ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS–42213A; FRL–6758–4]

RIN 2070–AD16

Testing of Certain High Production Volume 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 (including importers) and processors of certain high production volume (HPV) chemical substances to conduct testing for acute toxicity; repeat dose toxicity; developmental and reproductive toxicity; genetic toxicity (gene mutations and chromosomal aberrations); ecotoxicity (in fish, Daphnia, and algae) and environmental fate (including five tests for physical chemical properties and biodegradation). EPA has preliminarily determined that each of the 37 chemical substances included in this proposed rule is produced in substantial quantities and that there is substantial human exposure to each of them. Moreover, EPA believes that 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 any combination of these activities. EPA has concluded that this proposed testing program is needed and appropriate for developing 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 take appropriate follow up action. Persons who export or intend to export any chemical substance included in the final rule based on this proposed 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, identified by docket control number OPPTS–42213A, must be received by EPA on or before April 25, 2001. If you want to request an opportunity to present oral comments, refer to Unit I.E. of the **SUPPLEMENTARY INFORMATION**. Your request must be in writing and must be received by EPA on or before January 25, 2001. Only if such a request is received, would EPA schedule a public meeting on this proposed rule, which would be announced in a subsequent document in the **Federal Register** and held in Washington, DC.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–42213A in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone numbers: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Keith Cronin, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260-8130; fax number: (202) 260–1096; e-mail address: ccd.citb@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you manufacture (defined by statute to include import) or process any of the chemical substances that are listed in § 799.5085(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 VI. , 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 40 CFR part 707, subpart D. Potentially affected entities may include, but are not limited to:

TABLE 1.—ENTITIES POTENTIALLY AFFECTED BY THE PROPOSED TESTING REQUIREMENTS

Type of entity	NAICS codes	Examples of potentially affected entities
Chemical Manufacturers (including Importers)	325, 32411	Persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.
Processors	325, 32411	Persons who process one or more of the subject chemical substances.

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 Table 1 of 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 is affected by this action, you should carefully examine the applicability provisions in Unit V.E. entitled *Would I be required to test under this rule?* and consult the proposed regulatory test. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

If you are an entity identified in Table 1 of this unit, you would only be subject to the testing requirements contained in this proposed rule if you manufacture or process any of the chemical substances that are listed in § 799.5085(j) of the proposed regulatory text.

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select

''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

You may also access additional information about the Chemical Right-to-Know Program at http://ww.epa.gov/chemrtk/ or about the TSCA testing program at http://www.epa.gov/opptintr/chemtest/. For your convenience, EPA may have also provided some non-EPA internet addresses. In doing so, the Agency has verified the accuracy of these addresses at the time of signature. However, since EPA is not responsible for these non-EPA sites, the Agency does not have any control over these addresses. A paper copy of any document referenced in this way has been included in the public version of the official record for this document as described in Unit I.B.2.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS–42213A. The official record consists of the documents referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, Rm. NE B–607, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–42213A in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: OPPT Document Control Office (DCO), East Tower Rm. G–099, Waterside Mall, 401 M St., SW., Washington, DC. 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) 260–7093.

3. *Electronically.* You may submit your comments electronically by e-mail to: oppt.ncic@epa.gov or mail your computer disk to the address identified above. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard computer disks in WordPerfect 6/7/8/9 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS–42213A. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

E. 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 January 25, 2001, EPA will hold a public meeting on this proposed rule in Washington, DC. This written request must be submitted to the address provided in Unit I.C.1 and 2. 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 document announcing the public meeting.

F. What Should I Consider as I Prepare My Comments for EPA?

EPA invites you to provide your views on the various options proposed, new approaches not yet considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final rule. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the rule or collection activity.

7. Make sure to submit your comments by the deadline listed under **DATES**.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Authority

This document proposes a test rule under section 4(a)(1)(B) of TSCA, 15 U.S.C. 2603(a)(1)(B), that would require certain health and environmental tests for 37 chemical substances that are produced in substantial quantities, and that enter or may reasonably be anticipated to enter the environment in substantial quantities and/or to which there is or may be significant or substantial human exposure. The tests pertain to acute toxicity; repeat dose toxicity; developmental and reproductive toxicity; genetic toxicity (gene mutations and chromosomal aberrations); ecotoxicity (tests in fish, Daphnia, and algae); and environmental fate (including five tests for physical chemical properties and biodegradation). Some or all of these

tests would be required for a particular chemical substance, depending upon what data are already available for that substance.

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

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

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

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

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

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

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

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

Once the Administrator has made a finding under TSCA section 4(a)(1), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or (B)(i) findings, as long as EPA finds that there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and that testing is necessary to develop the data. This approach is explained in more detail in EPA's statement of policy for making findings under TSCA section 4(a)(1)(B) (frequently described as the ''B'' policy) in the **Federal Register** of May 14, 1993 (58 FR 28736) (Ref. 24 at 28738–28739).

In this proposed rule, EPA intends to use its broad TSCA section 4 authority to obtain the data necessary to support the development of preliminary or ''screening level'' hazard and risk characterizations for certain HPV chemical substances (see § 799.5085(j) of the proposed regulatory text for the list of chemicals). EPA has made preliminary findings for these chemicals 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. Testing for additional HPV chemical substances (Ref. 1) will be proposed at a later date as the Agency learns more about these additional substances with respect to human exposure, release, and sufficiency of the data and experience available on the hazards of the substances.

III. Background

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

EPA found that, of those non-polymeric organic substances produced or imported in amounts equal to or greater than 1 million pounds per year based on 1990 reporting for EPA's Inventory Update Rule (IUR) (40 CFR part 710), only 7% have a full set of publicly available internationally recognized basic health and environmental fate/effects screening test data (Ref. 2). Of the over 2,800 U.S. HPV chemicals based on 1990 data, 43% have no publicly available basic hazard data. For the remaining chemicals, limited amounts of the data are 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 right-to-know about the hazards of chemicals that are found in their environment, their homes, their workplaces, and the products that they buy. It is EPA's intent to close this knowledge gap. EPA believes that for most of the HPV chemicals, insufficient data are readily available to reasonably determine or predict the effects on health or the environment from the manufacture (including importation), distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities. EPA has concluded that a program to collect and, where needed, develop basic screening level toxicity data is necessary and appropriate to provide information in order to assess the potential hazards/risks that may be posed by exposure to HPV chemicals.

On April 21, 1998, a national effort, known as the ''Chemical Right-To-Know'' (ChemRTK) Program, was announced in order to empower citizens with knowledge about the most widespread chemicals in commerce—chemicals that people may be exposed to in the places where they live, work, study, and play. EPA's ChemRTK Program is being designed in such a way as to make certain basic information about HPV chemicals available to the public.

EPA plans to make available to the public the summarized data obtained on HPV chemicals. Additional information that EPA receives will also be shared with the public, other Federal agencies, and any other interested parties. 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. In addition, EPA and other parties agreed to work with other nations and international groups to ensure commensurate increases in the pace of complementary voluntary international data collection and development efforts on HPV chemicals.

This ChemRTK Program is consistent with the U.S. policy as presented in the TSCA. 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 and those who process such chemical substances and mixtures.''

B. What Do We Currently Know About the Basic Health and Environmental Hazards of HPV Chemicals?

The information relevant to understanding the basic health and environmental hazards of HPV chemicals is derived from a battery of tests agreed upon by the international community as appropriate for screening international HPV chemical substances for toxicity. Six basic testing endpoints have been adopted by the Organization for Economic Cooperation and Development (OECD) as the minimum required to screen international HPV chemical substances for toxicity (Ref. 4). The agreed-upon testing endpoints, known as the OECD's Screening Information Data Set (SIDS) include: Acute toxicity; repeat dose toxicity; developmental and reproductive toxicity; genetic toxicity (gene mutations and chromosomal aberrations); ecotoxicity (studies in fish, Daphnia, and algae); and 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). As conceived by the OECD, the ''SIDS battery'' of tests can be used by governments to conduct an initial assessment of the hazards and risks posed by HPV chemical substances and prioritize HPV chemicals to identify those in need of additional, more in-depth testing and assessment.

A need for basic screening level data on HPV chemicals has been identified and supported by various data availability studies conducted by EPA and others. Toxic Ignorance, which was prepared by Environmental Defense (formerly the Environmental Defense Fund), raised a variety of concerns about the untested chemicals that are produced in and/or imported into the United States (Ref. 28). Environmental Defense found that baseline data on health effects were not publicly available for a selected set of 100 HPV chemicals.

In April 1998, EPA completed a study entitled *Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals?* (Ref. 2) that evaluated the public availability of screening level health hazard data and environmental hazard/fate data on U.S. HPV chemicals. EPA's study found major gaps in the basic information on HPV chemicals that is readily available to EPA and to the public, and reinforced the need for governmental leadership on this issue. The study analyzed the availability of test data for 2,863 HPV chemicals (defined as those non-polymeric organic substances produced in or imported into the United States in amounts equal to or greater than 1 million pounds per year based on 1990 reporting for EPA's IUR (40 CFR part 710). EPA searched for publicly available data on these chemicals and learned that most of them may never have been tested for any or most of the SIDS endpoints. The search strategy used a total of 11 publicly accessible data bases in its analysis. Details of the search strategy can be found in the report (Ref. 2). The major conclusions of EPA's study are described in Unit III.A.

In June 1998, the American Chemistry Council (ACC, formerly the Chemical Manufacturers Association (CMA)) issued a report (Ref. 3) regarding public data availability for HPV chemicals based on a study conducted with 11 main data sources, including data sources other than those searched by EPA for its study. The ACC report, entitled *Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals* (Ref. 3) reached conclusions similar to EPA, that is, that only limited toxicity and environmental fate data appear to exist in the public domain for many U.S. HPV substances. Details of the search strategy used can be found in the ACC report (Ref. 3).

EPA recognizes that additional data may exist beyond those identified through either the EPA, ACC, or Environmental Defense studies. To the extent that additional relevant data are known to exist, EPA is particularly interested in receiving this information as part of the HPV Initiative (see Unit III.D.), including a full citation for publications and ''robust'' (i.e., detailed) summaries of pertinent published and unpublished studies. If relevant scientifically adequate existing data are submitted at any time before testing is initiated, including after the final rule is issued, the Agency will consider such data to determine if they satisfy the testing requirement and will take appropriate necessary action to ensure that unnecessary testing is no longer required. In addition, exemption procedures to be used are found at 40 CFR 790.80 and 790.82. Guidance on the preparation of robust summaries is available on EPA's ChemRTK website (Ref. 34).

C. Why is EPA Focusing on HPV Chemicals?

It is generally accepted that chemicals having a high level of production have an increased potential for exposure in comparison to low production volume chemicals. The focus on HPV chemicals is derived from the experience gained over the past 15 years by EPA and the OECD. The OECD is an intergovernmental organization consisting of 29 developed countries, including the United States, with advanced worldwide market economies. The OECD is helping coordinate a cooperative, international effort to secure basic toxicity information on HPV chemicals in use worldwide.

The OECD, after considering a variety of priority setting approaches, concluded in 1990 that consideration of HPV status provided a useful and effective organizing focus for a voluntary testing and assessment effort to screen and thereby identify priorities among international HPV chemicals.

In the late 1980s, OECD initiated a voluntary program to ensure that basic information is available on international HPV chemicals. This program, which is a part of the OECD's program on existing chemicals, produced an internationally agreed upon set of basic SIDS screening tests and is working to develop complete SIDS data sets for all international HPV chemicals. The SIDS includes information on the identity of each chemical, uses, sources and extent of exposure; physical and chemical properties; environmental fate; and certain limited toxicity data for humans and the environment. The SIDS is not intended to describe a chemical thoroughly, but rather is intended to provide enough information to support an initial (or screening) assessment and to assign a priority for further work. By 1990, the United States and 13 other OECD member countries established a voluntary international testing program to develop the basic data set for all international HPV chemicals. To date, the OECD has initiated or completed work on approximately 500 chemicals.

The OECD threshold for high production volume chemicals is 2.2 million pounds (equivalent to 1 million kilograms) reported in any member country. (Note that the OECD HPV threshold, like the U.S. HPV threshold, is not applied to polymers. However, the OECD threshold, unlike the U.S. HPV threshold, is applied to inorganics (Ref. 5)). The presence of a chemical on the OECD's list of HPV chemicals was and continues to be accepted (Ref. 5) by OECD member countries as providing a sufficient indicator of potential

exposure to warrant testing at the SIDS level.

EPA 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. 24). 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).

In response to EPA's proposed ''B'' policy (Ref. 23), both ACC and the Society of the Plastics Industry Inc., commented that EPA's proposed production volume threshold of 1 million pounds is a reasonable interpretation of ''substantial production'' under TSCA (Ref. 6 and 7). Additionally, they indicated that the OECD 2.2 million pound threshold would be preferable to achieve consistency between EPA's activities under TSCA section 4 and the OECD HPV SIDS program.

The 1 million pound threshold for production normally used by EPA under the ''B'' policy generally narrowed the universe of chemicals potentially subject to TSCA section 4(a)(1)(B) to 11% of the TSCA Inventory of chemical substances (see TSCA sections 8(a) and 8(b)), using Inventory information available in 1988 (Ref. 23 at 32296). However, that small percentage of the Inventory accounts for 95% of total chemical production in the United States. EPA believes it reasonable to use this information as a basis for making a finding of ''substantial production'' for substances produced at or above that threshold. Furthermore, EPA equates ''substantial production'' with production in ''high volumes.''

The United States committed to conducting SIDS testing and assessment on 25% of the international HPV chemicals as its contribution to the OECD HPV SIDS effort; other countries' commitments for conducting SIDS testing and assessment on international HPV chemicals vary in proportion to the size of the country's gross domestic product. Because most of the international HPV chemicals are also commercially available in the United States, EPA considers the OECD HPV SIDS program to be an integral part of domestic testing activities. EPA, in developing and implementing the OECD HPV SIDS program, worked jointly with industry and environmental groups in the United States and with governments and industry in other OECD member countries to achieve the common goal of developing this minimum level of testing for HPV chemicals. EPA continues to work with other parties (international organizations, environmental groups, unions, animal welfare groups, other Federal agencies, and others) to secure their interest and continued support for this effort.

Nevertheless, because of the slow pace of the OECD's international efforts to generate the needed data (which would have potentially required over 30 years to complete), the OECD has recognized the need to accelerate its efforts in order to ensure the availability of the basic data needed to support screening level assessments of international HPV chemicals. EPA has also recognized the need to accelerate its efforts to develop SIDS data on US HPV chemicals to support domestic efforts on chemicals. The HPV Initiative, which is described in Unit III.D., reflects EPA's interest in collecting, developing and making publicly available these needed data.

D. Why is EPA Proposing to Take this Action?

A major component of the Agency's ChemRTK activity is the HPV Initiative, which is a data collection and development program established by EPA for existing U.S. HPV chemicals. Under this Initiative, HPV chemicals are defined as non-polymeric organic chemicals manufactured (including imported) at or above 1 million pounds per year based on information submitted under the 1990 TSCA IUR. The strategy and overall approach that EPA is using to address data collection needs for U.S. HPV chemicals are discussed in a separate document entitled *Data Collection and Development on High Production Volume (HPV) Chemicals* that is published elsewhere in this issue of the **Federal Register** (Ref. 27).

Through the HPV Initiative, which includes a voluntary component (the HPV Challenge Program), certain international efforts, and rulemaking under TSCA such as this proposed rule, basic screening level hazard data necessary to provide critical information about the environmental fate and potential hazards associated with HPV chemicals will be collected or, where necessary, developed. Data collected and/or developed under the HPV Initiative, when combined with information about exposure and uses, will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action. The HPV Initiative will generally be carried out in a manner consistent with the OECD HPV SIDS program to ensure that the data and information generated can be contributed to the international effort and, conversely, that international SIDS testing and assessments can be used to fulfill the data gaps identified as part of the HPV Initiative. Additional detailed information is available on the SIDS website (http://www.oecd.org/ehs/sidsman.htm) and EPA's ChemRTK website (http://www.epa.gov/chemrtk).

The following is a brief summary of this HPV Initiative. For additional background information related to the HPV Initiative, please refer to the document that is published elsewhere in this issue of the **Federal Register** (Ref. 27).

1. *Voluntary HPV Challenge Program.* A primary component of this HPV Initiative is the voluntary HPV Challenge Program, which was created in cooperation with industry, environmental groups, and other interested parties, and is designed to assemble and make publicly available basic screening level data on the potential hazards of U.S. HPV chemicals while avoiding unnecessary or duplicative testing. The voluntary HPV Challenge Program is described in detail the document that is published elsewhere in this issue of the **Federal Register** (Ref. 27).

As of November 9, 2000, EPA has received full or provisional commitments from 469 companies, individually or through 187 consortia to sponsor 2,155 chemicals under in the voluntary HPV Challenge Program. Continually updated information regarding the chemicals being sponsored under the voluntary HPV Challenge Program and the names of company sponsors and consortia can be found on EPA's ChemRTK website (http://www.epa.gov/chemrtk/sumresp.htm), and on the US HPV Chemical Tracking System (http://www.hpvchallenge.com).

Under the voluntary HPV Challenge Program, alternatives to the testing proposed under this proposed rule are 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 relationships (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.

While EPA is encouraging the use of scientifically appropriate categories of related chemicals and SAR under the voluntary component of the HPV Initiative, these approaches are not included in this proposed rule. However, EPA has not identified any possibilities that will allow inclusion of the category and SAR approach for any chemicals listed in this proposed rule. EPA believes that the incorporation of such elements in a test rule would require complex, time consuming, and resource intensive procedural steps, such as multi-phase rulemaking. EPA specifically solicits comments and suggestions on procedures that would allow inclusion of such approaches in HPV test rules. EPA solicits comments on simplified procedures which would allow inclusion of such approaches in TSCA section 4 HPV SIDS rulemaking.

Although the Agency believes that none of the chemicals included in this proposed rule appear to be candidates for these 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 comments which substantiate this belief. If, based on submitted information and other information available to EPA, the Agency determines that a chemical meets the requirements for consideration under a category or SAR approach, and that practicable measures are available at the time to modify the testing requirement, EPA will take such measures as are necessary to avoid unnecessary testing. Modifications can also be applied for after the final rule issues under 40 CFR 790.55 up to 60 days before the specified reporting deadline. Category or SAR approaches which represent significant alterations in the scope of testing, however, would likely require multi-phase rulemaking involving publication of additional **Federal Register** document(s) soliciting comment on the proposed procedures to be used. Comment is specifically requested on simplified approaches which might allow for the efficient and effective handling of category and SAR approaches via rulemaking.

a. *Can I still participate in the voluntary HPV Challenge Program?* Certainly. Although the participants in the voluntary HPV Challenge Program were asked to submit commitments by December 1, 1999, you can still volunteer through a viable commitment (as described in Unit III.D.1.b) to sponsor chemicals under the HPV Challenge Program. Sponsors who wish to use alternative approaches to those proposed for a chemical listed in a proposed TSCA section 4 HPV SIDS rulemaking should seriously consider sponsoring that chemical in this under the voluntary HPV Challenge Program prior to the close of the comment period for that rulemaking.

b. *How can I participate in the voluntary HPV Challenge?* At this stage, persons who wish to sponsor a chemical through a viable commitment under the HPV Challenge Program must submit the following:

i. Commitment letter;

ii. Test plan, robust summaries of existing studies with full citations of published studies and full copies of unpublished studies; and

iii. Robust summaries of any newly conducted studies, and full copies of these studies.

Commitments must be consistent with the guidance available on the ChemRTK website. Full commitments must specify the names and the Chemical Abstract Service (CAS) numbers of the chemicals to be sponsored, the year in which sponsors will begin the assessment of each chemical, and the name and contact information for the technical person within the company who should be reached for more information. Commitment letters under the voluntary HPV Challenge Program must be submitted to the EPA Administrator according to the instructions on the ChemRTK website (Ref. 35).

EPA encourages industry and other interested parties to identify and provide any additional existing data which are relevant to the hazard characterization to avoid any unnecessary or duplicative testing. Furthermore, anyone may provide any relevant information to the Agency that indicates that certain endpoints need not be tested. If EPA judges the available data to be adequate, the data gap identified in the HPV Initiative will be considered to be filled. To the extent that additional data relevant to the HPV chemicals are known to exist, EPA is interested in receiving this information under the voluntary HPV Challenge Program. In addition to submitting the full citation for published studies and full copies of any unpublished studies, Commenters under the HPV Challenge Program and/or a proposed TSCA section 4 HPV SIDS rule(s) who wish to submit any additional relevant studies, are encouraged to also prepare a robust summary (Ref. 34) for each study to facilitate making the information publicly available, as well as facilitate its review.

EPA plans to include in a final TSCA section 4 HPV SIDS rulemaking any chemical that is listed in a proposed rule, unless a sponsor, in addition to agreeing to making a viable commitment under the voluntary HPV Challenge Program, provides the following additional information:

i. Evidence that work is underway and proceeding in a timely manner;

ii. Data required to complete the SIDS battery are developed within the time frame set by EPA in the proposed rule; and

iii. Robust summaries, and full copies of all final study reports from new studies and existing data submitted to EPA in a timely manner.

Viable commitments that involve SAR and categories and that are consistent with the guidance available on the website (Ref. 30 and 31) regarding SAR and categories under the voluntary component of the HPV Initiative can still be submitted to EPA, but submission as early as possible will best avoid unnecessary or duplicative testing. If a viable commitment is made and kept, and the information is deemed adequate, EPA would not include that chemical in a final TSCA section 4 HPV SIDS rulemaking.

Additional information on the voluntary HPV Challenge Program is available on the ChemRTK website.

2. *Certain international efforts.* To fill any data gaps not addressed as part of the voluntary HPV Challenge Program, EPA is continuing to participate in the international efforts coordinated by the OECD to secure basic hazard information on HPV chemicals in use worldwide, including some of those on the U.S. HPV chemicals list. This includes agreements to sponsor a U.S. HPV chemical under either the OECD HPV SIDS Program, including sponsorship by OECD member countries beyond the United States, or the international HPV Initiative that is being organized by International Council of Chemical Associations (ICCA). The OECD HPV SIDS Program has already been described in Unit III.C. 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 ICCA HPV Initiative calls for the testing and screening-level assessment of 1,000 ''high priority'' chemicals by the end of the year 2004. Most of the chemicals on the ICCA working list (Ref. 8) are also U.S. HPV chemicals. The ICCA testing/assessment work will be tied directly to that under

the OECD HPV SIDS Program and to the U.S. HPV Initiative.

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 intended to be addressed in either the voluntary HPV Challenge Program or in any TSCA section 4 HPV SIDS rulemaking unless the international commitments are not met.

3. *TSCA rulemaking*. In establishing the HPV Initiative in 1998, the Agency indicated that data needs which remain unmet in the voluntary HPV Challenge Program or through international efforts may be addressed through TSCA rulemaking. This proposed rule is the first rulemaking associated with the HPV Initiative, and addresses the unmet data needs of the 37 chemicals that are included in this proposed rule.

E. What Information is being Collected on HPV Chemicals?

In identifying the data needs for chemicals contained in the HPV Initiative, EPA is utilizing information and sources in EPA's study, the *Chemical Hazard Data Availability Study* (Ref. 2), and ACC's report, i.e, *Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals* (Ref. 3), to determine whether screening level data for characterizing the hazards of these HPV chemicals are publicly available. If no data are available for a SIDS testing endpoint, there cannot be sufficient data to characterize the potential hazards and risks associated with the chemical. As the Agency found in its study, insufficient data are available to characterize the hazards and risks of many of the U.S. HPV chemicals with respect to the internationally accepted SIDS testing endpoints, including acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, genetic toxicity (gene mutations and chromosomal aberrations), ecotoxicity (tests in fish, Daphnia, and algae), and for environmental fate (including five tests for physical chemical properties [melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility], and biodegradation). As a result, EPA and others cannot reasonably determine or predict the human health and environmental effects resulting from manufacture, processing, and use of these chemical substances.

The OECD HPV SIDS Program is part of the OECD overall program on existing chemicals, and includes information on the identity of each chemical, its uses, sources and extent of exposure; physical and chemical properties; environmental fate; and certain limited toxicity data for humans and the environment. The SIDS data set is not intended to describe a chemical thoroughly, but rather is intended to provide enough information to support an initial (or screening level) assessment and to assign a priority for further work, if necessary. To date, the OECD has initiated or completed work on approximately 500 HPV chemicals. The OECD HPV SIDS Program seeks the development of test data, if such data are not already available, related to six health and environmental effects endpoints for international HPV chemicals (see Unit III.B.). The SIDS data set is regarded as the minimum data set required to make an informed preliminary judgment about the hazards of a given HPV chemical.

EPA is implementing the HPV Initiative as part of its domestic industrial chemical screening efforts, in a manner that is consistent with OECD efforts. The information to be gathered under EPA's HPV Initiative comes from the same battery of tests agreed upon by the OECD member countries as being appropriate for screening international HPV chemicals for toxicity and environmental fate (Ref. 4). As conceived by the OECD, the SIDS data set can be used by governments and others worldwide to conduct an initial assessment of the hazards and risks posed by HPV chemical substances and to prioritize chemicals to identify those which are in need of additional, more in-depth testing and assessment, as well as those of lesser concern.

This proposed test rule is intended to obtain needed SIDS testing for 37 of the approximately 2,800 chemicals (excluding polymers and inorganics) that are produced and/or imported at high volumes in the United States. EPA has chosen this group of 37 chemicals for its initial TSCA section 4 HPV SIDS rulemaking because of their high production and/or importation volumes and their potential for exposure to a substantial number of workers.

In developing the list of candidates for this proposed test rule, EPA included only chemical substances which were reported on 1994 TSCA section 8(a) IUR as being manufactured (including imported) in the United States in amounts greater than or equal to one million pounds. In addition, each of the candidate chemical substances listed in this proposed rule was identified in the National Occupational Exposure Survey (NOES) as having a total potential exposure of greater than 1,000 or more workers. A potential exposure of 1,000 or more workers to a chemical substance is a threshold for ''substantial human exposure'' under EPA's ''B'' Policy (Ref. 24).

The data availability study conducted by EPA, discussed in Unit III.B., demonstrated that only a limited number of HPV chemicals have a full set of publicly available SIDS data. For chemicals for which some data are available on one or more SIDS endpoints, EPA is not requiring testing for those endpoints. However, no definitive determination has been made as to the adequacy of those data for an initial assessment of a chemical's hazards or risks to health or the environment. The Agency intends to promulgate additional test rules for any HPV chemicals for which SIDS testing is needed and for which a voluntary commitment to collect, develop, and make publically available the needed data has not been received.

F. What Role do Existing Data Play Under the HPV Initiative?

The HPV Initiative, including this rulemaking, is designed to make maximum use of scientifically adequate existing test data and to avoid unnecessary, duplicative testing, thereby avoiding the excessive use of animal testing. If at any time, including after this rule is finalized, the Agency receives adequate existing data that fulfill a specific data gap, EPA will ensure that unnecessary testing is not required.

During the continued development of the HPV Initiative, EPA was encouraged to consider the relationship between existing data submitted under the HPV Initiative and reporting requirements under TSCA section 8(e). In response to these concerns, and as part of the Agency's efforts to ensure the fullest use of existing test data, EPA intends to consider existing data submissions in the manner described in an October 14, 1999, letter to the voluntary HPV Challenge Program participants (herein after ''the October 14, 1999, letter'') (Ref. 29). EPA's guidance document on literature searches, which deals with part of this issue, is available on the Agency's ChemRTK website (Ref. 36). EPA believes that it is in the economic best interest of companies to identify and make publicly available all relevant existing data in order to reduce possible testing costs.

Studies that have been conducted as specified in appropriate OECD test guidelines (as noted in the SIDS Manual (Ref. 4) or comparable EPA test guidelines (such as the OPPTS Harmonized Guidelines available at http://www.epa.gov/opptsfrs/home/guidelin.htm), and appropriate Good Laboratory Practice Standards (GLPS)

like those for TSCA (40 CFR part 792) consistently generate data adequate to fulfill the HPV Initiative needs. Data from studies that did not follow these procedures, however, may not be adequate.

As stated in the October 14, 1999, letter to the voluntary HPV Challenge Program participants, in analyzing the adequacy of existing data, participants shall conduct a thoughtful and qualitative analysis rather than using a rote checklist approach (Ref. 29). The same principle applies to persons evaluating existing data in connection with this rulemaking. If EPA judges the available data to be adequate, the data gap identified in the HPV Initiative will be considered to be filled. EPA has developed a guidance document on determining data adequacy which is available on EPA's ChemRTK website (Ref. 37).

EPA solicits comment concerning the availability of SIDS data on the chemicals included in the HPV Initiative and encourages industry and other interested parties to identify and provide any additional existing data which are relevant to hazard characterization to avoid any unnecessary or duplicative testing. Anyone may provide any relevant information to the Agency that indicates that certain endpoints need not be tested. If EPA judges the available data to be adequate, the data gap identified in the HPV Initiative will be considered to be filled. To the extent that additional data relevant to the HPV chemicals are known to exist, EPA is interested in receiving this information, including a full citation for publications and full copies of unpublished studies. Although the Agency encourages anyone with such information to submit it to EPA during the early stages of this Initiative in order to avoid any unnecessary testing, such submissions may be made at any time to allow EPA to take appropriate action. Commenters are also encouraged to prepare a robust summary (Ref. 34) for each study to facilitate EPA's review of the full study report or publication. It is important to note that EPA does not intend to include any chemicals which are Generally Recognized as Safe (GRAS) for a particular use by the Food and Drug Administration (FDA) in this initial TSCA section 4 HPV SIDS rulemaking. However, such chemicals may be included in a future TSCA section 4 HPV SIDS rulemaking where SIDS data needs remain unmet.

G. How Would the Data Developed Under this Test Rule be Used?

The availability of hazard information on individual chemicals is fundamental to EPA's ability to accomplish its mission of environmental protection—risk assessment, risk management, safeguarding children's health, expanding the public's right-to-know, and promoting the pollution prevention ethic. Activities to ensure the availability of basic hazard information on HPV chemicals are an integral part of meeting these objectives.

The testing proposed is essentially identical in scope and applicability to that which has been internationally agreed upon by the OECD as providing the minimum needed to screen HPV chemicals and identify priorities for additional testing or assessment. While the SIDS data set does not fully measure a chemical's toxicity, it does provide a consistent minimum set of information that can be used to determine the relative hazards and risks of chemicals and to judge if additional testing or assessment is necessary. Thus, EPA will use the data obtained from this proposed test rule to support development of preliminary hazard and risk assessments for these HPV chemicals. Furthermore, the data obtained under this testing program will be used to set priorities for further testing that will produce hazard information on these chemicals which is needed by EPA , other Federal agencies, the public, industry, and others, to support adequate risk assessments. EPA has used data from test rules to support such activities as the development of water quality criteria, Toxic Release Inventory listings, chemical advisories, and reduction of workplace exposures.

H. What is the Role of this Proposed Rule with Regard to the HPV Initiative?

To fill data gaps not addressed as part of the voluntary HPV Challenge Program or international efforts, EPA indicated in the document that is published elsewhere in this issue of the **Federal Register** (Ref. 27) that it would supplement the voluntary HPV Challenge Program and international efforts with rulemaking under TSCA. Specifically, EPA intends to use its authority under section 4 of TSCA to propose the testing of those chemicals listed at http:/www.epa.gov/chemrtk/hpvchmtl.htm which have an indicator value of ''0,'' which identifies a chemical as a candidate for sponsorship under the voluntary HPV Challenge Program and a sponsorship status value of ''N,'' i.e., not sponsored. EPA intends to issue additional test rules as needed to cover chemicals with unmet data needs or if voluntary HPV Challenge Program commitments are not met. 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. 8) will not be listed in any of these follow-up TSCA section 4 HPV SIDS rulemaking, unless commitments under those international programs are not met (see Unit. IV.G. of the document that is published elsewhere in this issue of the **Federal Register** (Ref. 27) for more information on these programs). In addition, as indicated in Unit IV.B.2. of the document that is published elsewhere in this issue of the **Federal Register** (Ref. 27), chemicals identified as GRAS for a particular use by FDA are only intended to be included in a future TSCA section 4 HPV SIDS rulemaking if SIDS data needs remain unmet.

As indicated in the October 14, 1999, letter to the participants in the voluntary HPV Challenge Program (Ref. 29), and restated in the document that is published elsewhere in this issue of the **Federal Register** (Ref. 27), EPA intends for the TSCA section 4 HPV SIDS rulemaking to proceed in a manner that is consistent with the principles outlined in the letter for the participants in the voluntary program. As such, EPA has incorporated the criteria established under the voluntary HPV Challenge Program into this rulemaking to the extent possible, and has also considered improvements based on experiences with implementing that Program.

• *Potential endpoints for testing under test rules.* As with the voluntary HPV Challenge Program, the test data needs that are addressed in this proposed rule pertain to physical/chemical properties, acute toxicity; repeat dose toxicity; developmental and reproductive toxicity; genetic toxicity, ecotoxicity; and environmental fate. Testing for some or all of these endpoints would be required for a particular chemical substance where such data are not already available for that substance. The specific testing, reporting, and recordkeeping requirements contained in this proposed rule are described for each chemical substance in the proposed regulatory text.

• *Potential timetable for testing under test rules.* EPA stated in the October 14, 1999, letter to the participants in the voluntary HPV Challenge Program (Ref. 29), that testing of closed system intermediates shall be deferred until 2003; and that testing of individual chemicals (i.e., those HPV chemicals not proposed for testing in a category) that require further testing on animals shall

be deferred until November 2001. EPA will use these time frames in the effective dates of TSCA section 4 HPV SIDS rulemakings as well.

• *Existing data submissions during the rulemaking phase.* As indicated in Unit III.B., if relevant scientifically adequate existing data are submitted to EPA during the comment period for this proposed rule, EPA does not intend to include that HPV chemical in the final rule. If relevant scientifically adequate existing data are submitted to EPA after the final rule is issued, or at any other time before testing is initiated, the Agency will consider such data to satisfy the testing requirement and will take any necessary action to ensure that unnecessary testing is not required.

• *Treatment of testing endpoints under HPV SIDS test rules.* EPA proposes that testing under this proposed rule be consistent with the voluntary HPV Challenge Program's treatment of the following endpoints:

—Acute aquatic toxicity studies would not always be needed under the TSCA section 4 HPV SIDS rulemaking associated with this Initiative (See Unit V.A.3.).

—Dermal toxicity or terrestrial toxicity testing would not be included in TSCA section 4 HPV SIDS rulemaking associated with this Initiative (See Unit III.I. and Unit V.A.).

—The LD_{50} test (OECD 401) would not be needed for mammalian acute toxicity testing under the TSCA section 4 HPV SIDS rulemaking associated with this Initiative (See Unit V.A.4.).

—EPA will encourage persons subject to the TSCA section 4 HPV SIDS rulemaking to use *in vitro* testing unless there are chemical properties (including chemical class considerations) or other aspects which may call its use into question (see Unit V.A.5.).

—EPA will consider combining some of the mammalian toxicity protocols under TSCA section 4 HPV SIDS rulemaking associated with this Initiative (See Unit V.A.6.).

If necessary for a particular chemical and/or endpoint, any variations are described in detail in this proposed rule.

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 the document that is published elsewhere in this issue of the **Federal Register** (Ref. 27), EPA is making every effort to ensure that as the HPV Initiative is implemented, 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 a vital role by developing test methods for consideration. Many test methods have begun the process of validation and several have completed the steps leading to government-wide regulatory acceptance. Within the SIDS battery of tests, certain *in vitro* genotoxicity tests, such as the Ames test for gene mutations in bacteria, have received uniform acceptance among regulatory agencies.

In addition, as part of the voluntary HPV Challenge Program, EPA asked participants in that program to observe certain principles laid out in the October 14, 1999, letter, in which the Agency also indicated its intention that related TSCA rulemaking proceed in a manner consistent with the principles (Ref. 29). This letter is available in the public version of the official record for this 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. EPA also asked that all animal testing on individual chemicals (as opposed to testing of categories of chemicals) under the voluntary HPV Challenge Program, or under an associated rule(s), not be initiated earlier than November 2001, and that testing of chemicals solely manufactured as closed system intermediates not begin earlier than 2003. 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.

Furthermore, a primary focus of the HPV Initiative, including the voluntary HPV Challenge Program and associated TSCA section 4 HPV SIDS rulemaking is to implement these efforts as contributors to a larger international activity with global involvement and in a manner consistent with meeting the needs of the OECD HPV SIDS program and to further the goals under Programme Area (c) of Agenda 21, Chapter 19 of the United Nations Conference on Environment and Development (UNCED) concerning information exchange on toxic chemicals and chemical risks. EPA solicits comment on the potential approaches that may be used to incorporate the principles contained in the October 14, 1999, letter in the context of TSCA section 4 HPV SIDS rulemakings (Ref. 29).

IV. EPA Findings

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

As indicated in Unit II., in order to develop a rulemaking under TSCA section 4(a) requiring the testing of chemical substances or mixtures, EPA must make certain findings regarding either risk (TSCA section 4(a)(1)(A)(i)); or production and 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).

In EPA's ''B'' policy (see Unit II.), ''substantial production'' of a chemical substance or mixture is generally interpreted to be aggregate production

(including import) volume equaling or exceeding 1 million pounds per year of that chemical substance or mixture. (Ref. 24 at 28747). For workers, the ''B'' policy threshold for ''substantial human exposure'' is the exposure of 1,000 workers annually to that chemical substance or mixture. (Ref. 24) See EPA's ''B'' policy for further discussion on how EPA makes decisions under TSCA section 4(a)(1)(B)(i). For the reasons set out in the ''B'' policy, EPA believes that the thresholds included in the ''B'' policy are appropriate for use in this proposed rule. (Ref. 24)

EPA has found preliminarily that, under TSCA section 4(a)(1)(B)(i), each of the 37 chemical substances included in this proposed rule is produced in ''substantial'' quantities (see Unit IV.B.) and that there is or may be ''substantial human exposure'' to each chemical substance (see Unit IV.C.). In addition, under TSCA section 4(a)(1)(B)(ii), EPA believes 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 IV.D.). In particular, EPA has preliminarily determined that there are insufficient data on these chemicals. EPA has also found preliminarily that testing the 37 chemical substances identified in this **Federal Register** document is necessary to develop such data (TSCA section 4(a)(1)(B)(iii)) (see Unit IV.E.). EPA has not identified any ''additional factors'' as discussed in the ''B'' policy (Ref. 24 at 28746) to cause the Agency to use decisionmaking criteria other than those described in the policy.

The chemical substances included in this proposed test rule are listed in § 799.5085(j) of the proposed regulatory text along with their CAS numbers.

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

Each of the chemical substances included in this proposal is produced and/or imported in an amount equal to or greater than one million pounds per year (Ref. 9), based on information gathered pursuant to the 1998 TSCA section 8(a) IUR (40 CFR part 710) which is the most recently available compilation of TSCA Inventory data, and which is contained in the TSCA Chemical Update System. EPA also considered the fact that all of these chemicals were produced and/or imported above 1 million pounds annually based on the 1990 and 1994 IUR. 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. 24 at 28746).

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

EPA finds that the manufacture, processing, and uses of the chemical substances included in this action result or may result in exposure to a substantial number of workers. These chemical substances are used in a wide variety of industrial applications, which result in potential exposures to workers, as described in the exposure support document for this proposed rule (Ref. 10).

EPA defines chemical exposure as the contact of a chemical with a person's outer boundary (for example, the skin or lungs) (Ref. 11). Worker exposure is the chemical exposure that occurs while a person is working. Exposure to workers may have various causes. Chemical releases are a common cause of exposure. For example, a chemical manufacturing plant can release a chemical from pumps as fugitive emissions, from reactor and condenser vents as stack emissions, and/or as a particulate. Diffusion and air currents may carry a chemical through the air in the plant. Plant workers breathe air containing this chemical, resulting in exposures. Human activity such as manually transferring a chemical from one container to another may cause exposures.

For each of the chemicals in this proposed rule, estimates for the number of exposed workers were identified in the National Occupational Exposure Survey (NOES). The NOES was a nationwide data gathering project conducted by the National Institute for Occupational Safety and Health (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 (Ref. 12). The NOES survey is the most recent and comprehensive source of this kind of information.

Each of the chemicals in this proposed rule was identified in the NOES as having a total potential worker exposure of greater than 1,000 workers (Ref. 10). 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 section 4(a)(1)(B)(i) of TSCA. 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 58 FR 28736, 28746.

D. Do Sufficient Data Exist for These Chemical Substances?

In developing the testing requirements for chemicals contained in this proposed rule, EPA utilized information and sources in EPA's study, the Chemical Hazard Data Availability Study (Ref. 2), and in ACC's study, the Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals (Ref. 3), to determine whether screening level data for characterizing the risks of these HPV chemicals are available. Section 799.5085(j) of the proposed regulatory text lists each chemical and the tests for which no data are currently available to the Agency. If no data are available for a SIDS testing endpoint, there cannot be sufficient data to characterize the risk associated with exposure to the chemical. The Agency preliminarily finds that for the SIDS testing endpoints, including acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, genetic toxicity (gene mutations and chromosomal aberrations), ecotoxicity (tests in fish, Daphnia, and algae), and for environmental fate (including five tests for physical chemical properties [melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility], and biodegradation), there are insufficient data and experience to reasonably determine or predict the human health and environmental effects resulting from manufacture, processing, and use of the chemical substances included in this proposal.

EPA solicits comment concerning the availability of SIDS data on these substances and encourages industry and others to identify and provide any additional existing test data which are relevant to the proposed testing. If EPA judges such data to be sufficient, corresponding testing will not be

included in the final rule. To the extent that additional data 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. Commenters are also encouraged to prepare a robust summary (Ref. 34) for each such study to facilitate EPA's review of the full study report or publication. EPA has not included any chemicals in this proposal which are GRAS for a particular use by the FDA. As indicated in Unit III.F., such chemicals may be included in a future TSCA section 4 HPV SIDS rulemaking where SIDS data needs remain unmet.

E. Is Testing Necessary for These Chemical Substances?

Of the nearly 3,000 chemicals that the U.S. manufactures at more than 1 million pounds per year, EPA's study concluded that 43% of them have no SIDS data. For the remaining chemicals, generally limited amounts of the data appear to be available (see Unit III.A. and Ref. 2). The lack of available data compromises EPA's and others' ability to determine whether these chemicals pose unreasonable risks to human health or the environment, as well as the public's right to know about the hazards of chemicals that are found in their environment, their homes, their workplaces, and the products that they buy. It is EPA's intent to close this knowledge gap. EPA will use the data obtained from this proposed rule to support development of preliminary hazard and risk assessments for these HPV chemicals and to set priorities for further testing that will produce more definitive hazard information where needed on such chemicals. 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 chemicals. EPA has used data from test rules to support such activities as the development of water quality criteria, Toxic Release Inventory listings, chemical advisories, and input for actions resulting in reduction of workplace exposures.

EPA believes that conducting the needed SIDS testing identified for the 37 subject chemicals will 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.

V. Proposed Rule

A. What Testing is being Proposed in this Action?

EPA is proposing specific testing and reporting requirements for the chemical substances specified in § 799.5085(j) of the proposed regulatory text.

All of the proposed testing requirements are listed in Table 2 in § 799.5085(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. Most of the proposed testing requirements for a particular endpoint are specified in one test standard, although in the case of certain endpoints, any of one or more listed methods could be used. The following endpoints and proposed test standards would be required under this proposed rule. For several of the proposed test standards, EPA has identified and is proposing certain ''Special Conditions'' as discussed below in this unit. Because terrestrial toxicity testing will normally be considered to belong at the OECD post-SIDS tier, EPA is not proposing any terrestrial toxicity testing (including avian toxicity) in this rulemaking.

1. *Physical/Chemical Properties.*

Melting Point: American Society for Testing and Materials (ASTM) E 324 (capillary tube)

Boiling Point: ASTM E 1719 (ebulliometry)

Vapor Pressure: ASTM E 1782 (thermal analysis)

n-Octanol/Water Partition Coefficient: Method A (40 CFR 799.6755—shake flask)

Method B (ASTM E 1147—liquid chromatography)

Method C (40 CFR 799.6756—generator column)

Water Solubility: Method A: (ASTM E 1148—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)

For the *n*-Octanol/Water Partition Coefficient and Water Solubility endpoints, EPA is proposing that certain ''Special Conditions'' in the form of the chemical substance's physical/chemical properties or physical state (acute only) be considered by test sponsors in determining the appropriate test method that would be used from among those included for these endpoints in Table 2 in § 799.5085(j) of the proposed regulatory text.

For the ''*n*-Octanol/Water Partition Coefficient'' endpoint, the test method, if any, would be determined by the test substance's estimated *n*-octanol/water partition coefficient (log 10 basis; ''log K_{ow}''). EPA proposes three methods for measuring the substance's *n*-Octanol/Water Partition Coefficient. The method that would be required would be based on the test substance's estimated log K_{ow}. 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 suggests that the method described in *Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients* (Ref. 13) be used in making such an estimation. EPA is proposing that test sponsors be required to 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 can be expected to provide adequate information for determining the log K_{ow}. 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) 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 highly recommends 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 below:

Testing category	Test requirements and references	Special conditions
Physical/Chemical Properties	*n*-Octanol/Water Partition Coefficient: The appropriate *n*-Octanol/Water Partition Coefficient test, if any, would be selected from those listed below—see Special Conditions in the adjacent column. Method A: 40 CFR 799.6755 (shake flask) Method B: ASTM E 1147 (liquid chromatography) Method C: 40 CFR 799.6756 (generator column)	*n*-Octanol/Water Partition Coefficient: Which method is required, if any, would be determined by the test substance's estimated *n*-octanol/water partition coefficient (log 10 basis). Test sponsors would be required to submit in the final study report the underlying rationale for the method selected. In order to ensure environmental relevance, EPA is recommending that the selected study be conducted at pH 7. 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.

For ''Water Solubility,'' the test method, if any among the four proposed, would be determined by the test substance's estimated water solubility. EPA recommends that water solubility be quantitatively estimated prior to initiating this study. One recommended method for estimating water solubility is described in Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient (Ref. 14). 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 highly recommends that all required Water Solubility tests be conducted 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 below:

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 below—see Special Conditions in the adjacent column . Method A: ASTM E 1148 (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 would be required to submit with the final study report the underlying rationale for the method selected. In order to ensure environmental relevance, EPA recommends that the selected study be conducted at pH 7. >5,000 milligram/Liter (mg/L): Method A or B. <5,000 mg/L but > 10 mg/L: Method A, B, C, or D. <10 mg/L but > 0.001 mg/L: Method C or D. <0.001 mg/L: No testing required.

2. *Environmental Fate and Pathways.*

Inherent Biodegradation: ASTM 1625–94 (Semicontinuous Activated Sludge Test) or International Standards Organization (ISO) 9888 (Zahn-Wellens Method)

3. *Aquatic Toxicity.*

Test Group 1: Acute toxicity to fish (ASTM E 729)

Acute toxicity to Daphnia (ASTM E 729)Toxicity to plants (algae) (ASTM E 1218)

Test Group 2: Chronic toxicity to Daphnia (ASTM E 1193)

Toxicity to plants (algae) (ASTM E 1218)

For ''Aquatic Toxicity,'' the OECD HPV SIDS test battery recognizes that for certain chemicals acute toxicity studies are of limited value in assessing the substances' aquatic toxicity. This issue arises when considering chemicals 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 toxic concentrations in the test organism. For such situations, the OECD HPV SIDS battery recommends use of chronic toxicity testing in Daphnia in place of acute toxicity testing in fish and Daphnia. EPA is proposing that the testing requirement be determined based on the test substance's log K_{ow} as determined by using the approach outlined in Unit V.A.1. ''*n*-Octanol/Water Coefficient'' and in Table 2 in § 799.5085(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 2 in § 799.5085(j) of the proposed regulatory text) are proposed: Acute toxicity to fish (ASTM E 729); Acute toxicity to Daphnia (ASTM E 729); and Toxicity to plants (algae) (ASTM E 1218). 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 2 in § 799.5085(j) of the proposed regulatory text) are proposed: Chronic toxicity to Daphnia (ASTM E 1193) and Toxicity to plants (algae) (ASTM E 1218). As outlined in Table 2 in § 799.5085(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.

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. Using SAR, a log K_{ow} of 4.2 corresponds with a fish bioconcentration factor (BCF) of about 1,000 (Refs. 15, 16, and 17). A chemical 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. 18). 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 proposed Persistent, Bioaccumulative and Toxic (PBT) Policy Statement under section 5 of TSCA (63 FR 53417, October 5, 1998) (FRL–5771–6) Policy Statement under TSCA section 5 entitled *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (64 FR 60194, November 4, 1999) (FRL–6097–7)] (Ref. 25). EPA has also used a measured BCF that is ''equal to or greater than 1,000x 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 under sections 5 and 26(c) of TSCA (54 FR 31307, July 27, 1989; see also 40 CFR 721.3) (Ref. 26). 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 TSCA section 4 test rule to be negligible.

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. One approach for dealing with such chemicals would be to allow test sponsors who wish to conduct Test Group 1 studies on chemicals with a log K_{ow} greater than or equal to 4.2 to submit to EPA for approval a written request to conduct these Test Group 1 studies. The written request would have to include the rationale for conducting these Test Group 1 studies and be approved by the Agency prior to (e.g., 90 days before) initiating these Test Group 1 studies. 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 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 2 in § 799.5085(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 2 in § 799.5085(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 or 40 CFR 799.9110(d)(1)(i)(A)) in Table 2 in § 799.5085(j) of the proposed regulatory text). Dermal toxicity testing is not required 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 use either 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 required to conduct testing for chromosomal damage are encouraged to use *in vitro* genetic toxicity testing (Mammalian Chromosome Aberration Test) to generate 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. 4). A subject person who uses one of the *in vivo* methods instead of the *in vitro* method to address this end-point must submit to EPA a rationale for conducting that alternate test in the final study report. EPA solicits comment on whether the Agency should instead require that a subject person wishing to use an alternate testing scheme submit to EPA a notice that includes the rationale for conducting the alternative tests prior to planned initiation of those studies. Comments should include suggestions for efficient procedures for such a notification process.

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 ''Mammalian Toxicity—Repeated Dose/Reproduction/Developmental,'' EPA recommends the use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365). EPA recognizes, however, that there may be reasons to test a particular chemical 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, 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 must submit to EPA a rationale for conducting these alternate tests in the final study reports. EPA solicits comment on whether the Agency should instead require that a subject person

wishing to use an alternate testing scheme submit to EPA a notice that includes the rationale for conducting the alternative tests prior to planned initiation of those studies. Comments should include suggestions for efficient procedures for such a notification process.

Certain of the chemicals 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. 32). As described in that guidance, such chemicals 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 chemicals 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 chemicals that are listed in the proposed regulatory text are solely closed system intermediates as defined by OECD/SIDS guidelines. Persons who believe that a chemical fully satisfies the terms outlined in the guidance document are encouraged to submit appropriate information along with their comments which substantiate this belief. If, based on submitted information and other information available to EPA, the Agency believes that a chemical is considered likely to meet the requirements for use solely as a closed system intermediate, EPA will address any developmental toxicity testing need in a subsequent 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. EPA intends that actual initiation of testing of closed system intermediates be deferred until 2003.

B. When Would any Testing Imposed by this Rulemaking Begin?

The testing requirements contained in this proposed rule are not effective until and unless the Agency issues a subsequent final rule. Based on the effective date of the final rule, which is typically 30 days after the publication of a final rule in the **Federal Register**, the test sponsor 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 § 799.5085(j) of the proposed regulatory text. As indicated previously, in establishing the time frame for testing under this rulemaking, the Agency will consider the time frames used under the voluntary HPV Challenge Program. Specifically, any testing of closed system intermediates (as described in Unit III.I.) will be deferred until 2003; and any testing of individual chemicals (i.e., those HPV chemicals not proposed for testing in a category) that require further testing on animals will be deferred until November 2001.

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 those testing and reporting requirements, and with the TSCA GLPS (40 CFR part 792).

D. What 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'' chemical substance. First introduced when EPA compiled the TSCA Chemical Substance Inventory, the term Class 1 chemical 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 chemical 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 § 799.5085(j) of the proposed regulatory text identifies the listed substances as either Class 1 or Class 2 substances.

EPA is proposing that, for the Class 1 chemical 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 chemical 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 chemical 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 chemical 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, C_{12}–C_{14} tert-akyl 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 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 which would require basic screening-level testing, the testing of any representative form of a subject Class 2 substance would be relevant to a determination of whether the chemical substance would or would not present an unreasonable risk to human health or the environment. 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 must 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 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 the rule would be jointly responsible for the testing of a representative form of each Class 2 substance.

EPA is also considering whether, for some or all Class 2 substances, more than one form of a substance should be tested. Regardless of which of the above approaches for testing Class 2 substances is ultimately chosen (i.e., persons subject to the rule choosing vs. EPA choosing the forms(s) of the Class 2 substances to be tested), EPA is considering requiring that persons applying for an exemption provide data to EPA that would allow the Agency to determine whether:

1. The form of the Class 2 substance with respect to which an exemption application is being submitted is equivalent to the form of a test substance for which data required under the rule have been or will be submitted; and

2. The submission of the required test data concerning a particular form of a Class 2 substance would be duplicative of data that have been or will be submitted to EPA in accordance with the test rule.

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. Additionally, EPA solicits comment on whether the proposed approach for testing Class 1 substances in the proposed rule, i.e., that Class 1 test substances have a purity of 99% or greater, should be applied to any Class 2 substances in the proposed rule. Similarly, EPA solicits comment on whether the proposed or alternative approaches for the testing of Class 2 substances should be applied to any Class 1 substances.

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 rulemaking. As a result, under TSCA section 4(b)(3)(B), manufacturers and processors of these substances would be subject to the rule with regard to those listed chemicals which they manufacture or process.

1. *Would I be subject to this rule?* You would be subject to this rule and may be required to test if you manufacture 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 V.E.2 , entitled *When would my manufacture or processing (or my intent to do so) cause me to be subject to this rule?* However, if you do not know or cannot reasonably ascertain that you manufacture or process a listed test 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.

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 substance listed in the 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 V.E.4. , entitled *How do the reimbursement procedures work?*

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 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) must 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) need not take any action unless they are notified by EPA that they are required to do so, as described in Unit V.E.3.d , entitled *What would my obligations be if I were in Tier 2?* Note that 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 V.E.4. , entitled *How do the reimbursement procedures work?*

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

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

Tier 1 (Persons initially required to comply)	Tier 2 (Persons not initially required to comply)
Persons who manufacture (as defined at TSCA section 3(7)), or intend to manufacture, a test rule substance, and who are not listed under Tier 2	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 substance (as defined at 40 CFR 710.4(b));

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

Tier 1 (Persons initially required to comply)	Tier 2 (Persons not initially required to comply)
	—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 (as described at 40 CFR 790.42(a)(5)) 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))

b. *When would it be appropriate for a person in Tier 1 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)) in Tier 1. You can find procedures relating to exemptions in 40 CFR 790.80 through 790.99, and § 799.5085(c)(2), (c)(5), and (c)(7) of the proposed regulatory text. In this rule, EPA would not require 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. See § 799.5085(j) of the proposed regulatory text for a description of the substances that would be tested under this proposed rule.

c. *What would happen if I were in Tier 1 and 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 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 § 799.5085(c)(6) of the proposed regulatory text. Note that persons in Tier 1 who obtain exemptions and persons in Tier 2 would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit V.E.4., entitled *How do the reimbursement procedures work?*

d. *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 V.E.4. You are considered to have an automatic conditional exemption. You would not need to take any action unless you are notified by EPA that you are required to do so.

If a problem occurs with the initiation, conduct, or completion of the required testing, or the submission of the required data to EPA, the Agency may require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5085(c)(6) 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 document in the **Federal Register** directing all persons in Tier 2 to submit to EPA letters of intent to conduct testing or exemption applications. See 40 CFR 790.48(b) and § 799.5085(c)(4) and (c)(5) 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.

e. *How did EPA decide who would be in Tier 1 and Tier 2 and who would be excluded from the rule?*

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

Under 40 CFR part 790, in TSCA section 4(a) test rules EPA traditionally has treated the persons specified below as being in Tier 2. (These rules are found at 40 CFR part 799, subparts B and D.):

• Processors (40 CFR 790.42(a)(2));

• Manufacturers of less than 500 kg (1,100 lbs) per year (''small-volume manufacturers'') (40 CFR 790.42(a)(4)); and

• Manufacturers of small quantities for research and development (''R&D manufacturers'') (40 CFR 790.42(a)(5)).

EPA has historically placed processors in Tier 2 because the Agency ''expected that, in most cases, testing will be performed by the manufacturers and that part of the cost of testing will be passed on to processors through the pricing mechanism, thereby enabling them to share in the costs of testing'' (50 FR 20652, 20654, May 17, 1985). In addition, ''[t]here are so many processors 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'' (48 FR 31786, 31789, July 11, 1983).

EPA has historically placed small-volume manufacturers and R&D manufacturers in Tier 2 because this type of manufacturing ''normally represents a small percentage of the overall production volume [and] test sponsors are not expected to expend the administrative resources to recover the small proportional amounts of the testing costs from these manufacturers'' (55 FR 18881, May 7, 1990).

In this proposed test rule, EPA has reconfigured these tiers. 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 proposed 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.

TSCA section 4(b)(3)(B) requires all manufacturers and processors of a chemical substance to test that chemical substance if EPA has made findings for that chemical substance, and therefore issued a TSCA section 4(a) test rule requiring testing. However, practicality must be a factor in determining who is subject to a particular test rule. Thus, persons who do not know or cannot reasonably ascertain that they are manufacturing or processing a substance would not be subject to the proposed rule. See Unit V.E.1. and § 799.5085(b)(2) of the proposed regulatory text.

Under 40 CFR 790.42(a)(4), certain small-quantity manufacturers (i.e., those who manufacture less than 500 kg (1,100 lb) of the test rule chemical annually) do not initially need to submit letters of intent to test or exemption applications under a test rule unless EPA specifically requires them to do so. EPA established this provision because such small-quantity manufacturing normally represents a small percentage of the overall production volume, so that test sponsors are not expected to expend the administrative resources necessary to seek reimbursement of the associated small proportional amounts of the testing costs from these small-quantity manufacturers. As a result, EPA determined that the reason for requiring an exemption application to be filed did not exist for these manufacturers (55 FR 18881, at 18881, May 7, 1990).

During interagency review, it was suggested that EPA consider increasing the small-quantity amount in this proposed rule in order to eliminate the need for certain persons subject to the rule to initially submit a letter of intent to test or an exemption application. As a result this group of persons would be shifted to Tier 2. As with the existing tiering system, these persons would still be subject to reimbursement requirements and could potentially be required to conduct testing (for example, if Tier 1 entities do not submit letters of intent to test).

EPA is interested in receiving comment on whether the 1,100 lb (500 kg) small-quantity threshold in this proposed rule should be raised (e.g., to 5,000, 10,000, or 25,000 lbs) in order to shift certain small-quantity manufacturers from Tier 1 to Tier 2. These persons would represent a small percentage of the overall production volume of a chemical in the test rule such that test sponsors would not be expected to expend the administrative resources necessary to seek reimbursement from these manufacturers. EPA is particularly interested in comments on the appropriate annual production amount at which test sponsors would not be expected to seek reimbursement such that the reason for requiring an exemption application to be filed by these manufacturers would not exist. Please provide a rationale and supporting information for any alternative threshold(s) suggested.

EPA is also soliciting comment on who should be included in Tier 1 and Tier 2. The Agency may define these categories differently in response to comments received. EPA is also soliciting comment on who should not be subject to the rule. The latter persons are described in Unit V.E.1. and § 799.5085(b)(2) of the proposed regulatory text.

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 are the Reporting Requirements 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 § 799.5085(j) of the proposed regulatory text.

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?

Yes. In 1996, EPA conducted a study of TSCA testing laboratories to evaluate the expected capacity of these laboratories to conduct various tests through the year 2000 (Ref. 19). The results suggest that laboratory capacity is expected to expand at a rate such that the testing that would be required by this proposed rule should be readily accommodated by testing laboratories (Ref. 9).

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

VI. Export Notification

Any person who exports, or intends to export, one of the chemical substances contained in this proposed rule in any form 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. However, export notification would generally not be required for articles, as provided by 40 CFR 707.60(b).

VII. Public Comment

As discussed in Unit III.D, EPA is interested in comments regarding specific procedures for incorporating the use of categories and SAR into this proposed rule.

Comments which identify existing data that may meet the requirements of studies under this proposed rule should include the data with the submission of comments to EPA. 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. 34). 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 solicits public comment on the test methods proposed in this, the approach discussed in Unit V.E. entitled *Would I be required to test under this rule?*, 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. Documents in the Official Record

The official record for this proposed rule has been established under docket control number OPPTS–42213A, and the public version of the official record is available for inspection as specified in Unit I.B.2. The following is a listing of the documents that have already been placed in the official record for this proposed rule, including those specifically referenced in this document. For your convenience, EPA may have also provided some non-EPA internet addresses to allow you to access the electronic version of the referenced document. In doing so, the Agency has verified the accuracy of these addresses at the time of signature. However, since EPA is not responsible for these non-EPA sites, the Agency does not have any control over these web addresses. A paper copy of any document referenced in this way has been included in the public version of the official record for this document as described in Unit I.B.2.

1. EPA, OPPT. ChemRTK, HPV Challenge Program Chemical List. (This list is updated periodically, and is available electronically at http://www.epa.gov/chemrtk/hpvchmlt.htm).

2. EPA, OPPT. Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? (April 1998) (An electronic copy of this document is available on the EPA website at http://www.epa.gov/opptintr/chemtest/hazchem.htm).

3. ACC (formerly CMA). Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals (June 12, 1998). Copies of ACC's report can be obtained by writing to ACC at 1300 Wilson Blvd., Arlington, VA 22209 or by calling ACC at (703) 741-–226.

4. OECD Secretariat. *SIDS Manual*. Third Ed. Screening Information Data Set Manual of the OECD Programme on the Co-Operative Investigation of High Production Volume Chemicals. Paris, France (July 1997). Electronic copies of this Manual can be obtained from OECD at http://www.oecd.org/ehs/sidsman.htm, or by accessing EPA's ChemRTK website at http://www.epa.gov/chemrtk/sidsappb.htm.

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

6. ACC. Comments on EPA's TSCA section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, EPA (September 17, 1991).

7. 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 TSCA Public Docket Office, EPA (September 17, 1991).

8. ICCA. ICCA HPV Working List 22–040–1999; Chemicals Common to 2 or more of the Regions: Canada, European Union (EU), Japan, and USA (1999). (Electronic copies of this list can be obtained from the ICCA website at http://www.icca-chem.org/hpv).

9. EPA, OPPT. Economic Impact Analysis of a Section 4 Test Rule for High Production Volume Chemicals (December 2000).

10. EPA. Comparison of 1990 High Production Volume (HPV) Chemicals with National Occupational Exposure Survey (NOES) Database (November 13, 1998).

11. EPA. Guidelines for Exposure Assessment, **Federal Register** (57 FR 28888, May 29, 1992).

12. Seta, J.A. et al., National Exposure Survey Field Guidelines. Cincinnati Ohio: National Institute for Occupational Safety and Health. DHHS (NIOSH) Publication No. 88–106 (1988).

13. Meylan WM, and Howard PH. Atom/Fragment Contribution for Estimating Octanol-Water Partition Coefficients. *Journal of Pharmaceutical Sciences*. Vol.84, No.1 (January 1995).

14. Meylan WM, Howard PH, and Boethling, RS. Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient. *Environmental Toxicology and Chemistry*. Vol. 15, No.2, pp. 1006–106 (1996).

15. Veith GD 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).

16. Bintein S, DeVillers J, and Karcher W. Nonlinear dependence of fish bioconcentration on *n*-octanol/water partition coefficient. SAR and QSAR in Environmental Research, Vol.1, pp. 29–39 (1993).

17. Meylan WM, Howard PH, Boethling RS, Aronson D, Printup H, and Gouchie S. Improved method of estimating bioconcentration/bioaccumulation factor from octanol/water partition coefficient. *Environmental Toxicology and Chemistry*, Vol.18, No.4, pp 664–672) (1999).

18. Smrchek JC and Zeeman MG. Assessing Risks to Ecological Systems from Chemicals, pp. 24–90. In. P. Callow (ed.), *Handbook of Environmental Risk Assessment and Management*, Blackwell Science Ltd., Oxford, UK. (1998).

19. EPA. EPA Census of TSCA Laboratories, Washington, DC (October 10, 1996).

20. EPA. Treatment of 12(b) Export Notification Unit Costs for Section 4 Test Rule Analyses, OPPT/EETD/EPAB, Washington, DC (April 1, 1999).

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

22. EPA. April 1999 Agenda of Regulatory and Deregulatory Actions; Semiannual regulatory agenda. Chemical Right-to-Know, sequence #3424 (64 FR 21898, April 26, 1999) (FRL–6238–9).

23. EPA. TSCA section 4(a)(1)(B) Proposed Statement of Policy (56 FR 32297, July 15, 1991).

24. EPA. TSCA section 4(a)(1)(B) Final Statement of Policy (58 FR 28736, May 14, 1993).

25. EPA. Document containing EPA's Policy Statement under TSCA section 5 entitled *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (64 FR 60194, November 4, 1999) (FRL–6097–7). (An electronic copy is available at http://www.epa.gov/opptintr/newchems/pbtpolcy.htm).

26. EPA. Significant New Use Rules; General Provisions for New Chemical Followup under sections 5 and 26(c) of TSCA (54 FR 31307, July 27, 1989).

27. Document describing the HPV Initiative, entitled *Data Collection/ development on High Production Volume (HPV) Chemicals; Notice*, which is published elsewhere in this issue of the **Federal Register** (FRL–6754–6). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/fedrgstr/).

28. Environmental Defense (formerly EDF). Toxic Ignorance. New York, New York (Summer 1997). Copies of Toxic Ignorance can be obtained by accessing Environmental Defense's website (http://www.environmentaldefense.org/Reports/ToxicIgnorance) or by calling 1–800–684–3322.

29. 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) (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/ceoltr2.htm).

30. EPA, OPPT. The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program (August 26, 1999). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/sarfinl1.htm).

31. EPA, OPPT. Development of Chemical Categories in the HPV Challenge Program (Draft) (August 25, 1999). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/categuid.htm).

32. EPA, OPPT. Guidance for Testing Closed System Intermediates for the HPV Challenge Program (Draft) (March 17, 1999). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/closed9.htm).

33. EPA, OPPT. Procedures for Removing Chemicals that are No longer HPV and Not Likely to Become HPV Again from the HPV List (Draft) (March 17, 1999). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/nolohpv8.htm).

34. EPA, OPPT. Draft Guidance on Developing Robust Summaries (October 27, 1999). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/robsumgd.htm).

35. EPA, OPPT. ChemRTK HPV Challenge Program Making Commitments (June 29, 2000). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/makecom.htm).

36. EPA, OPPT. Draft Guidance on Searching for Chemical Information and Data (August 1999). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/srchguid.htm).

37. EPA, OPPT. Determining the Adequacy of Existing Data (February 10, 1999). (An electronic copy of this document is available on the EPA website at http://www.epa.gov/chemrtk/datadfin.htm).

38. SBA. Office of Advocacy-Statistics-Major Industry, Firms, Establishment, Employment, Payroll and Receipts, 1995. Information from the Small Business Administration on the Internet (http://www.sba.gov/advo/stats/us-ind95.html. Downloaded on December 10, 1998).

IX. Regulatory Assessment Requirements

A. Executive Order 12866

Under E.O. 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has designated this proposed rule a ''significant regulatory action'' subject to review by OMB under E.O. 12866, because this action may 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 E.O. EPA therefore submitted this proposed rulemaking to OMB for review under E.O. 12866, and any comments or changes made during that review have been documented in the public version of the official record for this rulemaking.

In addition, EPA has prepared an economic assessment entitled *Economic Impact Analysis for the Proposed Section 4 Test Rule for High Production Volume Chemicals* (Ref. 9), a copy of which has been placed in the public version of the official record for this 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 49 chemicals, 12 more than identified in the proposal, therefore, the costs presented here are expected to be an overestimate. The total social cost of providing test data on the 49 chemicals that were evaluated in this economic analysis is estimated to be $13 million (Ref. 9).

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 § 799.5085(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 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's sale price. This measure compares annual revenues from the sale of a chemical to the annualized testing costs for that chemical to assess the percentage of testing costs that can be accommodated by the revenue generated by that chemical. Annualized testing costs divide testing expenditures into an equivalent, constant yearly expenditure over a longer period of time. To calculate the percent price impact, testing costs (including laboratory and administrative expenditures) are annualized over 15 years using a 7% discount rate. Annualized testing costs are then divided by the estimated annual revenue of the chemical to derive the cost-to-sales ratio. EPA estimates the total annualized compliance cost of testing for the 49 chemicals evaluated in the economic analysis to be $ 1.5 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 be $83.38 for the first time that an exporter must comply with TSCA section 12(b) export notification requirements, and $19.08 for each subsequent export notification submitted by that exporter (Refs. 9, 20, and 21). The Agency's estimated total costs of testing (including both

laboratory and administrative costs) annualized testing cost, price impacts, and public reporting burden hours for this proposed rule are presented in the economic assessment.

Under a least cost scenario, 28 out of the 45 chemicals for which price data were available (62%) would have a price impact at less than the 1% level. Similarly, 28 out of the 45 chemicals (58%) 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 58% of the chemicals in this proposed rule. Approximately 17 (19) chemicals (38% (42%)) of the 45 chemicals 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.

The Agency computed ''critical prices'' for all 49 chemicals, including the 37 chemicals included in this proposed TSCA section 4 HPV SIDS rule. Using chemical specific volume and test cost data, the critical price per pound that would result in a 1% impact on the annual revenue of the chemical was estimated. The critical prices are particularly informative for the 4 chemicals for which price data are unavailable because they represent the minimum price that is required to support testing at the 1% level.

Of the 4 chemicals for which price data were unavailable, an approximate price range could be inferred for 2 chemicals based on the knowledge of the nature of these chemicals. Based on the critical prices and basic information on their nature or use, it is expected that neither of these chemicals is likely to be impacted at greater than the 1% level. For the remaining 2 chemicals without price information, it is unclear whether they will be impacted at greater than the 1% level.

EPA believes, on the basis of these calculations, that the proposed testing of the chemicals presents a low potential for adverse economic impact for the majority of chemicals. 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 chemicals. There are, however, some chemicals 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 chemicals. In these cases, companies may choose to use revenue sources other than the profits from the individual chemicals to pay for testing. Therefore, the Agency also compared the costs of compliance to company sales for small businesses.

B. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601(b) *et seq.*, the Agency hereby certifies that this rulemaking, if promulgated as proposed, will not have a significant 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 rule (Ref. 9), and is briefly summarized here.

Two factors are examined in EPA's small entity impact analysis (Ref. 9) in order to characterize the potential small entity impacts of this rule:

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

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

Section 601(3) of the 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 the Small Business Administration (SBA) establishes small business size standards (13 CFR 121.201). For this 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, the RFA recognizes that it may be appropriate at times to use an alternate definition of small business. As such, section 601(3) of the 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 entity impacts for this proposed rule, EPA does not believe that the SBA size standards are generally the best size standards to use in assessing potential small entity impacts with regard to TSCA section 4(a) test rules.

The SBA size 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., SIC 28 and SIC 29), 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 750, 1,000, or 1,500 employees. As a result, when assessing the potential impacts of test rules on chemical manufacturers, EPA believes that a standard based on total annual sales may provide a more appropriate means to judge the ability of a chemical manufacturing firm to support chemical testing without significant costs or burdens.

EPA is currently determining what level of annual sales would provide the most appropriate size cutoff with regard to various segments of the chemical industry usually impacted by TSCA section 4(a) test rules, but has not yet reached a determination. As stated above, therefore, the factual basis for the RFA determination for this proposed rule is based on an analysis using the default SBA size standards. Although EPA is not 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. 9). For a conservative estimate of the number of small businesses affected by the HPV rule, the Agency chose an employment threshold of less than employees 1,500 for all businesses regardless of the NAIC-specific threshold to determine small business status.

For each manufacturer of the 49 chemicals in the economic analysis, the parent company (ultimate corporate entity, or UCE) was identified and sales and employment data were obtained for companies where data was available. The search determined that there were 103 affected UCEs. Sales and employment data could be found for 102 of these UCEs (99%).

Parent company sales data were collected to identify companies that qualified for ''small business'' status.

Based on the SBA size standard applied, 35 companies were identified as small. Employment data were unavailable for 1 company. A separate analysis, contained in the economic assessment prepared for this proposed rule, was conducted for these companies to determine the potential economic impact of this proposed rule.

The significance of this proposed HPV 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%, greater than 3%. This analysis was conducted under both the least and the average cost scenarios.

Of the 35 companies that qualified for small business status per the SBA size standards, only 1 had cost-to-sales ratios of greater than 1% under least and average cost scenarios. None were impacted at greater than the 3% level. Given these results, there does not appear to be a significant impact on a substantial number of small entities as a result of this proposed rule.

As stated earlier in this unit, employment data were unavailable for 1 of the identified 103 companies (1%). While data on their company level sales were also unavailable, the volumes of the chemicals included in this proposed rule that it produced could be identified from the 1994 IUR database. Combining secondary data on chemical prices with production volume data, the sales value of these chemicals could be estimated for this company. In addition, the minimum critical sales level that would be needed to avoid an impact at the 1% and the 3% levels was calculated. These critical sales were then compared to the sales estimated using the method described in this unit. Using these estimates, EPA concluded that this company is not impacted at greater than 1% of sales in the least or average cost scenarios

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 $83.38 for the first time that an exporter must comply with TSCA section 12(b)(1) export notification requirements, and $19.08 for each subsequent export notification submitted by that exporter (Refs. 9, 20, and 21). 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.

Therefore, the Agency certifies that this proposed rule, if finalized, would not have a significant economic impact on small entities. Information relating to this determination has been included in the public version of the official record for this proposed rule. This information will also be provided to the SBA Chief Counsel for Advocacy upon request. 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**.

C. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, and included on the related collection instrument. The information collection activities related to chemical testing under TSCA section 4(a) have already been approved under OMB control number 2070–0033 (EPA ICR No.1139), and 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 action does not contain any new information collection activities requiring additional OMB review and approval.

Although the information collection activities contained in this proposed rule have already been approved by OMB, the total burden hours currently approved for the information collection activities related to chemical testing may not reflect the estimated burden hours specifically related to the activities contained in this proposed rule because the total number of chemicals included in this proposed rule exceeds the total number of chemicals estimated in the ICR. As described in the information collection instrument for chemical testing (EPA ICR No. 1139), the Agency's total burden estimate specifically accounts for the potential issuance of approximately three average test rules per year, each assumed to involve five chemicals and three sponsors. With an estimated burden of approximately 263 hours for each study, the Agency estimated an average burden of 14,444 hours per test sponsor . When a final rule based on this proposed rule is issued, EPA will verify that the approved burden hours contained in the ICR are sufficient to cover the estimated burden for the final rule. If not, EPA will request that the total approved burden hour for the ICR be increased accordingly.

The standard chemical testing program involves the submission of letters of intent to test (or exemption applications), study plans, administering the tests, progress reports, and test results. For this proposed rule, EPA estimates that the information collection activities related to chemical testing for all chemicals in this proposal (representing the submission of letters of intent or exemption applications, administering the tests, and submitting the final reports—the study plan is represented by this proposed rule and progress reports are not required by this proposed rule because testing will be completed within 1 year) would result in an annual public reporting burden of approximately 12,942 hours per sponsor, assuming seven chemicals per sponsor.

The annual public reporting burden related to export notification is estimated to be 0.5–1.5 burden hours for each chemical/country combination (Ref. 9). 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 the 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 the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposal.

D. Unfunded Mandates Reform Act and Executive Orders 13084 and 13132

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, EPA has determined that this 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 XI.A. , would be $13 million. The total annualized costs of this proposed rule are estimated to be $1.5 million. In addition, EPA has determined that this proposed rule does 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.

Under E.O. 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA has determined that this proposed rule would not significantly or uniquely affect the communities of Indian tribal governments. This determination is based on the Agency's experience over the years which indicates that, as a practical matter, the burden of chemical testing under TSCA section 4(a) rules has traditionally fallen on large, private sector manufacturers rather than on tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this proposed rule. Nor will this action have a substantial direct effect on 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 E.O. 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

In the history of the TSCA section 4(a) testing program, the Agency has never received a letter of intent to test or an exemption application from a State, local, or tribal government. EPA is requesting comment on whether any State, local, or tribal government is engaged in the manufacture or processing of these HPV chemicals such that they might be subject to the requirements of this proposed rule. On the basis of these comments, EPA may determine that it is appropriate to consult with representatives of potentially affected State, local, or tribal governments prior to promulgating the final rule.

E. Executive Order 12898

This proposed rule does not involve special considerations of environmental-justice issues pursuant to E.O. 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

F. Executive Order 13045

E.O. 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), does not apply to this proposed rule, because it is not designated as an ''economically significant'' regulatory actions as defined under E.O. 12866, and it does not establish an environmental standard that is intended to mitigate environmental health or safety risks that EPA has reason to believe may have a disproportionate effect on children. EPA interprets E.O. 13045 as applying only to those regulatory actions that establish an environmental standard intended to mitigate health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation.

Although this proposed rule is not subject to this E.O., the information obtained by the testing proposed in this rule will be used to inform the Agency's decision making process regarding chemicals to which children may be disproportionately disposed. This information will also assist the Agency and others in evaluating these chemical substances for potential health or safety risk concerns, and will serve to further the Agency's goal of identifying and controlling human and environmental risks as well as provide greater protection and knowledge to the public.

In addition, in a separate **Federal Register** document (64 FR 46673, August 26, 1999), EPA announced the initiation of a stakeholder involvement process to involve stakeholders in the design and development of a voluntary program to test commercial chemicals to which children may have a high likelihood of exposure. The purpose of the voluntary testing program is to obtain toxicity data needed to assess the potential risks resulting from childhood exposure to certain commercial chemicals.

G. 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.

If the Agency has made findings under TSCA section 4(a), EPA is required by TSCA section 4(b) to include specific standards for the development of data in test rules. For some of the testing that would be required by this rule, EPA is proposing the use of voluntary consensus standards issued by the ASTM and ISO which evaluate the same type of toxicity as the TSCA and OECD test guidelines, where applicable. Copies of the ASTM and ISO standards referenced in this proposed rule have been placed in the public version of the official record for this rulemaking. 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 rulemaking, and, specifically, invites the public to identify potentially applicable consensus standard(s) and to explain why such standard(s) should be used here.

H. Executive Order 12630

EPA has complied with E.O. 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the E.O.

I. Executive Order 12988

In issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of E.O. 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

List of Subjects in 40 CFR Part 799

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

Dated: December 14, 2000.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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

PART 799—[AMENDED]

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

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

2. By adding § 799.5085 to subpart D of part 799 that would read as follows:

§ 799.5085 Testing of certain High Production Volume (HPV) chemicals.

(a) *What substances will be tested under this section?* Table 2 in § 799.5085(j) identifies the chemical substances that must be tested under this section. For the chemical substances identified as ''Class 1'' substances in Table 2, 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, a representative form of each substance must be tested.

(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 799.5085(j) 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 § 799.5085(j) 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: 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.

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

Persons initially required to comply with this section (Tier 1)	Persons not initially required to comply with this section (Tier 2)
Persons not otherwise specified in column 2 of this table that manufacture (as defined at TSCA section 3(7)) or intend to manufacture a chemical substance included in this section.	Persons that 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 kilograms (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)). Persons that 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 expands the list of persons specified in 40 CFR 790.42(a)(2), (a)(4) and (a)(5), 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) and (c)(5) of this section.

(2) If you are in Tier 1 with respect to a chemical substance listed in Table 2 in § 799.5085(j), you will be required to comply with this section with regard to that chemical substance, as described in paragraph (d) of this section, no later than 30 days after the effective date of the final rule. Sections 790.45(a) and 790.80(b)(1) of this chapter do not apply to this section.

(3) If you are in Tier 2 with respect to a chemical substance listed in Table 2 in § 799.5085(j), 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) or (c)(6) 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 § 799.5085(j) within 30 days after the effective date of the final rule, EPA will publish a **Federal Register** document that will specify the test and the chemical substance for which no letter of intent has been submitted.

Section 790.48(b)(2) of this chapter does not apply to this section.

(5) If you are in Tier 2 with respect to a chemical substance listed in Table 2 in § 799.5085(j), and if you manufacture or process this chemical as of the effective date of the final rule, or within 30 days after publication of the **Federal Register** document described in paragraph (c)(4) of this section, you must do the following: For each test on that chemical specified in the **Federal Register** document described in paragraph (c)(4) of this section, either notify EPA by letter of your intent to test or submit to EPA an exemption application. You must comply within 30 days after the date of publication of the **Federal Register** document described in paragraph (c)(4) of this section. Sections 790.48(b)(3), and 790.80(a)(2) and (b)(1) of this chapter do not apply to this section.

(6) 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 § 799.5085(j), under the procedures in 40 CFR 790.93 and 790.97 EPA will terminate all testing exemptions with respect to that 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. Notification will be given by certified letter or by publication in the **Federal Register**.

(7) If you are required to comply with this section, but your manufacture or processing of a chemical substance listed in Table 2 in § 799.5085(j) begins after the applicable compliance date referred to in paragraphs (c)(2), (c)(5) or (c)(6) of this section, you must comply by submitting a letter of intent to test or an exemption application as of the day you begin manufacture or processing. Sections 790.45(d)(1) and (d)(2), and 790.80(b)(2) and (b)(3) of this chapter do not apply to this section.

(d) *What must I do to comply with this section?* (1) To comply with this section you must either:

(i) submit to EPA a letter of intent to test, conduct the testing specified in Table 2 in § 799.5085(j), and submit the test data to EPA; or

(ii) apply to and obtain from EPA an exemption from testing.

(2) 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.

(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. Sections 790.45(e) and (f) of this chapter do not apply to 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 § 799.5085(j) is subject to part 707, subpart D, of this chapter.

(h) *What test standards must I follow?* Follow the guidelines and other test methods described in Table 2 in § 799.5085(j).

(i) *Reporting requirements.* A final report for a specific test must be submitted by the deadline indicated in Table 2 in § 799.5085(j).

(j) *Designation of specific chemical substances and applicable testing requirements.* The substances identified by name and the Chemical Abstract Service (CAS) number in Table 2 of this section must be tested in accordance with the designated testing requirements, the requirements described in Part 792—Good Laboratory Practice Standards of this chapter, and any additional requirements and limitations specified in the following Table 2:

TABLE 2—CHEMICAL SUBSTANCES AND APPLICABLE TESTING REQUIREMENTS

CAS No.	Chemical name	Chemical class	Required tests (See Key)	Deadline for final report (Months from effective date of final rule)
55–63–0	1,2,3-Propanetriol, trinitrate	1	A, C6, E2, F2.	13
62–56–6	Thiourea	1	A.	13
74–95–3	Methane, dibromo-	1	A, C1, E2, F2.	13
75–36–5	Acetyl chloride	1	A, B, C2, E2, F1.	13
75–75–2	Methanesulfonic acid	1	A, C1, E1, E2, F1.	13
78–11–5	1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester)	1	A, B, C6, F2.	13
84–65–1	9,10-Anthracenedione	1	A, F2.	13
84–69–5	1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester	1	A, E2, F2	13
88–18–6	Phenol, 2-(1,1-dimethylethyl)-	1	A, C2, D, E1, E2, F1.	13
90–00–6	Phenol, 2-ethyl-	1	A, B, C1, E2, F2.	13
90–15–3	1-Naphthalenol	1	A, C5, F2	13
98–11–3	Benzenesulfonic acid	1	A, C3, E2, F1.	13
105–67–9	Phenol, 2,4-dimethyl-	1	A, C6, E2, F2.	13
107–16–4	Acetonitrile, hydroxy-	1	A, B, C1, E2, F2.	13
107–18–6	2-Propen-1-ol	1	A, C6, E2.	13
108–19–0	Imidodicarbonic diamide	1	A, B, C1, D, E1, E2, F1.	13
110–44–1	2,4-Hexadienoic acid, (E,E)-	1	A, C4, F2.	13
112–52–7	Dodecane, 1-chloro-	1	A, B, C3, D, E1, E2, F1	13
118–82–1	Phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)-	1	A, B, D, E1, E2, F2.	13

TABLE 2—CHEMICAL SUBSTANCES AND APPLICABLE TESTING REQUIREMENTS—Continued

CAS No.	Chemical name	Chemical class	Required tests (See Key)	Deadline for final report (Months from effective date of final rule)
131–57–7	Methanone, (2-hydroxy-4-methoxyphenyl)phenyl-	1	A, C1, D, E2, F2.	13
149–44–0	Methanesulfinic acid, hydroxy-, monosodium salt	1	A, B, C1, E2, F1.	13
409–02–9	Heptenone, methyl-	2	A, B, C1, D, E1, E2, F1.	13
594–42–3	Methanesulfenyl chloride, trichloro-	1	A, B, C1, E1, E2, F2.	13
624–83–9	Methane, isocyanato-	1	A, C1.	13
732–26–3	Phenol, 2,4,6-tris(1,1-dimethylethyl)-	1	A, C2, E1, E2, F1.	13
870–72–4	Methanesulfonic acid, hydroxy-, monosodium salt	1	A, B, C1, E1, E2, F1.	13
1324–76–1	Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]-	2	A, B, C1, D, E1, E2, F1.	13
1333–39–7	Benzenesulfonic acid, hydroxy-	2	A, B, C1, E1, E2, F1.	13
2941–64–2	Carbonochloridothioic acid, S-ethyl ester	1	A, B, C1, E2, F1.	13
3622–84–2	Benzenesulfonamide, N-butyl-	1	A, B, C1, E1, E2, F2.	13
6473–13–8	2-Naphthalenesulfonic acid, 6-[(2,4-diaminophenyl)azo]-3-[[4-[[4-[[7-[(2,4-diaminophenyl)azo]-1-hydroxy-3-sulfo-2-naphthalenyl]azo]phenyl]amino]-3-sulfophenyl]azo]-4-hydroxy-, trisodium salt	1	A, B, C1, D, E1, E2, F1.	13
8005–02–5	C.I. Solvent Black 7	2	A, B, C1, D, E2, F1.	13
28188–24–1	Octadecanoic acid, 2-(hydroxymethyl)-2-[[(1-oxooctadecyl)oxy]methyl]-1,3-propanediyl ester	1	A, B, C1, D, E1, E2, F1.	13
65996–78–3	Light oil, coal, coke-oven	2	A, B, C1, D, E1, E2, F1.	13
68153–30–0	Quaternary ammonium compounds, benzylbis(hydrogenated tallow alkyl)methyl, salts with bentonite	2	A, B, C1, D, E1, E2, F1.	13
68611–64–3	Urea, reaction products with formaldehyde	2	A, B, C1, D, E1, E2, F1.	13
68953–58–2	Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, salts with bentonite	2	A, B, C1, D, E1, E2, F1.	13

KEY TO THE TEST REQUIREMENTS FOR THE CHEMICALS LISTED IN TABLE 2 AND SPECIFIED BY ALPHANUMERIC SYMBOLS (E.G., A OR C5)

Testing category	Test symbol	Test requirements and references[1]	Special conditions
Physical/Chemical Properties	A	1. Melting Point: ASTM E 324 (capillary tube) 2. Boiling Point: ASTM E 1719 (ebulliometry)	*n*-Octanol/Water Partition Coefficient: Which method is required, if any, is determined by the test substance's estimated[2] *n*-octanol/water partition coefficient (log 10 basis). Test sponsors are required to provide in the final study report the underlying rationale for the method selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7.
		3. Vapor Pressure: ASTM E 1782 (thermal analysis)	
		4. *n*-Octanol/Water Partition Coefficient: (See Special Conditions for the *n*-Octanol/Water Partition Coefficient test requirement and select the appropriate method to use, if any, from those listed below.) Method A: 40 CFR 799.6755 (shake flask) Method B: ASTM E 1147 (liquid chromatography) Method C: 40 CFR 799.6756 (generator column)	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.

KEY TO THE TEST REQUIREMENTS FOR THE CHEMICALS LISTED IN TABLE 2 AND SPECIFIED BY ALPHANUMERIC SYMBOLS (E.G., A OR C5)—Continued

Testing category	Test symbol	Test requirements and references[1]	Special conditions
		5. Water Solubility: (See Special Conditions for the Water Solubility test requirement and select the appropriate method to use, if any, from those listed below.) Method A: ASTM E 1148 (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, is determined by the test substance's estimated[3] water solubility. Test sponsors are required to provide in the final study report the underlying rationale for the method selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7. >5,000 mg/L: Method A or B. < 5,000 mg/L but > 10 mg/L: Method A, B, C, or D. <10 mg/L but > 0.001 mg/L: Method C or D. < 0.001 mg/L: no testing required.
Environmental Fate and Pathways—Inherent Biodegradation	B	For B, choose either of the following methods: 1. ASTM 1625 (semicontinuous activated sludge test) OR 2. ISO 9888 (Zahn-Wellens method)	None
Aquatic Toxicity	C1	For C1, Test Group 1 or Test Group 2 below must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C1*: 1. Acute Toxicity To Fish: ASTM E 729 2. Acute Toxicity To Daphnia: ASTM E 729 3. Toxicity To Plants (Algae): ASTM E 1218 *Test Group 2 for C1*: 1. Chronic Toxicity To Daphnia: ASTM E 1193 2. Toxicity To Plants (Algae): ASTM E 1218	The following are the Special Conditions for C1, C2, C3, C4, C5, and C7 testing; there are no Special Conditions for C6. log K_{ow} <4.2: Test Group 1 is required log K_{ow} ≥ 4.2: Test Group 2 is required Which test group is required is determined by the test substance's log K_{ow} as obtained under A.
	C2	For C2, Test Group 1 or Test Group 2 below must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C2*: 1. Acute Toxicity To Daphnia: ASTM E 729 2. Toxicity To Plants (Algae): ASTM E 1218 *Test Group 2 for C2*: 1. Chronic Toxicity To Daphnia: ASTM E 1193 2. Toxicity To Plants (Algae): ASTM E 1218	
	C3	For C3, Test Group 1 or Test Group 2 below must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C3*: 1. Acute Toxicity To Fish: ASTM E 729 2. Toxicity To Plants (Algae): ASTM E 1218 *Test Group 2 for C3*: 1. Chronic Toxicity To Daphnia: ASTM E 1193 2. Toxicity To Plants (Algae): ASTM E 1218	

KEY TO THE TEST REQUIREMENTS FOR THE CHEMICALS LISTED IN TABLE 2 AND SPECIFIED BY ALPHANUMERIC SYMBOLS (E.G., A OR C5)—Continued

Testing category	Test symbol	Test requirements and references[1]	Special conditions
	C4	For C4, Test Group 1 or Test Group 2 below must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C4*: 1. Acute Toxicity To Fish: ASTM E 729 2. Acute Toxicity To Daphnia: ASTM E 729 *Test Group 2 for C4*: 1. Chronic Toxicity To Daphnia: ASTM E 1193	
	C5	For C5, Test Group 1 or Test Group 2 below must be used to fulfill the testing requirements—See Special Conditions. *Test Group 1 for C5*: 1. Acute Toxicity To Daphnia: ASTM E 729 *Test Group 2 for C5*: 1. Chronic Toxicity To Daphnia: ASTM E 1193	
	C6	Toxicity To Plants (Algae): ASTM E 1218	
	C7	For C7, Test Group 1 or Test Group 2 below must be used to fulfill the testing requirements See Special Conditions. *Test Group 1 for C7*: 1. Acute Toxicity To Fish: ASTM E 729 *Test Group 2 for C7*: 1. Chronic Toxicity To Daphnia: ASTM E 1193	
Mammalian Toxicity—Acute	D	See Special Conditions for this test requirement and select the required method to use from those listed below. *Method A*: Acute Inhalation Toxicity (rat): 40 CFR 799.9130 *Method B*: EITHER: 1. Acute (Up/Down) Oral Toxicity (rat): ASTM E 1163 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 (25oC). For those test substances that are gases at room temperature, Method A is required; otherwise, use of either of the two methods listed under Method B is required. In Method B, 40 CFR 799.9110(d)(1)(i)(A) refers to the OECD 425 Up/Down test methodology. NOTE: In the case of a potentially explosive test substance, care must be taken to avoid the generation of explosive concentrations.
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 *In vivo* Mammalian Bone Marrow Chromosomal Aberration Test (rodents: Mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9538 OR *In vivo* Mammalian Erythrocyte Micronucleus Test [sampled in bone marrow] (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 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 this end-point must submit to EPA a rationale for conducting that alternate test in the final study report.

KEY TO THE TEST REQUIREMENTS FOR THE CHEMICALS LISTED IN TABLE 2 AND SPECIFIED BY ALPHANUMERIC SYMBOLS (E.G., A OR C5)—Continued

Testing category	Test symbol	Test requirements and references[1]	Special conditions
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) (Identified as F2 below) AND Repeated Dose 28-Day Oral Toxicity Study in rodents: 40 CFR 799.9305) (Identified as F3 below)	EPA recommends use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test. However, EPA does recognize that there may be valid reasons to test a particular chemical using both F2 and F3 to fill Mammalian Toxicity Repeated Dose/Reproduction/Developmental data needs. A subject person who uses the combination of F2 and F3 in place of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test must submit to EPA a rationale for conducting these alternate tests in the final study reports.
	F2	Reproduction/Developmental Toxicity Screening Test: (40 CFR 799.9355)	
	F3	Repeated Dose 28-Day Oral Toxicity Study in rodents: (40 CFR 799.9305)	

[1] Copies of the ASTM and ISO standards referenced in this proposed rule have been placed in the public version of the official record for this rulemaking. For 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.

[2] 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 Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients (Ref. 1).

[3] 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 Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient (Ref. 2).

(k) *Effective date.* (1) The effective date of this section is [*insert effective date of the final rule.*]

(2) The guidelines and other test methods cited in this section are referenced as they exist on the effective date of this section. You can apply for a modification under 40 CFR 790.55.

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