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Part IV

Environmental Protection Agency

Sustainable Futures — Voluntary Pilot Project Under the TSCA New Chemicals Program; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0011; FRL-7198-6]

RIN 2070-AD60

Sustainable Futures — Voluntary Pilot Project Under the TSCA New Chemicals Program; Notice

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces a voluntary pilot project by EPA, entitled Sustainable Futures, to encourage the application of pollution prevention principles during the development of new chemicals submitted as premanufacture notices (PMNs) under section 5 of the Toxic Substances Control Act (TSCA). Certain expedited review under section 5 of TSCA is proposed as an incentive to PMN submitters. The goal of this pilot project is to encourage pollution prevention and the development of inherently low hazard chemicals. Furthermore, the Agency seeks to gain additional data and experience regarding the pollution prevention, risk reduction, and source reduction benefits of use of hazard, exposure, and risk screening methodologies such as EPA's Pollution Prevention Framework in new product development efforts.

DATES: Comments are solicited on or before June 9, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

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

For technical information contact: For New Chemicals Program regulatory information: Kenneth T. Moss, Chemical Control Division (7405M), Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; e-mail address: moss.kenneth@epa.gov. For information about P2 Framework and Training or Workshops: Bill Waugh or Maggie Wilson, Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone numbers: (202) 564-7657 or 564-8924; e-mail addresses: waugh.bill@epa.gov or wilson.maggie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are or may in the future be a submitter of a PMN under TSCA. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers or importers (NAICS 325, 32411, 28, 2911). Anyone who plans to manufacture or import a new chemical substance (as defined in TSCA section 3) for a non-exempt commercial purpose is required to provide the EPA with a PMN at least 90 days prior to the activity. Any TSCA Chemical substance that is not on the TSCA Inventory is classified as a new chemical.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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.**

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT-2002-0011. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566-0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the

2

version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPPT–2002–0011. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to oppt.ncic@epa.gov, Attention: Docket ID Number OPPT–2002–0011. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *By hand delivery or courier.* Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Building Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT–2002–0011. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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

We invite you to provide your views on the various options we propose, new approaches we have not 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 action. 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 that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. To ensure proper receipt by EPA, be sure to identify the docket ID 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. Background

Under section 5(a) of TSCA, persons must notify EPA at least 90 days before manufacturing or importing a new chemical substance for non-exempt purposes. A new chemical substance, as defined in section 3(9) of TSCA, is any chemical substance (as defined in section 3(2) of TSCA) that is not included on the Inventory compiled under section 8(b) of TSCA. EPA requires that submissions be made on EPA Form 7710–25– Premanufacture

3

Notice (PMN). The Agency encourages chemical manufacturers to incorporate health and environmental issues into product decisionmaking during the development of new chemical substances. EPA has several ongoing initiatives intended to help stakeholders better assess risk issues during the early stages of chemical development efforts. Examples include the Design for Environment Program, the Green Chemistry Program, and the Pollution Prevention Framework (P2 Framework), among other programs. Of specific relevance to today's notice is the P2 Framework as utilized in the development of safer new chemicals submitted as PMNs under section 5 of TSCA.

A. What Action is the Agency Taking?

The Agency seeks to gain additional data and experience regarding the pollution prevention, safer chemicals, risk reduction, and source reduction benefits of use of hazard, exposure, and risk screening methodologies such as the P2 Framework in new product development efforts. To help build this knowledge base the Agency has established this pilot project, entitled Sustainable Futures, to encourage application of pollution prevention principles during the development of new chemicals under TSCA, known hereafter as the "pilot project." While EPA's major goal is development of safer new chemicals, for purposes of the pilot it will also consider low-moderate hazard chemicals for which exposure assessment indicates potentially low risk. This pilot project is entirely voluntary and will enable the Agency to develop information to support a possible future exemption under section 5(h)(4) of TSCA based on experience gained in Sustainable Futures. Under this initiative, pilot project participants would be encouraged to become proficient with and to apply the Pollution Prevention Framework (P2 Framework) or other scientifically acceptable hazard, exposure, and risk screening methods in new chemical development efforts. To encourage industry participation in this voluntary pilot project, the Agency will consider providing certain expedited review to participants in the pilot project. This notice provides additional detail relating to the expedited review available under this pilot project and discusses criteria or factors EPA will consider to determine eligibility for the pilot project and associated expedited review.

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

This pilot project is entirely voluntary and will enable the Agency to develop information to support a possible future exemption to the PMN reporting requirements of section 5 of TSCA, under section 5(h)(4) of TSCA and based on experience gained in Sustainable Futures. See below for a further explanation of these requirements and general information on the New Chemicals Program.

C. Overview of the PMN Process

Under section 5(a) of TSCA, persons must notify EPA at least 90 days before manufacturing or importing a new chemical substance for non-exempt purposes. EPA requires that submissions be made on EPA Form 7710–25 – Premanufacture Notice (PMN). Along with the PMN submitters must send in all available data on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure. In addition, submitters must send in all existing health and environmental data in the possession of the submitter, parent company, or affiliates. All of this information is considered by Agency risk assessors to determine whether manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, presents an unreasonable risk of injury to health or the environment. In some cases, EPA can require submission of any additional data, including development of data through testing, when the information included with the PMN, coupled with that available to its risk reviewers from internal archives is not adequate to allow EPA to make this determination. The Instruction Manual for Premanufacture Notification of New Chemical Substances explains all reporting requirements.

EPA has limited or no reporting requirements for new chemical substances in the following cases:

- Low Volume Exemption (LVE) — 10,000 kilograms or less of the substance will be manufactured or imported each year under the requirements at (40 CFR 723.50). Notification required, using EPA Form 7710–25 (the PMN Form).
- Research and Development (R&D) — the substance is manufactured in small quantities for research and development, and special procedural and recordkeeping requirements are met (40 CFR 720.36 and 720.78). Notification not required.
- Low Releases and Low Exposures (LoREX) Exemptions — the substance is expected to have low release and exposure under the requirements at 40 CFR 723.50. Notification required, using the PMN Form.
- Test Marketing Exemption (TME) — the substance is being manufactured or imported for TME, under the requirements at 40 CFR 720.38. Notification required, using the PMN Form.
- Polymer Exemption — the substance is a polymer that meets certain specified criteria where the substance is not considered chemically active or bioavailable under the requirements at 40 CFR 723.250. Annual report to the Agency is required for those exempt polymers commenced for the first time in the preceding calendar year.

Section 5 of TSCA gives EPA 90 days to review a PMN (also referred to as a "section 5 notice"). The PMN program has evolved into an efficient mechanism to identify new chemicals which are of greatest concern during the early stages of the 90-day review process and focus detailed analysis on these cases with the ultimate goal of identifying and controlling unreasonable risks. EPA utilizes an integrated approach that draws on knowledge and experience across scientific and organizational lines to identify and evaluate concerns regarding health and environmental effects, exposure and release and economic impacts. PMNs and exemption notices share the early stages of the 90-day PMN review process; LVE and LoREX applications conclude review by day 30 and TME applications by day 45.

A large majority of PMN submissions are reviewed, evaluated and dropped from further consideration during the early stages, i.e., first 30 days, of the PMN review period. The early stages of the PMN review period include:

1. The Chemical Review and Search Strategy Meeting;
2. The Structure Activity Team Meeting;
3. Development of the Exposure and Release Profile; and
4. The Focus Meeting.

The Chemical Review and Search Strategy (CRSS) meeting (day 8–12) examines chemical identity; structure/chemical nomenclature; structural analogs/TSCA Inventory Status; synthesis (including byproducts and impurities); use/TSCA jurisdiction as provided by the PMN submitter, open literature, or as identified by EPA for similar chemical substances; physical/chemical properties (physical state, molecular weight, melting and boiling point, vapor pressure, solubility, octanol water partition co-efficient, pH); and

4

pollution prevention aspects, using information provided by the PMN submitter. EPA also may make suggestions for alternate synthetic pathways. Decisions at this meeting include notice completeness, validity, reportability, eligibility for exemption, candidacy for exposure-based review (PMN has potential for substantial production volume and substantial or significant human exposure or substantial environmental release), and whether the notice meets certain CRSS drop criteria.

The Structure Activity Team meeting (day 9–13) is an interdisciplinary meeting of scientists, including chemists, biologists, toxicologists, and information specialists, which evaluates potential environmental fate, health effects and environmental hazard through the use of structure activity relationships (SAR), test data on the new chemical substance, data on structural analogs, and expert judgment.

The Initial Exposure and Release Assessments are developed by Day 10–19 and examine occupational exposure, environmental releases, and environmental, general population and consumer exposures.

The Focus meeting (Day 15–20) is the earliest risk management meeting in the section 5 notice review period; representatives from all PMN technical disciplines are involved in this assessment. Initial decisions are developed at this meeting. For Exemption notices, the initial decisions are to grant or deny the notice, with or without certain conditions of use specified in the notice, to which the submitter is legally bound. Focus meeting decisions for PMNs can range from identifying the need to consider a ban or section 5(e) of TSCA regulation of the new chemical to a "drop" from further Agency review. A PMN can also continue on to a more detailed review which occupies much of the remainder of the 90-day period. Regardless of whether the Agency drops a PMN submission during the early stages of review at the Focus meeting or near the end of the statutorily mandated 90-day PMN review period, the PMN submitter is nonetheless not allowed to commence manufacture before day 90 of the review period.

The review period can be extended under section 5(c) of TSCA for good cause; it may also be suspended voluntarily by the mutual consent of EPA and the PMN submitter. During the review period for PMNs, EPA may take action under section 5(e) or (f) of TSCA to prohibit or limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns. If EPA has not taken action under section 5(e) or (f) of TSCA, the PMN submitter may manufacture or import the new chemical substance when the review period expires (i.e., day 90) and need merely notify the agency of commencement of manufacture or import. Similarly, during the review period for PMN exemption notices, EPA may take action to prohibit or limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns. If EPA has not taken action to deny the exemption application, under section 5(h)(1) for TMEs or section 5(h)(4) of TSCA for LVE and LoREX notices, the notice submitter may manufacture or import the new chemical substance when the respective review period for those notices expires (i.e., day 45 for TME or day 30 LVE and LoREX).

No later than 30 days after the PMN submitter initiates manufacture or import of the PMN substance, it must provide EPA with a notice of commencement of manufacture or import (NOC). Section 8(b) of TSCA provides that, upon receipt of such a notice, EPA must add the substance to the TSCA Inventory. Thereafter, other manufacturers and importers may engage in activities involving the new substance without submitting a PMN, unless the Agency has used its Significant New Use Rule (SNUR) authority under section 5(a)(2) of TSCA to designate a use of a chemical substance as a "significant new use." Section 5(a)(1)(B) of TSCA would then require persons to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the substance for the use designated as significant. The required SNUN provides EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs.

D. History

EPA has over 20 years experience in reviewing PMNs and exemption notices under TSCA on a wide variety of classes or categories of chemicals. During this period the Agency has reviewed over 38,000 PMNs and section 5 of TSCA exemption notices.

Historically, it has been EPA's policy to not allow simultaneous submission of section 5 exemption notices and PMNs for the same substance. For LVEs, EPA restricts submission of a PMN until nine months after the date on which a LVE is approved by EPA (i.e., 90 days before termination of the one year low volume period) and restricts a LVE when a pending PMN estimates a production volume greater than 10,000 kilograms per year. This policy, in interpreting the intent of the rule, places emphasis on the rule's use of the words 10,000 kilograms "per year," rather than per any lesser time period. Accordingly, EPA has denied a LVE because a PMN simultaneously submitted by the same company on the same chemical estimated the production volume to be over 10,000 kilograms per year.

Test Market Exemption (TME) applications have been allowed in combination with Premanufacture Notices (PMNs) only if the submitter's description clearly distinguishes the test marketing activity from full-scale commercial production or research and development. EPA's New Chemical Information Bulletin Exemptions for Research and Development and Test Marketing (USEPA, 1986, see Unit XV.1.) describes how the Agency, in order to discourage the use of simultaneous submissions to simply obtain PMN review of a chemical substance in 45 days, closely examines such submissions to determine if genuine test marketing activity is involved; if it is not, the application has been denied. The suggested mechanism for such a combination submission has been that, following the submission of a TME application, the same company may not submit a PMN for the same chemical until 90 days before the end of the test marketing period specified by the company in its TME application pursuant to 40 CFR 720.38(b)(5).

III. What is the P2 Framework?

The P2 Framework (USEPA, 2000, see Unit XV.2.) is a set of computer models that predict hazards and exposures of chemicals using structure activity relationships (SARs), exposure assessment models and databases, and standard (default) scenarios. These models have been developed over a 20-year period by EPA's Office of Pollution Prevention and Toxics, and others in the scientific and technical community, to screen new chemicals in the presence of limited data. Annually, EPA evaluates over 2,000 new chemicals submitted under section 5 of TSCA. TSCA requires that EPA evaluate the chemicals within 90 days. Although the law does not generally require that the submitter conduct laboratory tests to evaluate potential hazards of the chemicals, PMN submissions must include all available existing information on exposure and environmental release on new chemicals and the Agency will use this information or, in absence of supplied information, professional judgment to

5

evaluated exposures and releases. Operating under this time limitation, and often a lack of data, EPA developed methods to quickly screen chemicals to assess human and environmental hazards, physical/chemical properties, environmental fate, human and environmental exposures, and risks.

The P2 Framework models listed in the table in this unit, capture the expertise of multiple EPA scientists, grantees, support contractors, and others in the scientific community working for over 20 years screening chemicals in the presence of limited data. The P2 Framework project presents these models to industry with the hope that the models will be useful in identifying potential problem chemicals and processes early in the research and development process. EPA believes that application of hazard screening methodologies early in new chemicals research and development will lead to commercialization of safer new chemical substances. In other instances where chemicals are projected to present a low-moderate hazard concern, exposure and risk screening methodologies can be used early in the research and development process to identify lower risk chemical alternatives. The table also provides information regarding the availability of the models.

P2 FRAMEWORK MODELS

Model	Endpoints addressed	Inputs needed	Availability
Models to Estimate Physical-Chemical Properties			
EPI Suite™	Melting and Boiling Points, Vapor Pressure; Octanol/water partition coefficient (Kow); Water solubility from log Kow; *Soil organic carbon partition coefficient* (Koc); Henry's law constant: vapor pressure/water solubility; Fish bioconcentration factor	Chemical Abstract Service Registry Number (CAS RN), if in Smilecas database – CAS database of Simplified Molecular Input Line Entry System (SMILES) – or Chemical Structure in SMILES notation	Download at no cost from http://www.epa.gov/oppt/exposure/docs/episuitedl.htm
Models to Estimate Environmental Fate			
EPI Suite™	Atmospheric oxidation potential; Biodegradation rate; Hydrolysis rate; Percent removal in POTW (Publicly Owned Treatment Works)	Chemical Abstract Service Registry Number (CAS RN), if in Smilecas database – CAS database of Simplified Molecular Input Line Entry System (SMILES) – or Chemical Structure in SMILES notation	Download at no cost from http://www.epa.gov/oppt/exposure/docs/episuitedl.htm
Models to Estimate Human Health and Environmental Hazards			
OncoLogic	Cancer hazard potential	Chemical structure	Developed by USEPA, OPPT and LogiChem under a cooperative agreement. Information http://logichem.com/
ECOSAR™	Acute and chronic toxicity to fish, invertebrates, algae	CAS RN (if in Smilecas db) or Chemical Structure in SMILES notation	Download at no cost from http://www.epa.gov/oppt/newchems/21ecosar.htm
Models to Estimate Exposure			
E-FAST	*Surface water ingestion, fish ingestion*, ground water ingestion, ambient air inhalation, indoor air inhalation, dermal exposure, aquatic environment exposure/risk	*Physical/chem properties, fate properties*, release amounts, release medium, release location, aquatic concentration of concern, National Pollutant Discharge Elimination System (NPDES) number.	Download at no cost from http://www.epa.gov/oppt/exposure/docs/efast.htm
ReachScan	Impact of surface water discharges on drinking water facilities, chemical concentration downstream at drinking water intake point	Facility location (NPDES), release data	EPA is updating ReachScan and will make information available on its use in this and other programs at http://www.epa.gov/oppt/exposure/docs/reachscan.htm
ChemSTEER	Occupational inhalation and dermal exposure during industrial and commercial manufacturing, processing, and use operations; industrial & commercial manufacturing, & processing releases to air, water, and land	Molecular weight, vapor pressure, density; production or use volume, fractions devoted to multiple uses; weight fractions, physical state. Numbers of sites & workers, batch amounts & times, release sources, worker activities; workplace concentrations, release amounts & media.	Download at no cost from http://www.epa.gov/oppt/exposure/docs/chemsteer.htm

6

IV. How Has the Agency Worked to Educate Industry About the P2 Framework?

Over the last several years the Agency has gained considerable experience in working with stakeholders (e.g., chemical manufacturers, formulators, users, consulting firms, etc.) in the application of the P2 Framework during new product development. EPA has conducted detailed P2 Framework workshops and training exercises, including workshops in California, Texas, Illinois, New Hampshire, and Virginia. These workshops were designed to introduce stakeholders to the P2 Framework and to help stakeholders develop experience in the use, interpretation, limitations and applicability of the P2 Framework methodologies in chemical hazard and exposure screening. The workshops also discussed use of the P2 Framework outputs in risk screening analyses. Approximately 100 companies, among other stakeholders, have participated in the P2 Framework workshops and training. In addition to providing workshops and training sessions, the Agency has worked with individual companies, and other stakeholders, regarding opportunities to apply the P2 Framework in the development of environmentally preferable new chemical products and other activities designed to identify and implement pollution prevention opportunities.

V. What Is the Potential Benefit Derived from Use of the P2 Framework?

Companies that develop new chemical substances often have alternative chemical structures that could become the subject of a PMN. Chemical manufacturers and users often lack hazard- and exposure-related information on new chemical alternatives and, as a result, sometimes choose among new chemical product alternatives without an understanding of the potential hazard and risk trade-offs of product alternatives under consideration. Many companies that have used the P2 Framework indicate that the P2 Framework generates screening-level information about human and environmental hazards and exposures, and that this information helps further differentiate among product alternatives, leading to identification of alternatives which are potentially safer or present lower potential risks or, in other cases, the development of environmentally preferable products and processes and other pollution prevention outcomes. It is hoped that the P2 Framework will enable PMN submitters to design safer products and conduct an analysis similar to that done by EPA for each new chemical submitted, and to identify and develop products and processes that can be sustained both environmentally and economically.

Chemical companies, consultants, research and development laboratories, etc. which have applied the P2 Framework during new chemical and product development activities have indicated that the P2 Framework:

1. Generates chemical specific hazard and exposure related information previously unavailable;
2. Helps compare new chemical product alternatives based on hazard, exposure, and risk considerations early in the product development process, when change is most cost effective;
3. Helps identify environmentally preferable new products and processes;
4. Reduces the generation of hazardous waste that typically occurs during product development; and
5. Results in potentially significant financial and business benefits, among other benefits (Tellus Institute, 1999, see Unit XV.3; Eastman Kodak, 1996, see Unit XV.4).

VI. What Is the Regulatory Incentive for Chemical Manufacturers under this Sustainable Futures Pilot Project?

For purposes of this voluntary pilot project, EPA will implement a program leading to the opportunity for simultaneous submissions of TME applications and PMNs on chemical substances for which the submitter demonstrates the application and use of the P2 Framework or other scientifically acceptable hazard and exposure screening methodologies. While EPA's major goal is the development of safer chemicals, it will also consider, for the purposes of this pilot, low-moderate hazard chemicals for which exposure assessment indicates potentially low risk. Thus, under the pilot, the submitter, following approval of the TME by the Agency, can begin manufacture of the chemical substance for test marketing purposes, in accordance with the TME after 45 days. They must continue to meet the exemption requirements for an additional 45 days, at which time the 90-day PMN review may be satisfactorily completed and they may then submit the NOC and begin manufacture for PMN purposes.

Under the voluntary pilot project, qualifying simultaneous PMN/TME submitters may begin manufacture of those chemical substances at 45 days in accordance with the TME. As described in Unit II.A., most decisions on PMNs or TMEs are made before day 30 of their review periods, which in the case of simultaneous submissions would run concurrently. Chemicals qualifying for this option will be restricted to those PMN/TME chemical substances that the Agency, in the case of a PMN, drops from review and, in the case of a TME, grants by the Focus meeting which occurs by day 30 of the 90- or 45-day review period, respectively, and which satisfy certain criteria described below (see Unit IX.). In granting a TME, the chemical substance (and its associated uses and exposures) must be judged by EPA to meet the requirement that it "will not present an unreasonable risk of injury to human health and the environment," after which the submitter can commence TME activities at 45 days. EPA will also review the simultaneously submitted PMN and, provided the TME is granted and the PMN is dropped during the first 30 days of the 90-day review period, the submitter may then commence full commercialization on or after day 90 of PMN review and file the NOC. All TME requirements must, however, be met until such time as commencement of manufacture occurs and the NOC is filed, at which point the substance becomes an existing chemical and is placed on the TSCA Inventory. If EPA grants the TME, but does not drop the PMN during the first 30 days of review, the submitter will be notified that the submitter must choose, by letter within 15 days of being notified of the Agency's decision, to continue only one of the two notification procedures (i.e., withdraw the TME and continue with the PMN, or continue with the TME and withdraw the PMN).

VII. How Could EPA Decide to Approve a TME but Identify Concerns with a PMN on the Same Chemical?

As mentioned in Unit II.B., a TME submitter's description must clearly distinguish the test marketing activity from full-scale commercial production or research and development. When EPA approves the TME, it has determined that test marketing the new chemical substance, under terms and conditions set out in the TME application and any additional controls stipulated in an accompanying **Federal Register** notice announcing Agency approval of the TME, will not present an unreasonable risk of injury to health or the environment. Such specific conditions of approval include the test market time period, production volume, number of customers, and use. Upon review of the same chemical when submitted as a PMN, the Agency could determine that a higher production volume or distribution and use of the

chemical without the limitations imposed under the TME may present an unreasonable risk to human health or the environment, and therefore take regulatory action under section 5(e) of TSCA. The Agency also reserves the right to rescind approval or modify the conditions and restrictions of a TME during the TME period should any new information that comes to its attention cast significant doubt on its finding that the test marketing activities will not present an unreasonable risk of injury to human health or the environment.

VIII. How Will Accepting Simultaneous PMN/TME Submissions for P2 Screened Chemicals Benefit the Agency and the Public?

This voluntary pilot project to accept simultaneous PMN/TME submissions will enable the Agency to develop information to support a possible future exemption under section 5(h)(4) of TSCA based on experience gained in Sustainable Futures. This would include information on the adequacy and effectiveness of companies' use of Agency tools and models to improve the environmental health and safety attributes of the new chemicals notified to EPA under section 5 of TSCA. It is hoped that this modification in the Agency's policy under section 5 of TSCA ultimately results in fewer section 5 notices requiring extensive Agency review or negotiation of necessary risk controls with submitters, and in safer chemicals being introduced to market.

IX. What Are EPA's Suggested Approach and Criteria for Participation in the Voluntary Sustainable Futures Pilot Project?

The Agency solicits participation on the part of chemical companies, and other stakeholders, in this voluntary pilot project. In order to qualify for this pilot project, and associated expedited review, companies subject to section 5 of TSCA reporting requirements must demonstrate experience and competence with the P2 Framework or other scientifically acceptable approaches to chemical risk screening. Typically, EPA expects that the following will be necessary:

A. Training

Companies interested in participating in this pilot project must demonstrate an understanding of the scope, applicability, interpretation, and limitations of pollution prevention and chemical hazard and exposure screening tools, such as the P2 Framework, that can be used to conduct screening level assessments of chemicals based on an analysis of chemical structure or other considerations. EPA will offer P2 Framework risk screening software to participating companies and other interested stakeholders. The Agency will also offer detailed training workshops to those interested in learning more about the P2 Framework models. EPA conducts workshops and presentations that provide an overview of the P2 Framework models to industry and other stakeholders (see Unit IV.). P2 Framework workshops are 2–3 days in length, involve hands-on training in the use, interpretation, and limitations of P2 Framework methodologies. Attendees of the P2 Framework workshops are encouraged to bring to the workshop the CAS Registry Numbers or structures of the types of chemicals of specific interest to them so that the attendee may use these as examples when that attendee runs the models during the workshop. Attendees should not bring any CBI chemicals to the workshops. P2 Framework workshops are particularly well suited for participants with a strong background in chemistry and familiarity with issues associated with human health and environmental hazard, exposure, and risk assessment. Those interested in learning about dates and times for upcoming training, whether given by EPA or other qualified individuals, should contact the persons listed under **FOR FURTHER INFORMATION CONTACT** or check the New Chemicals Program web site www.epa.gov/oppt/newchems/.

B. Apply Hazard and Exposure Screening Tools

Companies must apply hazard and exposure screening tools to gain hazard-, exposure-, and risk-related information on chemical alternatives under consideration in the R&D and product development stages and demonstrate to EPA that this information has been used to inform decisionmaking to select safer new chemical alternatives to submit as the subject of a new chemical notification, and, where appropriate, to identify opportunities to eliminate or control exposures through process controls.

The Agency is interested in learning if, how, and when hazard and exposure screening tools are of value to participants in the pilot as they choose among chemical alternatives that may become the subject of a PMN notice. This type of information will be considered in the development, if deemed appropriate, of a new exemption under section 5(h)(4) of TSCA based on experience gained in Sustainable Futures. In order to help determine if a new exemption is appropriate, participants in this pilot project may be asked to provide either summary or detailed information to EPA, described below, that demonstrates that the submitter has used information gained using the hazard and exposure screening tools to inform their decisionmaking to select safer new chemical alternatives that became the subject of the submission. Pilot project participants should provide this information on or as an attachment to page 11 ("Optional Pollution Prevention Information") of the PMN form. Submitters should be aware that EPA may request additional information where warranted in support of the goal of this pilot project. The goal of this project is to encourage pollution prevention and the development of inherently low hazard chemicals. The Agency solicits comments on the type of information to submit to EPA that (a) captures an increase in proficiency in a company's use of these assessment tools or (b) discusses hazard or risk reduction in PMNs ultimately submitted to the Agency, in contrast to those chemicals not submitted because of concerns raised through the use of the tools.

Summary level information should include:

1. The number of chemical alternatives (if more than one) evaluated,
2. The screening models used,
3. Factors on which decisions were based, such as vapor pressure, PBT characteristics, aquatic toxicity, potential human exposure, etc., and
4. The submitter's perspective on the extent to which the P2 Framework, or similar methodologies, helped in the understanding of hazard-, exposure-, and risk-related issues of the PMN chemical. In addition, information is solicited regarding the extent to which the methodologies helped the submitter compare or contrast product or process alternatives based on hazard-, exposure-, and risk-related information.

Three different examples of summary level information are provided below:

- Due to a number of factors, only one chemical substance was identified as having necessary product performance characteristics. As a result, there were no product alternatives to evaluate. Our company used the P2 Framework models on the single chemical meeting product performance characteristics. This analysis indicated low hazard potential for both human health and ecological effects. In addition, the material showed low persistence and low bioconcentration potential. As a result, we concluded the material presents low hazard/low risk.
- Five alternatives were evaluated for environmental fate and persistence,

8

bioconcentration potential, aquatic toxicity, and health effects using XYZ methodologies (e.g., the P2 Framework). While the aquatic toxicity and human health hazard profiles of all five were equivalent (i.e., low), two compounds were seen as persistent and with bioconcentration potential much higher than the other three alternatives. The PMN substance was selected from among these three alternatives having lower persistence and bioconcentration potential. In addition, application of exposure models indicated that exposure controls on specific areas, e.g., environmental release, occupational etc., were warranted. These controls have been identified and their effectiveness has been sufficiently described in the PMN submission.

- The results of the P2 Framework model runs helped to differentiate among product alternatives based on hazard and exposure issues. It helped our company identify a product that is the most environmentally preferable based on its hazard (e.g., low aquatic toxicity and low concern for adverse effects to human health) and exposure (e.g., less persistent) properties. The P2 Framework software package helped us think about chemical design options and exposure issues, including manufacturing controls to choose among product alternatives. These controls have been identified and their effectiveness has been sufficiently described in the PMN submission.

More detailed information may also be provided, for example, the actual outputs from the methodologies used, or screening level hazard assessments for low hazard chemicals and, for low-moderate hazard chemicals, submission of a screening-level exposure and risk assessment. EPA's P2 Framework, as well as other hazard, exposure, and risk screening methods, can be used to assist in many, although not all, components of such an assessment. This screening level assessment could include:

1. Physical/chemical properties, potential environmental transport, and environmental fate;
2. Human health effects such as cancer hazard potential, organ toxicity, reproductive and/or developmental toxicity, neurotoxicity or other health endpoints of potential concern;
3. Toxicity to the aquatic environment, i.e., aquatic vertebrates, invertebrates and plants;
4. As appropriate, environmental releases, exposure to the general population, consumer exposure, occupational exposure, and environmental exposure;
5. Descriptions of exposure and release mitigation steps, such as personal protective equipment and engineering controls information; and
6. Summary conclusions regarding the hazards, exposure, and risks of product alternatives including a determination if alternatives under consideration exceed EPA new chemicals program criteria for PBT (Persistent, Bioaccumulative and Toxic) chemical substances (64 FR 60194, November 4, 1999), or ecotoxicity concern levels described in the P2 Framework Manual (see http://www.epa.gov/pbt/P2 _ Manual _6-00.pdf – "ECOSAR to Estimate Aquatic Toxicity").

Assessments need not include every factor listed in this unit, depending on the specific chemical submitted, intended uses, etc. For example, toxicity to aquatic organisms would not need to be evaluated if no environmental releases are anticipated under expected conditions of manufacture, processing, and use of the new chemical. Additional guidance regarding preparation of screening-level assessments, including examples of screening-level assessments, and other technical assistance, will be provided during P2 Framework training workshops, discussed above.

C. Submit 5-10 Successful PMNs or PMN Exemption Notices

Companies will need to submit 5-10 successful (i.e., not regulated by EPA) PMNs or PMN exemption notices which have been developed using chemical hazard and exposure screening tools, and which had, as part of the submission, documentation (summary or detailed) of chemicals evaluated, models used, endpoints on which decisions were based, and the submitter's perspectives on the extent to which the screening tools provided useful information to compare alternatives and select safer chemicals.

Pilot project participants' PMN submissions will be evaluated by EPA consistent with the normal PMN review process. Participants will typically be eligible for the expedited review described in Unit VI. of this notice after 5–10 new chemical cases (PMNs or PMN exemption notices) have been successfully screened by the company, as described above, submitted to EPA, and determined to be low hazard and/or low risk by EPA. The Agency will, at its discretion, consider requests for expedited review before completion of this 5–10 case experience base. Participants requesting relief before completion of the 5–10 case experience base will need to demonstrate that their approach to hazard, exposure, and risk screening is the functional equivalent of a 5–10 case experience base. The Agency may also make an exception with regards to the definition of "successful" for PMNs regulated only under TSCA section 5 exposure-based authority.

The Agency considered several factors when determining the number of successful new chemical cases needed to qualify for expedited review under this pilot project. Some stakeholders submit relatively few PMNs or exemption notices, e.g., some stakeholders submit one PMN every two to three years. Setting the number of successful new chemical cases at a level greater than 5–10 would mean that infrequent submittters of PMNs might take many years to reach the 5–10 PMN or exemption notice experience base. Some stakeholders submit many PMNs annually, e.g. 20 PMNs per year or more. In this case of a stakeholder submitting 20 PMNs or exemption notices per year, the experience base could be achieved in approximately six months. The Agency believes that 5–10 successful PMNs or exemption notices, or the functional equivalent, is a reasonable experience base to qualify for expedited review under this pilot project. The Agency will use its discretion when determining if and when a company has sufficient experience. For example, for a company whose PMN submissions have historically been limited in scope, e.g., PMNs submissions only for surfactants, 5 successful PMN submissions might be considered adequate for the Agency to judge that the submitter has effectively used the screening methodologies. On the other hand, a company with PMNs covering a wide spectrum of industrial chemistry might need to submit 10 successful PMNs to qualify. The Agency solicits comment on this issue.

If a pilot project participant's PMN or exemption submission is determined by EPA to be low hazard or low risk (meaning the submission is dropped from further review during the early stages of the PMN review process, i.e., first 30 days), and the participant submits descriptive information to demonstrate that chemical hazard and exposure screening models contributed to their decisions regarding the new chemical substance, this will likely be judged sufficient to demonstrate an ability (for that particular PMN or exemption submission) to effectively use the screening methodologies. All such decisions under the pilot are within the sole discretion of the Agency and no rights are extended by this pilot.

X. How Can Chemical Manufacturers Demonstrate Their Proficiency in Effective Use of Hazard and Exposure Screening Tools and Thereby Qualify for Expedited Review Under Section 5 of TSCA?

As mentioned in the previous section, in order to demonstrate proficiency in the use of the P2 Framework or other comparable hazard and exposure screening tools, companies would, following formal training, submit 5–10 PMNs, or functional equivalent, which were developed via application of these tools, and that EPA determines to be low hazard and/or low risk. This number of PMN cases are considered a sufficient sample to judge the adequacy and effectiveness of a company's use of the P2 Framework in the evaluation of PMNs prior to their submission to the Agency. Companies submitting PMNs under this pilot project (either as part of the initial qualifying process or in conjunction with TMEs upon successful completion of that process) may be asked to supplement their submissions, using page 11 ("Optional Pollution Prevention Information") of the PMN form, with additional information which demonstrates the application of the P2 Framework and provide a basis for EPA to judge the application of the P2 Framework. See Unit IX. for more details on training and "additional information."

A chemical manufacturer, formulator, or import who has submitted 5–10 successful (i.e., not regulated by EPA) PMNs that EPA determines to be low hazard and/or low risk, or the functional equivalent and who is interested in participating in the pilot project should approach the Agency to request the expedited review under section 5 of TSCA described in Unit VI. This should be done by submitting in writing to the Director of the Chemical Control Division (address below), documentation of the following:

- The date of training completed in accordance with Unit IX.A.,
- A list of the PMNs which were submitted and the outcome of Agency review, i.e., the chemicals were not regulated,
- A summary table presenting the hazard and exposure screening tools used to evaluate each PMN substance, including identification of methods and models/tools used in the assessment, and
- An overall qualitative or quantitative assessment of the value of the use of hazard and exposure screening tools to evaluate these PMN substances (see Unit IX.B.).

Submitters are encouraged to submit nonconfidential reports to the extent possible. If necessary, check http://www.epa.gov/oppt/newchems/cbi.html for information on properly transmitting CBI material to EPA. A non-CBI or sanitized version of the information described above should be submitted to: Charles M. Auer, Acting Director, Chemical Control Division (7405M), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001.

Upon review of this information, EPA will respond in writing to notify candidates of their eligibility for expedited review (i.e., being allowed to submit simultaneous TMEs and PMNs). Following EPA review of the PMNs submitted under the pilot during an approximately 2 year period starting from the date of this notice, the Agency can at its discretion extend the time period of this pilot project to gain additional experience, or conclude the pilot. EPA solicits comments on this overall approach.

XI. Will EPA Allow the Use of Other Hazard and Risk Screening Tools Besides the P2 Framework?

EPA understands that the P2 Framework is just one example of pollution prevention and chemical hazard, exposure, and risk screening tools that could be used to evaluate chemicals, in general and under this pilot project in particular. Although the Agency is aware that other assessment methodologies are widely available and that use of these other methods may be of value in identifying less risky or environmentally preferable alternatives, the Agency lacks experience with their use. The Agency will consider the applicability of other pollution prevention and chemical hazard, exposure, and risk screening tools, but PMN submissions for consideration under this pilot project should describe the alternate methodology used and the results obtained. To assist and improve EPA's understanding of other tools, the Agency may ask, where evaluations resulting from the P2 Framework and alternative methodologies differ in conclusions, that additional detail on the basis and underlying assumptions for these conclusions be provided.

XII. How Will the Agency Incorporate Other Information on Risk Reduction, Such as Control Technology, into this Pilot Project?

Although the Agency's primary goal in this pilot project is encouraging the use of chemical hazard identification and risk screening methods at R&D and the development of inherently low hazard chemicals, it is expected that for low-moderate hazard chemicals the information generated through use of the P2 Framework, and other methods, can also contribute to identification of exposure and risk reduction steps, through use of control technologies or other measures that can mitigate potential risks. Pilot project participants could apply the hazard and exposure screening tools and demonstrate the ability to use the information generated by the P2 Framework to identify opportunities to eliminate or control exposures through process controls, recycling, or reuse. Companies are encouraged under the pilot project to identify and apply control technology or other mitigation steps which results in low risk outcomes and to include discussion of this aspect in their PMN submissions.

XIII. What is the Relationship of Sustainable Futures to Project XL?

On September 14, 2000, the Agency signed Final Project Agreements (FPAs) with Eastman Kodak (Kodak, 2000; see Unit XV.5.) and PPG Industries (PPG 2000; see Unit XV.6.) under the Agency's XL Program, based on application of hazard and exposure screening tools in new product development. Project XL, which stands for "eXcellence and Leadership," is a national program that allows state and local governments, businesses and federal facilities to develop with EPA innovative strategies to test better or more cost-effective ways of achieving environmental and public health protection. Under the FPAs, the Agency allows Kodak and PPG to simultaneously submit a TME and a PMN on a new chemical substance, thus enabling each company to begin manufacture of that new chemical substance in accordance with the TME after 45 days, provided the TME is granted and the PMN is dropped from further review during the first 30 days of the review period. Under both FPAs the companies propose to take other actions that go beyond compliance. See the Kodak or PPG FPAs at the Project XL web site for additional details: http://www.epa.gov/projectxl/. The Agency has worked very closely with both Kodak and PPG regarding use and interpretation of the P2 Framework in new product development. Both Kodak and PPG have participated in P2 Framework workshops, seminars and other training and outreach efforts. Both Kodak and PPG have used the P2 Framework to evaluate product alternatives and to inform their judgement regarding commercialization of environmentally preferable products.

Both PPG and Kodak have submitted well over 10 PMNs or PMN exemption notices that were developed using the P2 Framework. The Agency has dropped these PMNs because they either present a low inherent human health and environmental hazard, or in those cases where potential risks were identified, the companies were able to develop mitigation strategies which adequately reduced those potential risks. Because of these companies' demonstrated experience in the use of the P2 Framework in new product development, and their contribution to advancing excellence in environmental protection, as evidenced by their project XL proposals, Kodak and PPG will not need to submit the minimum ten PMNs (see Unit IX.) for review under the pilot project. Kodak and PPG have been eligible for the requested expedited review with the first complying new chemical submission received after signature of their respective FPAs.

XIV. What's Next After Completion of this Pilot Program?

As mentioned in Unit II., EPA will use the data and experience gained though this Sustainable Futures pilot project, and through related Project XL initiatives, to improve Agency understanding of how early hazard, exposure, and risk screening can lead to development of environmentally preferable products and processes, among other pollution prevention outcomes. Based on this experience, EPA may develop an exemption under section 5(h)(4) of TSCA to provide expedited review for low hazard/low risk PMNs that have been the subject of early hazard, exposure, and risk screening. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule to exempt the manufacturer or importer of new chemical substance from some or all of the provisions of section 5 of TSCA, if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk of injury to health or the environment. As described in Unit II., EPA has implemented other exemptions under section 5(h)(4) of TSCA and these may provide a model for any such future exemption.

XV. References

1. USEPA. 1986. New Chemical Information Bulletin: Exemptions for Research and Development and Test Marketing. Office of Toxic Substances, U.S. Environmental Protection Agency. (November, 1986) and at http://www.epa.gov/oppt/newchems/tmeranddbulletin.pdf.

2. USEPA. 2000. Pollution Prevention (P2) Framework. Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency (EPA-748-B-00-001; June, 2000) and at http://www.epa.gov/opptintr/p2framework/

3. Tellus Institute. 1999. Design for Competitive Advantage: The Business Benefits of the EPA Pollution Prevention Assessment Framework in New Product Development, by Thomas J. Votta and Allen L. White, Ph.D. Boston, MA; http://www.tellus.org (September 28, 1999).

4. Eastman Kodak Company. 1996. EPA-Developed Methodologies for Assessing the Fate and Hazards of Industrial Chemicals: A Summary of Eastman Kodak Company's Experience with Their Use and Applicability in Risk Assessment. Kodak Technology Transfer Team, Health and Environment Laboratories, Rochester, NY. (May 13, 1996).

5. Eastman Kodak Company. 2000. Kodak Pollution Prevention Framework Final Project Agreement (Draft, July, 2000) http://www.epa.gov/ProjectXL/kodak/fpakd7-21.pdf (http://www.epa.gov/ProjectXL/groupfrn.pdf for **Federal Register** notice of September 14, 2000 signing).

6. PPG Industries, Inc. 2000. PPG Industries, Inc. Pollution Prevention Framework Final Project Agreement, Project XL, September 14, 2000 http://www.epa.gov/ProjectXL/ppg/913fpa.pdf (http://www.epa.gov/ProjectXL/groupfrn.pdf for **Federal Register** notice of September 14, 2000 signing).

XVI. Statutory and Executive Order Reviews

This notice announces a voluntary pilot project to encourage the application of Pollution Prevention principles during the development of new chemicals under TSCA. Since this voluntary project does not include a regulation or otherwise require notice and comment and does not impose any new binding requirements, it is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), or Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). For the same reason, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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 as defined by the PRA, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

This document does not contain any new information collection requirements that would require additional OMB review and approval under the PRA. The information collection activities related to the submission of information pursuant to TSCA section 5 are already approved by OMB under OMB control number 2070-0012 (EPA ICR No. 574). The hours for respondent reporting burden for a full PMN submission is estimated to range between 95 and 114 hours, with an average respondent burden of 105 hours. This burden applies also to the submission of SNUN, LVE, and LoREX submissions since each of these notices requires the submission of a complete PMN form. The respondent burden for submission of a test market exemption is estimated to average 98 hours.

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.

This action will not have substantial direct effects on State or tribal governments, on the relationship between the Federal government and States or Indian tribes, or on the distribution of power and responsibilities between the Federal government and States or Indian tribes. As a result, no action is required under Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999), or under Executive Order 13175,

11

entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Nor does it impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

Nor does it require special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to 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).

List of Subjects

Environmental protection, Chemical substances, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 27, 2002.

Stephen L. Johnson,

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

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12