test Requirements and References	Special Conditions
Physical/Chemical Properties	A	1. Melting Point: ASTM E 324–99 (capillary tube) 2. Boiling Point: ASTM E 1719–05 (ebulliometry) 3. Vapor Pressure: ASTM E 1782–03 (thermal analysis) 4. *n*-Octanol/Water Partition Coefficient (log 10 basis) or log K_{ow}: (See Special Conditions for the log K_{ow} test requirement and select the appropriate method to use, if any, from those listed in this column.) Method A: 40 CFR 799.6755 (shake flask) Method B: ASTM E 1147–92(2005) (liquid chromatography) Method C: 40 CFR 799.6756 (generator column) 5. Water Solubility: (See special conditions for the water solubility test requirement and select the appropriate method to use, if any, from those listed in this column.) Method A: ASTM E 1148-02 (shake flask) Method B: 40 CFR 799.6784 (shake flask) Method C: 40 CFR 799.6784 (column elution) Method D: 40 CFR 799.6786 (generator column)	*n-Octanol/water Partition Coefficient* or log K_{ow}: Which method is required, if any, is determined by the test substance's estimated [i] log K_{ow} as follows: log K_{ow} < 0: no testing required. log K_{ow} range 0–1: Method A or B. log K_{ow} range > 1–4: Method A or B or C. log K_{ow} range > 4–6: Method B or C. log K_{ow} > 6: Method C. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7. *Water Solubility*: Which method is required, if any, is determined by the test substance's estimated [ii] water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7. > 5,000 mg/L: Method A or B. > 10 mg/L—5,000 mg/L: Method A, B, C, or D. > 0.001 mg/L—10 mg/L: Method C or D. ≤ 0.001 mg/L: no testing required.
Environmental Fate and Pathways—Ready Biodegradation	B	For B, consult ISO 10634 for guidance, and choose one of the methods listed in this column: 1. ASTM 1720–01 (sealed vessel CO_2 production test) OR 2. ISO 14593 (CO_2 headspace test) OR 3. ISO 7827 (analysis of DOC) OR 4. ISO 9408 (determination of oxygen demand in a closed respirometer) OR 5. ISO 9439 (CO_2 evolution test) OR 6. ISO 10707 (closed bottle test) OR 7. ISO 10708 (two-phase closed bottle test)	Which method is required, if any, is determined by the test substance's physical and chemical properties, including its water solubility. ISO 10634 provides guidance for selection of an appropriate test method for a given test substance. Test sponsors must provide in the final study report the underlying rationale for the method selected.
Aquatic Toxicity	C1	For C1, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C1*: 1. Acute Toxicity To Fish: ASTM E 729–96(2002) 2. Acute Toxicity To Daphnia: ASTM E 729–96(2002) 3. Toxicity To Plants (Algae): ASTM E 1218–04e1 *Test Group 2 for C1*: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97(2004) 2. Toxicity To Plants (Algae): ASTM E 1218–04e1	The following are the special conditions for C1, C2, C3, C4, C5, and C7 testing; there are no special conditions for C6. Which test group is required is determined by the test substance's measured log K_{OW} as obtained under Test Category A, or using an existing measured log K_{OW}. [iii] If log K_{ow} < 4.2: Test Group 1 is required. If log K_{ow} ≤ 4.2: Test Group 2 is required,

TABLE 3.—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2 OF THIS PARAGRAPH—Continued

Testing Category	Test	Test Requirements and References	Special Conditions
	C2	For C2, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See special conditions. *Test Group 1 for C2*: 1. Acute Toxicity To Daphnia: ASTM E 729–96 (2002) 2. Toxicity To Plants (Algae): ASTM E 1218–04e1 *Test Group 2 for C2*: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97(2004) 2. Toxicity To Plants (Algae): ASTM E 1218–04e1	
	C3	For C3, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See special conditions. *Test Group 1 for C3*: 1. Acute Toxicity To Fish: ASTM E 729–96 (2002) 2. Toxicity To Plants (Algae): ASTM E 1218–04e1 *Test Group 2 for C3*: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97(2004) 2. Toxicity To Plants (Algae): ASTM E 1218–04e1	
	C4	For C4, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See special conditions. *Test Group 1 for C4*: 1. Acute Toxicity To Fish: ASTM E 729–96 (2002) 2. Acute Toxicity To Daphnia: ASTM E 729–96 (2002) *Test Group 2 for C4*: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004) 2. [Reserved]	
	C5	For C5, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See special conditions. *Test Group 1 for C5*: 1. Acute Toxicity To Daphnia: ASTM E 729–96 (2002) 2. [Reserved] *Test Group 2 for C5*: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004) 2. [Reserved]	
	C6	Toxicity To Plants (Algae): ASTM E 1218–04e1	

TABLE 3.—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2 OF THIS PARAGRAPH—Continued

Testing Category	Test	Test Requirements and References	Special Conditions
	C7	For C7, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See special conditions. *Test Group 1 for C7*: 1. Acute Toxicity To Fish: ASTM E 729–96 (2002) 2. [Reserved] *Test Group 2 for C7*: 1. Chronic Toxicity To Daphnia: ASTM E 1193–97 (2004) 2. [Reserved]	
Mammalian Toxicity—Acute	D	See special conditions for this test requirement and select the method that must be used from those listed in this column. *Method A*: Acute Inhalation Toxicity (rat): 40 CFR 799.9130 *Method B*: EITHER: 1. Acute (Up/Down) Oral Toxicity (rat): ASTM E 1163–98 (2002) OR 2. Acute (Up/Down) Oral Toxicity (rat): 40 CFR 799.9110(d)(1)(i)(A)	Which testing method is required is determined by the test substance's physical state at room temperature (25°C). For those test substances that are gases at room temperature, Method A is required; otherwise, use either of the two methods listed under Method B. In Method B, 40 CFR 799.9110(d)(1)(i)(A) refers to the OECD 425 Up/Down Procedure. [iv] Estimating starting dose for Method B: Data from the neutral red uptake basal cytotoxicity assay [v] using normal human keratinocytes or mouse BALB/c 3T3 cells may be used to estimate the starting dose.
Mammalian Toxicity—Genotoxicity	E1	Bacterial Reverse Mutation Test (*in vitro*): 40 CFR 799.9510	None
	E2	Conduct any one of the following three tests for chromosomal damage: *In vitro* Mammalian Chromosome Aberration Test: 40 CFR 799.9537 OR Mammalian Bone Marrow Chromosomal Aberration Test (*in vivo* in rodents: mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9538 OR Mammalian Erythrocyte Micronucleus Test [sampled in bone marrow] (*in vivo* in rodents: mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9539	Persons required to conduct testing for chromosomal damage are encouraged to use the in vitro Mammalian Chromosome Aberration Test (40 CFR 799.9537) to generate the needed data unless known chemical properties (e.g., physical/chemical properties, chemical class characteristics) preclude its use. A subject person who uses one of the in vivo methods instead of the in vitro method to address a chromosomal damage test requirement must submit to EPA a rationale for conducting that alternate test in the final study report.
Mammalian Toxicity—Repeated Dose/Reproduction/Developmental	F1	Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9365 OR Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355 AND Repeated Dose 28–Day Oral Toxicity Study in rodents: 40 CFR 799.9305	Where F1 is required, EPA recommends use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365). However, there may be valid reasons to test a particular chemical using both 40 CFR 799.9355 and 40 CFR 799.9305 to fill Mammalian Toxicity—Repeated Dose/Reproduction/Developmental data needs. A subject person who uses the combination of 40 CFR 799.9355 and 40 CFR 799.9305 in place of 40 CFR 799.9365 must submit to EPA a rationale for conducting these alternate tests in the final study reports. Where F2 or F3 is required, no rationale for conducting the required test need be provided in the final study report.
	F2	Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355	
	F3	Repeated Dose 28–Day Oral Toxicity Study in rodents: 40 CFR 799.9305	

i. EPA recommends, but does not require, that log K_{OW} be quantitatively estimated prior to initiating this study. One method, among many similar methods, for estimating log K_{OW} is described in the article entitled *Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients* by W.M. Meylan and P.H. Howard in the *Journal of Pharmaceutical Sciences*. 84(1):83–92. January 1992. This reference is available under docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334 in the EPA West Bldg. located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

ii. EPA recommends, but does not require, that water solubility be quantitatively estimated prior to initiating this study. One method, among many similar methods, for estimating water solubility is described in the article entitled *Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient* by W.M. Meylan, P.H. Howard, and R.S. Boethling in *Environmental Toxicology and Chemistry*. 15(2):100–106. 1996. This reference is available under docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334 in the EPA West Bldg. located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

iii. Chemical substances that are dispersible in water may have log K_{ow} values greater than 4.2 and may still be acutely toxic to aquatic organisms. Test sponsors who wish to conduct Test Group 1 studies on such chemicals may request a modification to the test standard as described in 40 CFR 790.55. Based upon the supporting rationale provided by the test sponsor, EPA may allow an alternative threshold or method be used for determining whether acute or chronic aquatic toxicity testing be performed for a specific substance.

iv. The OECD 425 Up/Down Procedure, revised by OECD in December 2001, is available under docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334 in the EPA West Bldg. located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

v. The neutral red uptake basal cytotoxicity assay, which may be used to estimate the starting dose for the mammalian toxicity-acute endpoint, is available under docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334 in the EPA West Bldg. located at 1301 Constitution Ave., NW., Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

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

[FR Doc. E8–16992 Filed 7–23–08; 8:45am]

BILLING CODE 6560–50–S