March 2008

Overview:
Office of Pollution Prevention and Toxics
Laws and Programs

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PREFACE

This document is intended to provide background and reference information on the U.S. EPA's Office of Pollution Prevention and Toxics' (OPPT) programs. The main body of the paper (sections 1 through 7) provides a brief overview of the OPPT's key programs, including:

- **Toxic Substances Control Act Implementation Activities**
- **National Program Chemicals Activities**
- **The Pollution Prevention Act and Voluntary Pollution Prevention Programs**
- **The High Production Volume (HPV) Challenge Program**
- **Nanotechnology Stewardship Activities**
- **Global Chemical Issues**
- **OPPT's Tools and Models**
- **Outreach and Coordination**

The remainder of the document (Appendices A through E), provides detailed information and references. Appendix A contains OPPT organizational information, and Appendix B contains supplementary information on selected OPPT regulations and programs. Appendix C provides a table of *United States Code* (U.S.C.), *Code of Federal Regulations* (CFR), and *Federal Register* (FR) citations relevant to OPPT programs discussed in this paper. A table of links to EPA source information, as well as links to additional information on a given topic, are included in Appendix D. Appendix E is original legislation relevant to OPPT.

LIST OF ABBREVIATIONS

ABPO	Asbestos Ban and Phase-Out Rule
AHA	American Hospital Association
AHERA	Asbestos Hazard Emergency Response Act
ASHAA	Asbestos School Hazard Abatement Act
ASHARA	Asbestos School Hazard Abatement Reauthorization Act
ATSDR	Agency for Toxic Substances and Disease Registry
BTS	Great Lakes Binational Toxics Strategy
CAA	Clean Air Act
CAS	Chemical Abstracts Service
CDC	Centers for Disease Control and Prevention
CEC	Commission for Environmental Cooperation
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
ChemRTK	Chemical Right-to-Know
CWA	Clean Water Act
DEI	Dioxin Exposure Initiative
DfE	Design for the Environment
DOC	Department of Commerce
DOD	Department of Defense
ECA	Enforceable Consent Agreement
ECE	Economic Commission for Europe (U.N.)
ECOS	Environmental Council of the States
ECOSAR	Ecological Structure Activity Relationships
E-FAST	Exposure-Fate Assessment Screening Tool
EPA	U.S. Environmental Protection Agency
EPP	Environmentally Preferable Purchasing
EU	European Union
FAO	Food and Agriculture Organization (U.N.)
FEE	Federal Environmental Executive
FOSTTA	Forum on State and Tribal Toxics Action
FWS	Fish and Wildlife Service
GHS	Globally Harmonized System
GPRA	Government Performance and Results Act
GSA	General Services Administration
GSN	Green Suppliers Network
H2E	Hospitals for a Healthy Environment
HPV	High Production Volume
HUD	U.S. Department of Housing and Urban Development
IFCS	Intergovernmental Forum on Chemical Safety
ITC	TSCA Interagency Testing Committee
IUR	Inventory Update Rule
LRTAP	Long-Range Transboundary Air Pollution
MAD	Mutual Acceptance of Data
MAN	Mutual Acceptance of Notifications
MCCEM	Multi-Chamber Concentration and Exposure Model
MSHA	Mine Safety and Health Administration

MTL	Master Testing List
NARAP	North American Regional Action Plan
NCSL	National Conference of State Legislatures
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NOC	Notice of Commencement
NPCD	National Program Chemicals Division
NTEC	National Tribal Environmental Council
NTP	National Toxicology Program
ODS	Ozone-Depleting Substance
OECD	Organization for Economic Cooperation and Development
OPPT	Office of Pollution Prevention and Toxics
OPPTS	Office of Prevention, Pesticides and Toxic Substances
OSHA	Occupational Health and Safety Administration
P2	Pollution Prevention
P2Rx	Pollution Prevention Resource Exchange
PAIR	Preliminary Assessment Information Reporting Rule
PBT	Persistent Bioaccumulative Toxics
PCB	Polychlorinated Biphenyls
PIC	Prior Informed Consent
PMN	Premanufacture Notice
POP	Persistent Organic Pollutants
PPA	Pollution Prevention Act
RCRA	Resource Conservation and Recovery Act
SAICM	Strategic Approach to International Chemicals Management
SAR	Structure-Activity Relationship
SIDS	Screening Information Data Set
SNUN	Significant New Use Notification
SNUR	Significant New Use Rule
TERA	TSCA Experimental Release Application
TOC	Tribal Operations Committee
TSCA	Toxic Substances Control Act
UNEP	United Nations Environmental Program
USGS	U.S. Geological Survey
USTR	U.S. Trade Representative
UVCB	Chemical Substance of Unknown or Variable Composition, Complex Reaction Products and Biological Materials
VAI	Vermiculite Attic Insulation
VCCEP	Voluntary Children's Chemical Evaluation Program
WPEM	Wall Paints Exposure Assessment Model

Overview of Office of Pollution Prevention and Toxics Laws and Programs

INTRODUCTION - OVERVIEW OF U.S. ENVIRONMENTAL PROTECTION AGENCY AND OFFICE OF POLLUTION PREVENTION AND TOXICS

Created in 1970, the United States Environmental Protection Agency (EPA) is an independent regulatory agency whose "mission is to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends." EPA Headquarters is organized by program Offices, generally by subject area, each with responsibility for specific environmental regulations and related initiatives. EPA has 10 regional offices that implement its programs throughout the nation, providing compliance assistance to regulated facilities, regional perspective on regulatory development, and serving as liaisons with State and local governments, as well as with EPA Headquarters. These regional offices are typically organized with subject area offices similar to headquarters. EPA also has 17 research laboratories across the U.S.[1] (http://www.epa.gov/epahome/locate3.htm) EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS), headed by an Assistant Administrator, is organized into three (sub) Offices: Office of Pollution Prevention and Toxics (OPPT)[2] (www.epa.gov/oppt), Office of Pesticide Programs, and Office of Science Coordination and Policy.

OPPT has a diverse portfolio of responsibilities relating to toxic chemicals and pollution prevention. The Office has strong scientific and technical capabilities with expertise in areas such as hazard, exposure, risk assessment, chemical testing, Structure-Activity Relationship (SAR) analysis, economic and cost benefit analysis, chemical technology and substitutes. Among the programs and initiatives that OPPT manages that relate to toxics and pollution prevention are: the High Production Volume (HPV) Challenge Program, the Voluntary Children's Chemical Evaluation Program (VCCEP), and the Nanotechnology Stewardship Program; the New and Existing Chemicals programs; the lead, asbestos, mercury, and polychlorinated biphenyls (PCBs) risk management programs; and the Design for the Environment (DfE), Green Chemistry, and Environmentally Preferable Purchasing (EPP) programs, which are pollution prevention oriented.

Four major goals comprise OPPT's mission and guide all OPPT programs:

- Promoting pollution prevention as the guiding principle for reducing industrial pollution;
- Encouraging the introduction and use of safer chemicals and environmentally beneficial choices through a combination of regulatory and voluntary efforts;
- Reducing risks from existing substances such as lead, asbestos, dioxin, PFOA (perfluorooctanoic acid and its salts), mercury, and PCBs; and
- Enhancing public understanding of chemical risks by developing and providing understandable, accessible, and complete information on chemical risks to the broadest audience possible.

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[1] Appendix A, Figure A-1 shows the overall organizational structure of the U.S. EPA and its various offices.

[2] Appendix A, Figure A-2 shows the organizational structure of OPPT and its various divisions and branches.

OPPT's primary responsibility is to administer the Toxic Substances Control Act (TSCA) (http://www.access.gpo.gov/uscode/title15/chapter53_.html) of 1976, and amendments, and the Pollution Prevention Act (PPA) (http://www.access.gpo.gov/uscode/title42/chapter133_.html) of 1990. To accomplish its work OPPT has a strategic framework of statutory and regulatory tools as well as voluntary and partnership approaches.

Under TSCA, OPPT is responsible for assuring that chemicals manufactured, imported, processed, or distributed in commerce, or used or disposed of in the United States do not pose any unreasonable risks to human health or the environment. TSCA covers all chemicals planned for production, manufactured in, imported to, or exported from the United States.[3]

When TSCA was passed in 1976, it was not known how many chemicals were in commerce in the U.S., in what quantities or where they were produced and/or imported. TSCA provides EPA authority to compile an inventory of existing chemical substances manufactured for commercial purposes. Currently, the TSCA Chemical Substance Inventory lists approximately 82,000 chemical substances as being available for sale and use in the United States at some point in time since the Inventory was first published in 1979.

The Inventory contains all existing chemicals produced, processed or imported for commercial purposes in the U.S. — the listing is not based on toxic or hazardous characteristics. The Inventory of existing chemicals grows as new chemicals enter into commerce and are added to the list on an ongoing basis.

Beginning in 1986, OPPT has been updating the Inventory at intervals of every four years to obtain basic information about those chemicals that are actively being manufactured, produced, processed or imported during a specified reporting period. The updates are gathered through the Inventory Update Rule (IUR) (http://www.epa.gov/oppt/iur/) and include data on the production volume and site location for chemicals substances manufactured or imported at levels over 10,000 pounds or more per year per site. The inventory updates provide a more contemporary picture of a smaller subset of the total 82,000 inventory chemicals that are active in commerce and are used by OPPT for priority-setting.

TSCA has differing mandates for "existing" chemicals (those already in commerce and on the Inventory) and for "new" chemicals (reviewed by EPA before they are produced or imported and added to the Inventory). OPPT has implemented TSCA by developing programs addressing existing chemicals with reporting, and testing requirements, and new chemicals through programs to assess, test, and manage identified potential risks from chemicals new to commerce, including biotechnology products resulting from industrial processes.

OPPT also manages focused risk reduction efforts for several toxic chemicals of national concern including PCBs, lead, mercury, and asbestos. TSCA information collection/dissemination actions serve to facilitate implementation of media-specific statutes, like the Clean Air Act, and the Safe Drinking Water Act.

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[3] Substances not covered under TSCA are pesticides; tobacco (or tobacco products); firearms and ammunition; source material by-products or special nuclear material defined by the Atomic Energy Act; and food, food additives, drugs, or cosmetics covered under the Federal Food, Drug and Cosmetic Act.

OPPT's implementation of its toxics programs includes both multimedia and pollution prevention perspectives. The Pollution Prevention Act of 1990 established the national policy that pollution should be prevented or reduced at the source whenever feasible. Over the last decade, focus has shifted from controlling individual chemicals to controlling larger numbers of related chemicals through testing, assessment and risk management efforts. For example, chemicals produced in high volume, chemicals that have certain behavior characteristics (e.g., Persistent Bioaccumulative and Toxic (PBT) chemicals and Persistent Organic Pollutants (POPs), initiated at the domestic and international levels, respectively), and life-cycle approaches that strive for environmental, economic, and social sustainability over time (e.g., Green Chemistry and Green Engineering programs, the Sustainable Futures Initiative, and Environmentally Preferable Purchasing by federal agencies).

The Government Performance and Results Act (GPRA) of 1993 (http://www.whitehouse.gov/omb/mgmt-gpra/gplaw2m.html), provides further focus to OPPT's office goals. GPRA requires Federal agencies to develop plans for what they intend to accomplish, measure how well they are doing, make appropriate decisions based on the information they have gathered, and communicate information about their performance to Congress and to the public. The intent of GPRA is to improve public confidence in Federal agency performance by holding agencies accountable for achieving program results. GPRA goals relevant to OPPT programs are discussed in further detail in Appendix B, B-8.1.

Concurrently, EPA/OPPT has recognized that a broader program of integrated voluntary and regulatory actions, with greater emphasis on stakeholder involvement, such as the HPV Challenge Program, VCCEP, the Green Suppliers Network, the Electronic Products Environmental Assessment tool, the developing nanotechnology stewardship program and the Design for the Environment Program, will be necessary to elevate environmental stewardship to the next level that the nation requires.

OPPT is also strongly committed to promoting public understanding of chemical risks by developing and providing scientifically sound, accessible, and comprehensive information to the broadest audience possible.

THE TOXIC SUBSTANCES CONTROL ACT

TSCA Overview and History

In 1970, the President's Council on Environmental Quality developed a legislative proposal to address the increasing problems of toxic substances. After six years of public hearings and debate, Congress enacted the Toxic Substances Control Act (TSCA) in the fall of 1976. EPA/OPPT is charged with implementing TSCA, which is a federally mandated statute. TSCA (Title I) does not provide opportunities for EPA to authorize state programs to operate in lieu of the federal program, although the office actively collaborates with regions, states and tribal governments.

Through the provisions of TSCA, EPA can collect or require the development of information about the toxicity of particular chemicals and the extent to which people and the environment are exposed to them. Such information allows EPA to assess whether the chemicals pose unreasonable risks to humans and the environment and TSCA provides tools for instituting appropriate control actions. TSCA provides the basis for EPA's programs on New and Existing Chemicals, the basis for the National Programs for major chemicals of concern such as lead

(TSCA Title IV) and asbestos (TSCA Title II), and the foundation for other OPPT programs such as the voluntary data development activities under the High Production Volume (HPV) Challenge Program, PFOA stewardship, and VCCEP.

TSCA §2(b)(1) establishes the underlying national policy 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."

EPA has authority under TSCA §6 to regulate the manufacture (including import), processing, use, distribution in commerce, and disposal of chemical substances and mixtures that present or will present an unreasonable risk to human health and the environment. EPA may ban the manufacture or distribution in commerce, limit use, require labeling, or place other restrictions on chemicals that pose unreasonable risks after making certain statutory findings. In order to regulate under §6, EPA must find that there is a reasonable basis to conclude that a chemical substance "presents or will present an unreasonable risk of injury to health or the environment," where "unreasonable risk" is a risk-benefit standard. EPA must consider risks, costs and benefits of a substance to be regulated, including the availability of substitutes. TSCA requires the Administrator to impose the "least burdensome" regulatory measure that provides adequate protections.

TSCA §4 (http://www.epa.gov/oppt/chemtest/pubs/pdflist4.htm) gives EPA broad authority to require manufacturers (includes importers) and processors to test chemicals for health and environmental effects. EPA uses the §4 rulemaking authority only when it can make certain statutory findings about the substance involved, including that there are insufficient data available to determine the effects of the substance on health and/or the environment; and testing is necessary to provide such data; and the chemical may present an unreasonable risk of injury to health or the environment, and/or may be produced at substantial quantities and is reasonably expected to enter the environment in substantial quantities, or may result in significant or substantial human exposure. TSCA §4 has generated data on approximately 200 chemicals since the 1970s.

TSCA §8 (http://www.epa.gov/oppt/chemtest/pubs/pdflist8.htm) has a variety of data-gathering authorities. Under TSCA §8(e) EPA must be notified immediately of new unpublished information on chemicals that reasonably supports a conclusion of substantial risk. TSCA §8(e) has been an important information-gathering tool that serves as an "early warning" mechanism.

TSCA §5 (http://www.epa.gov/oppt/chemtest/pubs/pdflist5.htm) requires manufacturers to give EPA a 90-day advance notice (via a premanufacture notice or PMN) of their intent to manufacture and/or import a new chemical (including microorganism). The PMN includes information such as specific chemical identity, use, anticipated production volume, exposure and release information, and existing available test data. The information is reviewed through OPPT's new chemicals program to determine whether action is needed to prohibit or limit manufacturing, processing, or use of a chemical. Many PMNs include little or no toxicity or fate data; consequently, OPPT uses several general approaches to address data gaps to rapidly

evaluate potential risks and make risk management decisions for new chemicals within the 90-day timeframe prescribed by TSCA. Under TSCA §5(a), EPA is authorized to designate a new use of a new or existing chemical as a Significant New Use Rule (SNUR), based on consideration of several factors, including the anticipated extent and type of exposure to humans and the environment.

TSCA §9 addresses EPA's authority to regulate chemical substances and associated activities that fall under both TSCA and other Federal laws, including laws administered by other Federal agencies and the EPA. It includes procedures under which EPA can refer the regulation of chemicals to other agencies and requirements to coordinate actions taken under activities with other Federal agencies "for the purpose of achieving the maximum enforcement of this act [TSCA] while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."

Industry or other submitting companies may also claim certain information as Confidential Business Information (CBI) under TSCA §14(a). The provision prohibits EPA from disclosing trade secrets, or commercial or financial information that is privileged or confidential, to the public (including States, Tribes, local governments), except in certain limited circumstances.

Under TSCA §21, any citizen may petition EPA to take action under TSCA §4 (rules requiring chemical testing), §6 (rules imposing substantive controls on chemicals), or §8 (information gathering rules). TSCA §21 also authorizes a petitioner to request the issuance, amendment, or repeal of orders, including certain orders under §§5 and 6.

OPPT has also the responsibility for implementing other Titles of TSCA, for example, The Residential Lead-Based Paint Hazard Reduction Act of 1992, also known as Title X of the Housing and Community Development Act (TSCA Title IV) and The Asbestos Hazard Emergency Response Act (AHERA) (TSCA Title II).

Further discussion of the above described provisions follows and additional information is included in Appendix B.

TSCA Chemical Substance Inventory

The initial TSCA Chemical Substance Inventory ("Inventory") of existing chemical substances (approximately 61,000 chemicals) was based on information reported to EPA by chemical manufacturers (including importers) and processors from 1975 - 1978. The Inventory lists all existing chemicals in commerce by chemical name and Chemical Abstracts Service (CAS) Registry numbers or accession numbers (accession numbers are used for chemicals whose identities have been claimed confidential business information (CBI)). The Inventory provides an overall picture of the organic, inorganic, polymers, and UVCB (chemical substances of Unknown, or Variable Composition, Complex Reaction Products, and Biological Materials) chemicals produced, processed or imported for commercial purposes in the United States; it is not a list of chemicals based on toxic or hazardous characteristics.

In 1986, EPA promulgated the Inventory Update Rule (IUR) (http://www.epa.gov/oppt/iur/), for the partial updating of the production volume data reported to the Inventory. The rule required

manufacturers of nonpolymeric organic chemical substances[4] included on the Inventory to report current data on the production volume, plant site, and site-limited status of these substances if produced or imported at levels of 10,000 pounds or more per year per site.

After the initial reporting during 1986, recurring reporting was required every 4 years (1990, 1994, 1998, 2002). EPA amended the TSCA IUR in a Federal Register (http://www.epa.gov/fedrgstr/EPA-TOX/2003/January/Day-07/t32909.htm) notice published on January 7, 2003. The IUR Amendments (IURA) update the TSCA Inventory by modifying the reporting threshold from the original 10,000 pounds per year per site to 25,000 pounds per year. In addition, the IURA will require reporting of processing and use information for substances above the reporting threshold of 300,000 pounds per year.

In the 2003 IURA, EPA also added requirements for the reporting of inorganic chemicals and additional exposure-related information to assist EPA and others in screening potential exposures and risks, modified the IUR reporting and record keeping requirements, removed one reporting exemption and created others, and modified its procedures for making Confidential Business Information claims.

There are currently approximately 82,000 chemical substances on the TSCA Inventory that are or have been produced in, processed or imported into the United States. These fall broadly into three types of substances:

1. discrete chemicals having definite structures (Class 1)
2. chemical substances having indefinite structures or substances that are of unknown or variable composition, complex reaction products, and biological materials (Class 2)
3. polymers.

Table 1.2-1 provide some basic information on the distribution of substance type in the inventory. Other characteristics of the Inventory are presented in Table 1.2-2. In 2002, about 11% of the chemicals on the Inventory were reported under the IUR. A significant (>20%) number of the chemicals on the Inventory have been added since 1979 (i.e., not identified in the original Inventory) and have gone through the OPPT new chemicals review process. Table 1.2-3 shows the number of new chemicals added to the original Inventory.

Table 1.2-1. Approximate Number of Substances by Type in TSCA Inventory (September, 2006)

Non-polymeric organics	50,200
Polymers	29,500
Inorganics	3200
TOTAL	82,700

[4] Inorganic chemicals are defined as any chemical substance that which does not contain carbon or contains carbon in specific forms (40 CFR 710.26(a)). Polymers are defined as any chemical substance described with the word "poly," "alkyd," or "oxylated." (40 CFR 710.26(b)).

Table 1.2-2. Approximate Number of Chemicals in TSCA Inventory (2006)

Number of non-polymeric organics	50,200
Original Inventory	~62,000
Number of new chemicals added to original Inventory via commenced PMNs[1]	~20,700
Total number of chemicals on the Inventory including	~82,700

[1] Total of 82,700 = 62,000 original chemicals + 20,700 chemicals added to the Inventory via commenced PMNs. Based on an average over the first five IUR reporting cycles (1986, 1990, 1994, 1998, 2002).

Table 1.2-3. Approximate Number of New Substances Added to Inventory (As of 2006)

Class 1 Substances	4,600
Class 2 Substances	3,600
Polymers	11,500
TOTALS	~20,700

Additional information on the TSCA Inventory is provided in Appendix B, section B-1.1.

NEW CHEMICALS PROGRAM

Chemicals not on the TSCA Inventory are considered "new" chemicals and are reviewed by EPA before they are produced or imported in the United States. Certain genetically modified microorganisms are also considered "new chemicals." The TSCA New Chemicals Program (http://www.epa.gov/oppt/newchems/) was established to help manage the potential risk from chemicals new to the marketplace.

The New Chemicals Program functions as a "gatekeeper" that can identify concerns and impose conditions, up to and including a ban on manufacture, on the commercialization of a new chemical before entry into commerce, or on a "significant new use" of an existing or new chemical. The New Chemicals Program also serves as an advocate for environmental stewardship in encouraging the development and introduction of safer or "green" new chemicals.

Premanufacture Notification and Significant New Uses

To implement TSCA requirements for new chemicals, OPPT developed the Premanufacture Notification (PMN) Review Process. Manufacturers and importers of new chemicals must give EPA a 90-day advance (premanufacture) notification of their intent to manufacture and/or import a new chemical. The PMN, which includes information such as specific chemical identity, use, anticipated production volume, exposure and release information, and existing available test data, is reviewed by OPPT to determine whether action is needed to prohibit or limit manufacturing, processing, or use of a chemical.

The PMN review process is designed to accommodate the large number of PMNs received (approximately 1,500 annually), while adequately assessing the risks posed by each substance within the 90-day timeframe prescribed by TSCA. The information included in PMNs is limited: 67% of PMNs include no test data and 85% include no health data. Consequently, OPPT uses several general approaches to address data gaps to rapidly evaluate potential risks and make risk management decisions for new chemicals.

For example, OPPT has developed and relies on Structure-Activity Relationship (SAR) (http://www.epa.gov/oppt/newchems/tools/21ecosar.htm) analyses to estimate or predict physical-chemical properties, environmental fate, and human and environmental effects. A SAR is the relationship between the chemical structure of a molecule and its properties, including any possible interaction with the environment or organisms. EPA's New Chemicals Program has established 55 chemical categories to facilitate the PMN review process.[5]

During the early 1990's, EPA undertook a study with the European Union (EU) that compared SAR estimates (the way the U.S. assesses new chemicals) with the results of base-set testing (the way the EU assesses new chemicals). See Appendix B, section B-1.2.2, for a summary of this joint project. For more information about International efforts, see the International Chemical Initiatives section of this report.

Every PMN that is submitted to OPPT goes through a streamlined initial review process. The first of four review phases is a chemistry review. (http://www.epa.gov/oppt/newchems/pubs/process.htm)

On about day 8 -12 after receipt of the PMN, OPPT chemists gather at a chemical review/search strategy meeting (CRSS), at which for each PMN they establish a chemical profile, including: chemical identity, structure and nomenclature, structural analogues and inventory status, notice completeness, synthesis, use/TSCA jurisdiction, and physical-chemical properties. The submitter of the PMN may be contacted at this point in the review if questions about the PMN arise.

On approximately days 9-13, the Structure Activity Team meeting occurs. At this meeting, additional OPPT experts evaluate the PMNs, utilizing SAR data, PMN data, and the information in the chemistry reports compiled at the CRSS meeting. All the PMNs are given hazard potential ratings for health effects, environmental effects and environmental fate.

An exposure release profile is developed on days 10-19. Again, OPPT experts look at each PMN, and by using the information in the PMN on process, exposure, and production volume, develop a profile of exposures and releases from manufacture, processing and use, including: occupational exposure/releases, environmental releases, consumer exposure, ambient or general population exposure.

[5] During the early 1990's, EPA undertook a study with the European Union (EU) that compared SAR estimates (the way the U.S. assesses new chemicals) with the results of base-set testing (the way the EU assesses new chemicals). See Appendix B, section B-1.2.2, for a summary of this joint project.

Twice a week, every week, a "Focus Meeting" is held and a PMN is reviewed at this meeting on days 15-20 of its review. At this multidisciplinary risk management meeting, decisions are made ranging from "dropping" a chemical from further review to banning a chemical, pending further information. Decisions are based on information compiled by the CRSS, SAT, and exposure reviews, as well as consideration of related cases and other relevant factors. If more information is needed to make a decision on a PMN, the submitter may be contacted for questions/clarifications, and/or the PMN may be placed into Standard Review.

A standard review goes through days 21-85 of the review period and is a detailed risk assessment of the PMN chemical (see Appendix B, section B-1.2.1).

Possible Outcomes of the PMN Review Process

Following the 90-day review period, if EPA takes no action, the submitter may begin manufacturing or importing the chemical. A "Notice of Commencement" (NOC) must be submitted to EPA within 30 days of first manufacture (including importation). Following receipt of the NOC, the chemical substance is added to the Inventory. Once a substance is listed on the TSCA Inventory, it is considered an existing chemical.

Voluntary withdrawal of the notice, often (but not always) in the face of possible EPA action.

Issuance of TSCA §5(e) Orders. EPA may negotiate a TSCA §5(e) (Consent) Order to prohibit or limit activities associated with the new chemical if EPA determines that insufficient information exists to evaluate the human health and environmental effects of the substance, and that: (1) it may present an unreasonable risk ("risk-based finding") or (2) be produced in substantial quantities, and substantial or significant exposure/release ("exposure-based finding").[6] TSCA §5(e) orders typically include: exposure or release mitigation, testing, labeling and hazard communication, and record keeping. Evaluating substitutes for ozone depleting substances (ODSs) is one example where the 5(e) process was applied.

TSCA §5(a)(2) Significant New Use Rules (SNURs). §5(e) Consent Orders are only binding on the original PMN submitter that manufactured or imported the substance. Consequently, after signing a §5(e) Consent Order, EPA may promulgate a Significant New Use Rule (SNUR) under TSCA §5(a)(2) that mimics the Consent Order to bind all other manufacturers and processors of former new chemicals to the terms and conditions contained in the Consent Order. Also, EPA has the authority to issue SNURs without a §5(e) Consent Order.

Under TSCA §5(a)(2), EPA can determine that a use of a chemical is a significant new use after considering several factors, including but not limited to the projected production and processing

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[6] OPPT's new chemicals program criteria for its exposure-based testing were announced to the chemical industry in 1988 (see www.epa.gov/oppt/newchems/expbased.htm):
Main Document Only. substantial production: 100,000 kg/yr
Main Document Only. substantial or significant human exposure: various combinations of numbers of workers and levels of exposure in mg/day by exposure route; or presence in consumer product where exposures are likely; or exposure to the ambient general population at levels greater than or equal to 0.003 mg/kg/day via drinking water, air, or groundwater; or greater than or equal to 10,000 kg/year release to environmental media
Main Document Only. substantial release to the environment: greater than or equal to 1,000 kg/year total release to surface water calculated after wastewater treatment.

volume of the chemical substance, and the anticipated extent to which the use increases the type, form, magnitude and duration of exposure to humans or the environment associated with the new use. The SNUR requires that manufacturers, importers, and processors of such substances notify EPA at least 90 days before beginning any activity that EPA has designated as a "significant new use" (40 CFR 721). The notification required by SNURs allows EPA to prevent or limit potentially adverse exposure to, or effects from, the new use of the substance. Such a SNUR would require the submission of a Significant New Use Notification (SNUN) 90 days prior to commercial manufacture not conforming to the conditions of the SNUR.

TSCA §5(f) actions. If EPA determines that the manufacturing, processing, distribution in commerce or disposal of a substance that is the subject of a PMN or SNUR notification requirements presents or will present an unreasonable risk before a TSCA §6 rule can be promulgated (see section 1.6), under TSCA §5(f), EPA may (1) limit the amount or impose other restrictions on the substance via an immediately effective proposed rule, or (2) prohibit the manufacturing, processing or distribution in commerce of the substance by issuing a proposed order or applying to a U.S. District Court for an injunction.

Voluntary Testing Actions (TSCA §5(e) Regulation Pending Development of Information): In a limited number of cases, PMN submitters voluntarily agree to suspend the notice review period and conduct hazard or environmental fate testing in response to a request from EPA. During the PMN review process, OPPT might find risks that cannot be mitigated by controls. The "voluntary" testing is performed during the 90-day review period with a suspension(s) until the testing is completed. The submitter must decide if it is economically feasible to do the testing before going into the marketplace. Submitters may also take the option of withdrawing instead of performing the testing.

EPA has received approximately 36,600 PMNs from 1979 to the present (see Table 1.3-1). Tables 1.3-2 provides some statistics on regulatory and voluntary testing actions that have occurred from 1979 to September 30, 2002. Notices of Commencement (NOCs) have been received for only about 50% of the total valid PMNs submitted since 1979 (see Table 1.3-1). Approximately 10% of PMNs and SNUNs submitted for EPA review are either restricted or regulated (see Table 1.3-2).

The PMN submissions contain information on future commercial activities of new substances, therefore it is common to find CBI claims in them. For example, in 1990 approximately 90% of the PMNs submitted claimed the chemical identification as CBI. However, for those substances that complete the PMN process and enter in commerce (i.e., those for which NOCs have been received), the chemical identification CBI claim rate drops to approximately 65% (based on NOC statistics from 1995-1999).

Table 1.3-1. Approximate Number of PMNs Submitted and New Substances Added to Inventory (October, 2003)

	PMNs Submitted	New Substances Added to Inventory	Percent PMNs Added to Inventory
Class 1 Substances	7,400	4,200	57%
Class 2 Substances	7,200	3,300	46%
Polymers	22,000	10,600	48%
TOTALS	36,600	18,100	50%

Table 1.3-2. Regulatory (And Voluntary Testing) Actions on PMNs through September 30, 2006

Regulatory Action	Number
§5(e) Consent Orders	1320
§5(e) Consent Orders with SNURs	734
Non-§5(e) SNURs	575
§5(f) Actions	4
PMNs withdrawn often in face of action	1,705
Approximate Voluntary Testing Actions	300+
TOTAL ACTIONS	3,899

There are several exemptions from filing a PMN for Inventory listing. Two are required by the statute:

- the Test Market Exemption (TME) is established at TSCA §5(h)(1), and its implementing regulations are at 40 CFR 720.38;
- the Research & Development Exemption (R&D) is established at TSCA §5(h)(3), and its implementing regulations are at 40 CFR 720.36 and .78 for commercial R&D, and 40 CFR 720.30(i) for non-commercial R&D.

TSCA §5(h)(4) gives the Administrator the authority to exempt manufacturers from some or all of the requirements of TSCA §5 upon a determination that the intended activities with the substances will not present an unreasonable risk to health or the environment. The Agency has established eligibility criteria for three exemptions based on §5(h)(4): the Low Volume Exemption (LVE), implementing regulations at 40 CFR 723.50(c)(1), the Low Release and Exposure Exemption (LOREX), implementing regulations at 40 CFR 723.50(c)(2), and the Polymer Exemption (PE), implementing regulations at 40 CFR 723.250.

Written submissions and Agency review/approval are required for the TME, the LVE, and the LOREX. The R&D and Polymer exemptions are based on the user's determination that they meet the requirements of the exemption, no review/approval need be sought from the Agency, though a user is required to report to the Agency that the Polymer Exemption has been used (an earlier version of the Polymer Exemption did require a request for permission, and polymers reported under that program were listed in the Inventory with "Y" status).

Table 1.3-3 lists the number of exemptions received through September 30, 2002. Additional information on PMN exemptions is provided in Appendix B, section B-1.2.1.

Table 1.3-3. New Chemicals Program Exemptions through September 30, 2006

Type of Exemption	Number
Test Marketing Exemptions	730
Low Volume Exemptions	8,826
Low Release/Low Exposure Exemptions	33
Polymer Exemptions	2,530[1]
TOTALS[2]	12,119

[1] This number represents exemptions from 1979-1995. After 5/30/95 *pre-manufacture* reporting for exempt polymers has not been required. The only requirement is for *post-manufacture* reporting by January 31st of the year subsequent to initial manufacture, of which EPA has received approximately 2,000 from 1996 - 2003.
[2] Total does not include exemption modifications or significant new use notices (SNUNs).

Biotechnology

A 1986 intergovernmental policy statement announced that certain intergeneric microorganisms (microorganisms created to contain genetic material from organisms in more than one taxonomic genera) would be considered new chemicals under TSCA §5 and subject to PMN reporting and review requirements (http://www.epa.gov/oppt/biotech/). Before the final rule was issued, the Agency requested voluntary compliance from industry. On April 11, 1997, EPA promulgated the "Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act." The Microorganism Rule describes the reporting requirements for subject microorganisms, establishes certain exemptions (e.g, closed system manufacturing), and provides for a TSCA Experimental Release Application (TERA). The notice also describes the manner in which the Agency will review and regulate the use of intergeneric microorganisms in commerce, or in commercial research.

Implementation of this regulation by the TSCA Biotechnology Program is designed to ensure that EPA can adequately identify and regulate risks associated with microbial products of biotechnology, and to ensure that such products are safely developed for commercial use in a broad range of industrial and environmental applications. Eight microorganism PMNs or MCANs (Microbial Commercial Activity Notices) have been received in addition to 70 exemptions and 10 TERA applications. Additional information on TSCA Biotechnology Program is provided in Appendix B, section B-1.2.3

Safer New Chemicals

OPPT acts as a "gatekeeper," that is, using regulations based on TSCA to limit or keep high risk new chemicals off the market. While the "gatekeeper" function is a necessary role, OPPT also

facilitates environmental stewardship by encouraging approaches that empower companies to develop and use safer or greener products. In the past five or so years, EPA has increased emphasis on pollution prevention and environmental stewardship. While the focus of these efforts is on new chemicals, partial results have been obtained with existing chemicals as well. OPPT works with companies by providing chemical assessment tools and educational and other programs to facilitate environmental stewardship. These approaches are then used voluntarily by industry. Examples of innovative tools and programs that OPPT has created are described below.

Sustainable Futures (http://www.epa.gov/oppt/sf/) -- Sustainable Futures is a new chemicals program based on tools used in the PMN review process and is designed to help industry develop chemical substances that are safer, and that save both industry and government time and money. Under the program, a company uses the same structure-activity relationship (SAR) screening tools that OPPT uses in evaluating a chemical, which enhances their ability to identify concerns and halt or redirect work on a potentially risky chemical in the early research and development phase. This approach can save a company resources it might otherwise invest in a chemical that ultimately may encounter problems during PMN review. By getting early feedback on the hazards of a potential new chemical a company can reduce regulatory uncertainty and make a commercialization decision that considers a broader array of factors about a potential new chemical.

PBT Profiler (http://www.epa.gov/oppt/sf/tools/pbtprofiler.htm) -- The PBT Profiler is an important screening tool that is part of the Sustainable Futures program. It enables companies to determine early in the design phase of a new chemical or in reformulation of an existing chemical if the product presents “red flag” properties of being persistent, bioaccumulative, and toxic (PBT). OPPT provides this software at no cost to companies for use in evaluating their new chemicals for PBT characteristics.

Green Chemistry (http://www.epa.gov/greenchemistry/) -- The Green Chemistry Program recognizes and promotes chemical technologies that reduce or eliminate the use or generation of hazardous substances through an annual Green Chemistry Awards Program, and research and educational efforts. The Program has catalyzed development of scores of green chemicals and technologies. Organizations representing academia, industry, other government agencies, scientific societies, and trade organizations are all partners in this endeavor.[7]

Design for the Environment (http://www.epa.gov/dfe/) -- EPA’s Design for the Environment (DfE) Program works in partnership with a broad range of stakeholders to reduce risk to people and the environment by preventing pollution. EPA's DfE program has reached more than 200,000 business facilities and approximately 2 million workers, reducing the use of chemicals of concern by approximately 237 million pounds per year.

DATA DEVELOPMENT AND COLLECTION ACTIVITIES

[7] To date, the Green Chemistry Program is responsible for the cumulative elimination of more than 326 million pounds of hazardous chemicals and solvents. The Program has also saved 390 million gallons of water and prevented 120 million pounds of carbon dioxide from being released from the manufacture of industrial chemicals and consumer products.

The current TSCA Inventory contains approximately 82,000 chemicals. For priority-setting purposes, OPPT has focused its data development and data collection efforts on a subset of approximately 15,000 non-polymeric chemicals reported in the two most recent IUR cycles as being produced in quantities greater than 10,000 pounds per year.[8] Currently, OPPT is focusing on a subset of approximately 3,000 High Production Volume (HPV) chemicals, which are produced and/or imported in annual volumes of 1 million pounds or more across all U.S. companies. For more information about the TSCA Inventory, see section 1.2.

In parallel, the Existing Chemicals Program's data development efforts also focus on chemicals of concern including perfluorooctanoic acid (PFOA) and perfluorooctyl sulfonate (PFOS).

Collected or developed data on chemicals are generally made accessible to the public (consistent with CBI safeguards) and are intended to provide input for efforts to evaluate potential risk from exposures to these chemicals. In some cases, CBI claims by industry regarding the chemical name, company name, production volume, or manufacturing/distribution site make it difficult to provide information on TSCA existing chemicals to the public (although this is generally less of an issue than for new chemicals). However, health and safety information submitted under §8 may not be claimed as CBI. Also, data gathered through the HPV Challenge are intended to be publicly available information and are not generally claimed as CBI. To provide the public easy access to the HPV data, EPA launched the HPV Information System (HPVIS) in April 2006.

Hazard and Exposure Data Development

EPA can require companies (producers, manufacturers, importers, processors) to conduct testing on selected chemicals for which data are needed to evaluate potential health or environmental hazards or exposures. Such data development requirements may be established through a test rule or through development of Enforceable Consent Agreements (ECAs), which are negotiated among identified parties and generally provide an alternative to formal rulemaking.

EPA applies §4 rulemaking authority when it can make certain statutory findings about the substance involved, including that there are insufficient data available to determine the effects of the substance on health and/or the environment; and testing is necessary to provide such data; and the chemical may present an unreasonable risk of injury to health or the environment, and/or may be produced at substantial quantities and is reasonably expected to enter the environment in substantial quantities or may result in significant or substantial human exposure.[9] TSCA §4 has

[8] On average, there are about 9,000 non-polymeric organic chemicals reported as produced in quantities greater than 10,000 pounds per year. However, the IUR is a relatively dynamic volatile database. OPPT experience is that up to 4,000 non-polymeric organic chemicals reported as produced in quantities greater than 10,000 pounds in one IUR cycle might not be reported in the following cycle. Many chemicals periodically fall above or below the reporting threshold and the lack of information concerning production status during the years between reporting years makes it difficult to determine production trends with certainty. Therefore, for priority setting purposes, OPPT considers data from two cycles (9,000 average + 4,000 reported in the previous cycle) to represent the number of organic chemicals in commerce at or above this level of production. OPPT also adds an estimated 2,000 inorganic chemicals, resulting in approximately 15,000 non-polymeric chemicals that are of interest for priority setting purposes.

[9] EPA must make statutory findings under either section §4(a)(1)(A) ("A" finding) or §4(a)(1)(B) ("B" finding) of TSCA before testing may be required of a manufacturer or processor. With regards to the "B" finding, TSCA

generated data on approximately 200 chemicals since the 1970s. ECAs also allow OPPT to obtain test data and can also involve agreed-upon pollution prevention and other types of product stewardship initiatives by the chemical industry as possible substitutes for or adjuncts to testing. ECAs have generated data on approximately 60 chemicals (included in the 200 chemicals for which data has been generated using TSCA §4).

OPPT's TSCA data development activities are complemented by non-regulatory and stewardship efforts such as the High Production Volume Challenge (HPV) Program and the Voluntary Children's Chemical Evaluation Program (VCCEP) (see sections 4.0 and 4.1).

The TSCA Interagency Testing Committee (ITC) (http://www.epa.gov/oppt/itc), established under TSCA §4(e), includes representatives from many federal agencies and organizations. The ITC is an independent advisory committee to the EPA Administrator that was created to identify TSCA chemicals for which there are suspicions of toxicity or exposure and for which there are few, if any, ecological effects, environmental fate, or health effects testing data.

The ITC adds chemicals for which there are suspicions of toxicity or exposure and few, if any, data to the Priority Testing List, and recommends them for testing or information reporting to the EPA Administrator to meet the data needs of its U.S. government member organizations. In response to ITC's recommendations, the EPA promulgates automatic final rules under TSCA §8 and the Administrator gives priority consideration to ITC's chemicals for the development of test rules under TSCA §4. Additional information on the TSCA ITC is provided in Appendix B, section B-1.3.1

Since 1990, EPA has been using the Master Testing List (MTL) to identify priority chemical testing needs and to set OPPT's Chemical Testing Program agenda. The MTL presents a consolidated listing of OPPT's existing chemical testing priorities under TSCA, as well as those brought forward to OPPT by other EPA Program Offices, other Federal agencies, the Organization for Economic Cooperation and Development (OECD), and the ITC. Additional information on the OPPT's MTL is provided in Appendix B, section B-1.3.2.

Collecting Information to Evaluate Potential Risks

OPPT's data-gathering activities under TSCA §8 provide information that EPA uses to identify, assess, manage, and reduce actual or potential risks posed by chemical exposure. The

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section §4(a)(1)(B)(i) requires the Administrator to find that 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." However, TSCA does not define the criteria or standards to be used, or the meanings of the words "significant" or "substantial." Additionally, the legislative history of TSCA provides no elucidation of these terms. In July 1991, EPA set forth its proposed statement of policy regarding section §4(a)(1)(B)(i) by articulating criteria for substantial production, substantial release, substantial human exposure and significant human exposure in a policy document subject to notice and comment in the Federal Register, known as the "exposure based" or "B" policy (56 FR 32294, July 15, 1991). After considering the public comments, EPA published its final statement of policy in May 1993 (58 FR 28736, May 14, 1993). The "exposure based" policy defines produced in substantial quantities as substantial production (1 million pounds) AND substantial release to the environment (1 million pounds or 10% of production) OR substantial human exposure (1,000 workers, or 10,000 consumers or 100,000 general population) OR significant human exposure (case-by-case). (See Appendix B, section B-1.3.3)

information obtained through §8 reporting is also valuable in helping EPA carry out its chemical testing mandate under §4 of TSCA. Information-gathering under TSCA §8 includes:

1. General Information Gathering Authority (§8(a))
2. Allegations of Significant Adverse Reactions (§8(c))
3. Unpublished Health and Safety Studies (§8(d))
4. Notice of Substantial Risk (§8(e)).

Health and safety data generally cannot be considered confidential business information (see TSCA §14(b)(I)(A&B)).

TSCA §8(a) provides EPA the authority to require, by rulemaking, manufacturers (including importers) and processors of chemical substances to maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates. Beyond the IURA data collected under TSCA §8 authority (http://www.epa.gov/oppt/chemtest/pubs/sect8a.htm), another example of a TSCA §8(a) reporting rule is the "Preliminary Assessment Information Reporting" (PAIR) rule.

Under PAIR, producers and importers of a listed chemical are required to report to EPA the following site-specific information based on annual production: quantity of chemical produced and/or imported; amount of chemical lost to the environment during production or importation; quantity of enclosed, controlled, and open releases of the chemical; and, the number of workers exposed and the number of hours exposed. The PAIR rules require a one-time reporting. As of September 2006, approximately 33 PAIR rules have been issued for about 1,200 chemicals.

Under TSCA §8(c) (http://www.epa.gov/oppt/chemtest/pubs/sect8c.htm)and its implementing regulation, companies must record, retain, and, when requested by EPA, report “allegations of significant adverse reactions” for any substance/mixture that they manufacture, import, process, or distribute in commerce. The significant adverse reaction may be to human health or to the environment. The TSCA §8(c) rule provides a mechanism to identify previously unknown chemical hazards that may reveal patterns of adverse effects that otherwise might not be noticed or detected. OPPT has used this authority to request the information infrequently. Only two reporting rules have been issued, covering two chemicals and two chemical categories. A total of 31 reports have been received.

Under TSCA §8(d) (http://www.epa.gov/oppt/chemtest/pubs/sect8d.htm), EPA can promulgate rules to require manufacturers, importers, processors or distributors in commerce of chemicals or mixtures to submit lists and/or copies of ongoing and completed unpublished health and safety studies that are known or available to the subject company. As of September 2006, EPA has issued 51 TSCA §8(d) "unpublished health and safety data" reporting rules covering approximately 1,200 chemicals. In response to these rules, the Agency has received more than 50,000 studies covering a broad range of health and ecological endpoints, as well as information on chemical/physical properties, environmental fate and exposure. All of the studies are available in OPPT's public docket and are referenced in the TSCA Testing Submissions (TSCATS) online database (http://www.syrres.com/esc/tscats_info.htm) as well as a number of other publicly available online databases (e.g., the National Library of Medicine's "Hazardous Substances DataBase.")

TSCA §8(e) (http://www.epa.gov/oppt/tsca8e/) requires that chemical manufacturers, processors, and distributors notify EPA immediately of new (e.g., not already reported), unpublished information on chemicals that reasonably supports a conclusion of substantial risk. TSCA §8(e) substantial risk information notices most often contain toxicity data but may also contain information on exposure, environmental persistence, or actions being taken to reduce human health and environmental risks. EPA considers TSCA §8(e) to be an important information-gathering tool that serves as an early warning mechanism. As of September, 2006, EPA had received 16,500 initial §8(e) submissions and approximately 7,750 supplemental or follow-up §8(e) submissions. EPA receives approximately 200 initial and 100 supplemental §8(e) submissions per year.

"For Your Information" (FYI) submissions are the voluntary adjunct to "substantial risk" notices, submitted to EPA under TSCA §8(e). Similar to §8(e) submissions, FYI submissions may contain information on human exposure, epidemiology, toxicity test results, environmental monitoring, environmental fate, or other information pertinent to risk assessment. FYI submissions may contain negative or equivocal findings that submitters may wish to share with EPA and the public. In other cases, FYI submissions contain positive data but are submitted on an FYI basis because the submitter does not have a TSCA reporting obligation (is not a chemical manufacturer, processor or distributor) or does not believe the data are reportable under §8(e). As of September, 2006, EPA had received 1,500 FYI (voluntary) submissions, averaging about 30 per year. Additional information can be found at: (http://www.epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestionsfaqs.htm).

EPA uses PAIR and its TSCA §8(d) authority to gather information needed by the ITC, other EPA Program Offices, and other Federal agencies. Additional information on TSCA §8 data-gathering activities is provided in Appendix B, section B-1.3.4.

PFOS and PFOA Data Development

OPPT began investigating perfluorinated compounds in late 1999, based on new studies submitted under TSCA §8(e) on perfluorooctyl sulfunate (PFOS). These studies indicated that PFOS was toxic in animal studies, found widely in the blood of humans and wildlife, and did not break down in the environment. Since some of these studies also found perfluorooctanoic acid (PFOA) in human blood, EPA wanted to know if PFOA might present similar concerns to those of PFOS.

PFOA (http://www.epa.gov/oppt/pfoa/) is a synthetic (man-made) chemical that is used as an essential processing aid in the manufacture of fluoropolymers, and that may be produced by the breakdown of other chemicals, known as fluorinated telomers. Fluoropolymers are used in the aerospace, automotive, building/construction, chemical processing, electrical and electronics, semiconductor, and other industries to impart valuable properties including chemical and fire resistance and water repellency to a wide variety of industrial and commercial products. Fluorinated telomers are used as surfactants in commercial cleaning and coating products, and as surface treatments to provide oil, stain, grease, and water repellency to carpets, leather, and textiles. Although fluoropolymers are made using PFOA, the finished products are not expected to contain PFOA.

Following voluntary phase-out by the U.S. manufacturer, EPA used its authority under §5(a)(2) to regulate PFOS chemicals. In March 2002, EPA issued a SNUR concerning 13 known discontinued PFOS chemicals. The SNUR made any new manufacture or import of any of the 13 substances a significant new use and therefore requiring a 90 day notification to EPA prior to commencing the manufacturing or importing of these substances. Subsequently, in December 2002, EPA issued a supplemental Final Rule including 75 additional chemicals and excluding from the definition of "significant new use" specifically defined low volume, controlled exposure uses in: semiconductor manufacture, aviation hydraulics, and photography.

In 2003, OPPT released a preliminary draft risk assessment and initiated an enforceable consent agreement (ECA) process to develop information on the sources of PFOA in the environment and the pathways leading to human and environmental exposures. In 2005, OPPT submitted a draft risk assessment to the Science Advisory Board (SAB) for public peer review and recommendations for further work and entered into two enforceable consent agreements (ECAs) with industry in July 2005 to determine whether incineration of fluoropolymers and telomers could be a source of PFOA. OPPT continues to work with industry and other interested parties to finalize a third ECA for testing to determine whether fluoropolymers can generate and release PFOA.

OPPT is taking action to help minimize the potential impact of PFOA on the environment. In January 2006, EPA Administrator Johnson initiated the PFOA Stewardship Program (http://www.epa.gov/oppt/pfoa/pubs/pfoastewardship.htm), in which the eight major companies in the industry committed voluntarily to reduce facility emissions and product content of PFOA and related chemicals on a global basis by 95 percent no later than 2010, and to work toward eliminating emissions and product content of these chemicals by 2015. In addition, OPPT has made the international community aware of PFOA-related issues and, under the auspices of the OECD, has developed a draft hazard assessment of PFOA with Germany. Comments from member countries have been received, and the document will be revised accordingly.

EXISTING CHEMICAL REVIEW AND ASSESSMENT PROCESS

A number of technical experts (scientists and engineers) review incoming information on chemicals to assess hazard, exposure and risk. This information may come to OPPT either as a result of a regulatory action, such as TSCA §§ 4 or 8, or voluntary efforts, such as the High Production Volume Challenge Program (see section 4.0). Although each program is different, there are common elements to the review process. OPPT's review and analysis of the information could lead to the decision that additional testing is needed to fully determine hazard or risk, or EPA may work with industry and/or the various stakeholders to identify and implement risk management strategies for the chemical. Appendix B, section B-1.3.5 has more information regarding the review process, and uses HPV and §8(e) as an example.

Addressing Risk

EPA has authority under TSCA §6 to regulate the manufacture (including import), processing, use, distribution in commerce, and disposal of chemical substances and mixtures that present or

will present an unreasonable risk to human health and the environment. EPA may ban the manufacture or distribution in commerce, limit use, require labeling, or place other restrictions on chemicals that pose unreasonable risks after making certain statutory findings. In order to regulate under §6, EPA must find that there is a reasonable basis to conclude that a chemical substance "presents or will present an unreasonable risk of injury to health or the environment," where "unreasonable risk" is a risk-benefit standard. EPA must consider risks, costs and benefits of a substance to be regulated, including the availability of substitutes. TSCA requires the Administrator to impose the "least burdensome" regulatory measure that provides adequate protections.

Therefore, in promulgating regulations under TSCA §6, EPA must consider:

- The effects of the chemical substance on health and the magnitude of human exposure
- The effects of the chemical substance on the environment and the magnitude of environmental exposure
- The benefits of the chemical substance and the availability of substitutes
- The economic consequences of the rule.

TSCA §§6(c) and 9 also require EPA to consider whether other Federal statutes and regulations are available to address a risk that would otherwise merit regulatory action under TSCA §6.

The National Program Chemicals section presents certain OPPT actions that have been conducted under TSCA §6 authority, including those directed at PCBs and asbestos.

EPA has regulated a number of substances under TSCA §6 via proposed and final rulemaking procedures, including metalworking fluids (40 CFR part 747) and hexavalent chromium chemicals (40 CFR part 749). In addition, polychlorinated biphenyls (PCBs) (40 CFR part 761), and asbestos (40 CFR part 763) risk management actions have also been promulgated under TSCA §6; however, in both cases statutory requirements were followed (TSCA §6(e) and TSCA §203 [part of Title II of TSCA], respectively). Table 1.6-1 provides a summary of the actions proposed and/or finalized pursuant to TSCA §6 authority.

Some EPA TSCA §6 proposals have either been remanded (asbestos) or withdrawn (acrylamide). In 1989, the Asbestos Ban and Phase-Out Rule (ABPO) under TSCA §6 banned asbestos and asbestos-containing products, such as pipeline wraps, vinyl tiles, and disc brake pads (54 FR 29460, July 12, 1989). In 1991, the United States Court of Appeals for the Fifth Circuit Court overturned much of the ABPO. Today, only a few items remain on the list as banned products, including roofing felt, millboard, rollboard; commercial, corrugated, specialty paper, and any new uses for asbestos (regulated under TSCA); spray-applied asbestos-containing materials and wet-applied or pre-applied asbestos pipe insulation (regulated under CAA) (58 FR 58964, November 5, 1993 and 59 FR 33208, June 28, 1994).

In the acrylamide case, EPA proposed a rule to prohibit the manufacture, distribution in commerce, and use of acrylamide grout (56 FR 49863, October 2, 1991) in order to protect grouters from potential neurotoxic and carcinogenic risks arising from significant dermal and inhalation exposure to the acrylamide and N-methylolacrylamide (NMA) in these grouts. The proposal was withdrawn 11 years later based on the development of affordable personal

protective equipment that could provide adequate protection from exposure to the acrylamide and NMA in these grouts (67 FR 71524, December 2, 2002).

Another regulatory risk management tool used for chemicals is TSCA §5(a)(2) – Significant New Use Rules (SNURs). Under TSCA §5(a)(2), EPA is authorized to designate a use of a chemical as a significant new use, based on consideration of several factors, including but not limited to the projected production and processing volume of the chemical substance, and the anticipated extent to which the use increases the type, form, magnitude and duration of exposure to humans or the environment associated with the new use. A SNUR requires that manufacturers, importers, and processors of such substances notify EPA at least 90 days before beginning any activity (via a Significant New Use Notification, or SNUN) that EPA has designated as a "significant new use" (40 CFR 721). OPPT reviews the SNUN to determine whether it is necessary or appropriate to further regulate the substance under TSCA §§5(e) or 6, for example, before the new use begins.

Table 1.6-1. Proposed or Final Control Actions Using TSCA §6 Authority

Action		Final Date	Prompting Action	Present Status
Ban on manufacture, processing, distribution in commerce of fully halogenated chlorofluoralkanes for aerosol propellents	5/13/77	3/17/78	Component of federal actions regarding ozone-depleting CFCs	Superceded by later air regulations
Ban on manufacturing, processing, distribution in commerce and use of PCBs	6/7/78	5/31/79	Implemented statutory ban on PCBs	Ban in place -- numerous other actions taken to regulate certain PCBs uses
Ban on storage and disposal of dioxin-contaminated waste at one facility in Arkansas	3/11/80	5/19/80	Imminent Hazard (withdrawn in light of RCRA authority)	Superceded by 1984 RCRA rule
Limited certain uses of metalworking fluids (3 separate actions)		1/23/84 6/14/84 9/20/84	Unreasonable risk of injury to human health	Bans presently in place
Ban on manufacture, importation, processing, and distribution of asbestos	1/29/86[1]	7/12/89	Unreasonable risk of injury to human health	Ban on existing uses overturned ("Corrosion Proof Fittings" case) in court in 1991 Ban on new uses remains in effect
Ban on hexavalent chromium chemicals in comfort cooling towers	3/29/88	1/30/90	Final EPA health assessment for chromium and subsequent listing as a hazardous air pollutant	Ban presently in place
Regulation of "Land Application of Sludge from Pulp and Paper Mills Using Chlorine and Chlorine Derivative Bleaching Processes"	5/10/91		Unreasonable risks to wildlife and humans presented by dioxins and furans in certain paper mill sludges	MOUs[2] entered into with pulp and paper industry; Water rule promulgated
Ban on acrylamide/–methylacrylamide grouts	10/2/91		Worker exposure issue – known human neurotoxicant, probable human carcinogen	Proposal withdrawn (12/2/2002) based on development of PPE[3]
Ban on lead fishing sinkers	3/9/94		Response to Citizen's Petition	Final action under development

1 Advanced notice of proposed rulemaking (ANPR) issued on 10/17/79.
2 MOUs = Memoranda of Understanding.
3 PPE = personal protective equipment. It was determined that the newly developed PPE provided adequate protection from exposure to acrylamide.

Imminent Hazards

If EPA determines that a chemical is likely to present an unreasonable risk of serious or widespread injury to health or the environment before normal rulemaking procedures can be completed, EPA may declare (when in the public interest) a proposed rule under TSCA §6 effective upon publication and until the effective date of the final action. For chemicals that present an imminent and unreasonable risk of serious or widespread injury to health or the environment, EPA may, under TSCA §7, ask a court to require whatever action may be necessary to protect against such risk.

High Production Volume (HPV) Challenge Program

Over the last decade, OPPT's regulatory programs, which initially focused on individual high-priority chemicals, have gradually moved to more comprehensive testing, assessment, and risk management efforts, integrated voluntary and regulatory actions, and efforts directed at larger numbers of related chemicals (e.g., chemicals produced in high volume). OPPT has also developed a strong commitment to the promotion of public understanding of chemical risks by developing and providing scientifically sound, understandable, accessible, and comprehensive information to the broadest audience possible. From the late 1990s to the present, OPPT's approach to actively develop and involve a knowledgeable public has been increasingly influenced by the rapid growth in information technology and the rapid evolution of the Internet as a primary public communication tool.

The HPV Challenge Program (http://www.epa.gov/hpv) is aimed at giving industry, governments, and citizens screening-level health and environmental effects information on chemicals found in thousands of products so they can make informed choices on the use of those chemicals. While this program emphasizes partnership with industry, and a general new approach, it still links to and coordinates with the regulatory mandates of TSCA.

On April 21, 1998, a national initiative known as the Chemical Right-to-Know (ChemRTK) Initiative, was announced and included the High Production Volume (HPV) Challenge Program and the Voluntary Children's Chemical Evaluation Program (VCCEP).

The HPV Challenge Program responds to survey studies that found that very little basic toxicity data were publicly available on most of the HPV chemicals listed on the TSCA Inventory. HPV chemicals are industrial chemicals that are produced in or imported into the U.S. in volumes of one million pounds or more per year. EPA found that, of the approximately 3,000 non-polymeric, organic substances manufactured or imported in amounts equal to or greater than 1 million pounds per year based on 1990 IUR reporting, only 7% had a full set of publicly available, internationally recognized, basic health and environmental fate/effects screening test data, and 43% had no such information publicly available.

The framework for the HPV Challenge Program was developed by Environmental Defense and the American Chemistry Council. U.S. producers and importers of HPV chemicals voluntarily

sponsor chemicals. Sponsorship entails the identification and initial assessment of the adequacy of existing information, the conduct of new testing (only if adequate information does not exist), and making the new and existing test results available to the public.

The basic hazard data collected and submitted on the HPV chemicals are derived from a battery of tests agreed upon by the international community as appropriate for hazard screening purposes. These endpoints have been adopted by the Organization for Economic Cooperation and Development (OECD) and are known as the OECD's Screening Information Data Set (SIDS). These data include:

- Physicochemical properties (melting point, boiling point, vapor pressure, water solubility, and octanol/water partition coefficient);
- Environmental fate (biodegradation, hydrolysis, and estimates of distribution/transport and photodegradation);
- Ecotoxicity (acute toxicity to aquatic vertebrates, invertebrates, and plants); and
- Studies in animals to assess human health effects (acute and repeat-dose toxicity, effects on the gene and chromosome, effects on reproduction and developmental effects).

A key component of the HPV Challenge Program is the public presentation of hazard data for the SIDS endpoints described above. After a company or consortium agrees to sponsor a chemical or group of chemicals (i.e., a chemical category), an HPV Challenge Program submission is made. The submission consists of a cover letter, a test plan, and data summaries that are also known as robust summaries:

- The cover letter generally identifies the company(ies), chemical(s), and usually whether any new testing is being proposed.
- The test plan can be a table or narrative (or both) that describes whether data exist for a given endpoint, whether the data are considered adequate, and may include the claim that no new testing is necessary. In the case where no data exist or the existing data are considered inadequate, the sponsor proposes to perform a test(s) for that endpoint. Additional data beyond the SIDS endpoints may also be submitted, when available.
- The robust summaries are generated for each individual study/experiment for each SIDS endpoint. They are designed to provide information to a technical audience in sufficient detail so it would not be necessary to retrieve or look at the original study report. Available data for endpoints beyond that in the SIDS (e.g., carcinogenicity or chronic ecotoxicological studies) are also submitted as robust summaries.

EPA has developed numerous guidance documents to assist sponsors in submitting their data. For example, the “Guidance on Developing Robust Summaries” provides templates for each of the SIDS endpoints. Other guidance documents exist for categories, structure-activity relationships, and the evaluation of data adequacy. Regarding data adequacy, guidance is given for the acceptability of hazard data generated under old or not widely used protocols, based on the experience gained through the OECD SIDS process; newly conducted testing is performed using current OECD or equivalent test guidelines.

Once a submission is received by EPA, it is posted on the HPV website (http://www.epa.gov/hpv) and a 120-day comment period begins. This comment period allows

interested parties, EPA, and the general public an opportunity to comment on a test plan or perhaps bring forward information or data unknown to the sponsor. All comments are publicly available and posted on the website. EPA strongly encourages companies that make commitments under the HPV Challenge Program to sponsor a chemical or chemicals, and not to make Confidential Business Information (CBI) claims on the chemical-company linkage.

Once the comment period is over, sponsors may respond to comments, revise the original submission, and/or begin any new testing. Once new testing is complete, new information (in the form of robust summaries) is submitted to EPA for posting on the website in order to make the submission complete.

Eighty percent of the chemicals sponsored in the HPV Challenge Program are being handled as part of a category. When certain chemicals are similar in structure and functionality, the sponsor can assert that existing data (or proposed testing) on some members of a category may be used to make screening-level determinations on other, untested category members with reasonable confidence. In contrast to single chemical submissions, completion of a category submission (once proposed testing is completed) includes a Category Analysis Document that determines whether the original category proposal was valid based on test results.

Industry has responded to the HPV Challenge Program by sponsoring over 2,200 HPV chemicals. As of August 2006, 373 companies and 104 consortia (groups of companies) have sponsored 1,383 chemicals directly in the HPV Challenge Program, with another 862 chemicals sponsored indirectly through the International Council of Chemical Associations (ICCA) HPV Initiative, a corresponding international effort. The Agency has received 404 test plans that cover 1,350 (or 98%) of the 1,383 chemicals that were sponsored directly in the program.

Since easy access to this HPV data by the public has always been a cornerstone of the HPV Challenge Program, EPA launched the HPV Information System (HPVIS) (www.epa.gov/hpvis) in April 2006. HPVIS is a web-based searchable, relational database that provides comprehensive and easy access to basic health and environmental effects information on HPV Challenge Program chemicals. It allows the public to access sponsor information, robust summaries, test plans, as well as physical/chemical properties, environmental fate information, and toxicity data. HPVIS has a number of options for data retrieval, including standard reports, custom queries, and the ability to view data for either individual chemicals or categories of chemicals. Users can thoroughly search across test plans and robust summaries and also comment on the adequacy of the data presented. In addition, data entry screens are provided for sponsors to enter data directly into the application.

HPVIS is also being used to run a step-wise Tiering Process (http://www.epa.gov/hpv/pubs/general/datascreening.htm), with the first tier establishing a logical order in which EPA's Office of Pollution Prevention and Toxics reviews individual chemicals and categories of chemicals, and the second tier will result in a screening-level characterization of the potential hazards of each chemical examined in the program.

After full review of HPV chemical data according to the tiering process, OPPT will have screening-level hazard characterizations (http://www.epa.gov/hpv/hpvis/abouthc.htm) for each chemical and category examined in the Challenge Program (i.e., all chemicals and categories

from the first and second priority groups, and any select chemicals from the third priority group). In addition, OPPT will have data needs documentation for any chemicals or categories for which further data collection has been deemed necessary. OPPT will use this information to guide its subsequent management activities for these HPV substances. Dependent upon the outcome of each review, a range of follow-up voluntary or regulatory actions are possible for each of these chemicals or categories.

Since not all of the 2,782 chemicals that were eligible for sponsorship in the HPV Challenge Program have been sponsored, EPA is addressing these unsponsored chemicals (http://www.epa.gov/hpv/pubs/general/regactions.htm). In December 2000, EPA issued a proposed test rule under TSCA Section 4 (65 FR 81658) to obtain needed hazard information on 37 of the HPV unsponsored chemicals; and the final rule of 17 chemicals was published in March 2006 (71 FR 13707).

Additional HPV test rules addressing other unsponsored chemicals are also under consideration. In August 2006, the Agency published TSCA Section 8(a) and 8(d) rules in an effort to gather information on 243 unsponsored chemicals. Like test rules, EPA is considering further TSCA Section 8(a)/8(d) rules to secure information regarding chemicals for which HPV Challenge Program chemical data was not submitted to the Agency.

Voluntary Children's Chemical Evaluation Program Pilot

Chemicals of potential concern to children's health are the subject of more detailed and extensive evaluation in the pilot Voluntary Children's Chemical Evaluation Program (VCCEP) (http://www.epa.gov/oppt/vccep/). VCCEP was developed to ensure that there are adequate publicly available data to assess the special impact that industrial chemicals may have on children.

In August 1999, EPA announced the initiation of a process in which it sought stakeholder input on all aspects of the VCCEP. EPA held three public meetings and took comments on possible designs for a voluntary program. EPA also took steps to consider animal welfare and to reduce or in some cases eliminate animal testing, while at the same time ensuring that adequate quality data will be developed.

After considering all the comments of interested stakeholders, the pilot VCCEP was announced in a *Federal Register* (http://www.epa.gov/fedrgstr/EPA-TOX/2000/December/Day-26/t32767.htm) notice on December 26, 2000. In the notice, EPA asked companies that produce and/or import 23 specific chemicals to volunteer to sponsor their evaluation in Tier 1 of a pilot of the VCCEP. The targeted chemicals have been found in human tissues and the environment in various monitoring programs. Thirty-five companies and ten consortia responded and volunteered to sponsor 20 of the chemicals.

The ultimate objective of the VCCEP is to ensure that there is adequate toxicity and exposure information available to assess the potential risks to children. A tiered approach is being pursued to gather the information, with each subsequent tier, of the three tiers, including more complex toxicology and exposure studies. The sponsor develops a chemical assessment at each tier of analysis.

The assessment includes four sections:

- Summary of the toxicology information
- Summary of the exposure information
- Risk characterization
- Data needs assessment

The data needs assessment discusses the need for additional data, which could be provided by the next tier, to fully characterize the risks the chemical may pose to children.

The studies in Tier 1 are the same as those in the HPV Challenge Program. Information from all three tiers may not always be necessary to adequately characterize the risk to children. The toxicology studies included in the program are a subset of the test battery developed by the EPA to assess the effects of pesticides on children's health. EPA's Science Advisory Panel reviewed and approved the VCCEP test battery as a means to assess the health effects of industrial chemicals to which children might be exposed. The exposure information includes population groups exposed, sources of the exposure, as well as frequencies, levels, and routes of exposure. The exposure information gathered at Tier 1 includes readily available screening level information with more detailed analyses submitted at upper tiers.

During the public stakeholder meetings, it was proposed that an outside group of scientific experts should have the opportunity to provide comments on the chemical assessments and in particular the data needs portion of the assessments. The approach adopted involves convening a group of scientific experts with extensive and broad experience in toxicity testing and exposure evaluations, as well as expertise in the specific chemical, referred to as a Peer Consultation Panel (http://www.epa.gov/oppt/vccep/pubs/peer.htm). The sponsor provides the assessments to an outside third party who is responsible for seeking input through the Peer Consultation Panel. The outside third party develops a summary of the opinions expressed at the Peer Consultation meeting and makes it available to the sponsor, EPA, and the public.

OPPT reviews the sponsor's assessment and the summary of opinions from the Peer Consultation and decides whether any additional information is needed to adequately characterize the potential risks to children. This "Data Needs Decision" (http://www.epa.gov/oppt/vccep/pubs/submit.htm#D) is subjected to an Agency wide review before it is sent to the sponsor and made available to the public on the VCCEP website (www.epa.gov/oppt/vccep).

OTHER TSCA PROVISIONS

Confidential Business Information

Information submitted under specific reporting requirements of TSCA, or in support of TSCA, is subject to the provisions of §14 of TSCA and to EPA's regulations on the confidentiality of business information. The statute provides that information collected under TSCA, but claimed Confidential Business Information (CBI) will only be released under very limited circumstances

related at TSCA §14(a)(1)-(4). TSCA §14(a) prohibits EPA disclosing CBI to the general public, including States, Tribes, and local governments. Under TSCA §14(b), health and safety information in a health and safety study submitted to EPA under TSCA is generally subject to public disclosure.

Relationship to Other Federal Laws

TSCA §9 addresses EPA's authority to regulate chemical substances and associated activities that fall under both TSCA and other Federal laws, including laws administered by other Federal agencies and the EPA. It includes procedures under which EPA can refer the regulation of chemicals to other agencies and requirements to coordinate actions taken under activities with other Federal agencies "for the purpose of achieving the maximum enforcement of this act [TSCA] while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."

Export Notification

TSCA §12(b) requires exporters to notify EPA when they export or intend to export a chemical substance or mixture that is subject to certain actions under TSCA §§4, 5, 6, or 7. TSCA §12(b) also requires EPA to notify importing (receiving) countries of the export or the intended export (also see Appendix B, section B-1.4.1). (http://www.epa.gov/oppt/chemtest/pubs/pdflist12.htm)

Import Certification

All importers of chemical substances are subject to TSCA and generally must meet the same requirements under TSCA as a chemical producer in the United States. TSCA §13 regulations require importers to "certify" that their imported chemical substances or mixtures are either: (1) in compliance with TSCA §§5, 6, and 7 at the time of import; or (2) not subject to TSCA. TSCA §13 provides authority for U.S. Customs, in conjunction with EPA, to implement these import certification requirements (also see Appendix B, section B-1.4.2). (http://www.epa.gov/oppt/chemtest/pubs/policies.htm)

Citizen Petitions

Under TSCA §21, any citizen may petition EPA to take action under TSCA §4 (rules requiring chemical testing), §6 (rules imposing substantive controls on chemicals), or §8 (information gathering rules). TSCA §21 also authorizes a petitioner to request the issuance, amendment, or repeal of orders under §5(e) (orders affecting new chemical substances) or §6(b)(2) (orders affecting quality control procedures). If the EPA Administrator grants a §21 petition, the Agency must promptly commence an appropriate proceeding. If the Administrator denies the petition, the reasons for denial must be published in the *Federal Register*.

NATIONAL PROGRAM CHEMICALS

Under TSCA §6 authority, OPPT develops regulations and policies designed to reduce risks to human health and the environment from several specific priority chemicals (i.e., National Program Chemicals). The National Program Chemicals include both chemicals that have

specific statutory requirements (e.g., PCBs, lead and asbestos), as well as other multimedia pollutants of concern (e.g., dioxin and mercury) that are addressed through national policies. In addition to managing regulatory programs for chemicals under TSCA statutes, OPPT plays a key policy coordination role for other multimedia pollutants being addressed in other EPA programs. Currently the National Program Chemicals include:

- Halogenated aromatic compounds: PCBs and dioxins
- Heavy metals: lead and mercury
- Fibers: asbestos, refractory ceramic fibers, and products contaminated with asbestos/fibers (e.g., vermiculite).

PCBs

The primary statutory authority addressing polychlorinated biphenyls (PCBs), TSCA §6(e), specifically directs EPA to regulate the disposal, marking, manufacturing, processing, distribution in commerce, and use of PCBs. PCBs were specifically named in TSCA when it passed in 1976 because Congress believed that the chemical and toxicological properties of PCBs posed unacceptable risks to public health and the environment. Subsequently, EPA/OPPT promulgated numerous implementing rules that address various aspects of the PCB life cycle, including prohibitions on its manufacture, processing, and distribution in commerce.

The use of PCBs in existing equipment was, for economic reasons, allowed to continue for the useful or normal life of the equipment as long as specific conditions were met, but TSCA strictly controls the phase-out of these existing uses and sees to their safe disposal. Thus, TSCA legislated true "cradle to grave" (i.e., from manufacture to disposal) management of PCBs in the United States.

Although TSCA provides the primary regulatory framework for controlling PCBs, these compounds are also regulated to some extent under the Clean Air Act (CAA), Clean Water Act (CWA), Resource Conservation and Recovery Act (RCRA), and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

EPA has promulgated more than a dozen major and minor rules since 1978 to implement the bans, provide authorization for use, and control the disposal of PCBs. EPA has more recently centered its efforts on the reduction and elimination of the use of PCBs and encouraging cleanup and safe disposal of PCBs. Toward this end, the PCB Site Revitalization Guidance (http://www.epa.gov/epaoswer/hazwaste/pcbs/pubs/guidance.htm#revitalization) for complying with TSCA regulations for the cleanup and disposal of PCBs was released in November, 2005.

Lead

The Residential Lead-Based Paint Hazard Reduction Act of 1992, also known as Title X of the Housing and Community Development Act, was designed to protect families from exposure to lead from paint, dust, and soil (http://www.epa.gov/lead/pubs/regulation.htm). This law developed a comprehensive federal strategy for reducing lead paint hazard exposure and provided the authority to establish standards and regulations by amending TSCA to include Title IV (Lead Exposure Reduction).

In implementing the various programs authorized by Title X and TSCA Title IV, OPPT has worked closely with the U.S. Department of Housing and Urban Development (HUD), the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), and the National Institute for Occupational Safety and Health (NIOSH). Additional information on OPPT's lead program is provided in Appendix B, section B-2.1.

Title X authorized the Agency, in partnership with other Federal agencies, to conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection, and abatement of lead hazards. As part of this program the Agency has, for example, developed standards for environmental sampling laboratories, and established a Hotline and Clearinghouse to collect and distribute information on lead hazards (including the development of a lead hazard information pamphlet).

Under the authority of Title X, EPA promulgated several regulations, including those calling for the establishment of national training and certification systems for renovation and abatement activities, lead hazard levels, and information disclosure. In addition, the Agency is in the process of finalizing training and certification regulations for renovation activities. Title IV of TSCA directs EPA to address the general public's risk of exposure to lead-based paint hazards through regulations, education, and other activities (e.g., see discussion of TSCA §§402, 403, 404 and 406 activities in Appendix B, section B-2.1).

Although the States in general have a limited role in TSCA, the TSCA lead program is an important exception. For example, TSCA §404 provides for EPA authorization of State programs for training and certification of lead-based paint contractors and for performing the education and outreach requirements of TSCA §406. In addition, TSCA §404(d) required EPA to promulgate a model State program that may be used by States seeking to administer programs. All State programs must be at least as protective as the model state program that EPA has promulgated and must provide adequate enforcement. In those States lacking their own programs, EPA must establish, administer, and enforce Federal programs.

EPA Regions implement OPPT's lead program in states that have not accepted responsibility for the program. As of August 2006, 39 States, 3 Tribes and 2 Territories administer their own abatement training and certification (402) program, and 2 States administer their own pre-renovation education (406) program. TSCA §404(g) also authorizes EPA to make grants to States to develop and carry out authorized programs.

Asbestos/Fibers

EPA's major asbestos[10] regulations are under the authority of TSCA and the Clean Air Act (CAA). Asbestos-related CAA programs are the responsibility of the Office of Air and

[10] Asbestos refers to a number of naturally occurring fibrous silicate minerals that have historically been used in numerous products due to their insulating and resistance properties (e.g., insulation). Due to emerging evidence indicating that airborne asbestos fibers were a health hazard (asbestos has been classified as a human carcinogen), by the 1980s the Federal government began to take action, including banning certain products and starting abatement programs. Airborne asbestos (e.g., from damaged or disturbed materials), when inhaled into the lungs,

Radiation. OPPT has the responsibility for various asbestos programs implemented under TSCA, as described below.

The Asbestos School Hazard Abatement Act of 1984 (ASHAA) established a loan and grant program to assist schools in abating asbestos hazards in their buildings. In 1986, Congress passed the Asbestos Hazard Emergency Response Act (AHERA), charging EPA with a significant expansion of the existing regulations on asbestos in schools. On October 30, 1987, EPA published the final AHERA implementing regulations. The rule prescribed procedures for conducting building inspections, requirements for the development of management plans for ACM present in a school's buildings, requirements for the training of custodial and maintenance personnel and other school employees, standards for school building operations and maintenance activities, and air clearance standards for areas where asbestos abatement projects have been completed. (http://www.epa.gov/asbestos/pubs/asbestos_in_schools.html). (http://www.epa.gov/asbestos/pubs/pubs.html)

As directed by the statute, EPA established a process for States to obtain waivers from the AHERA regulations. As of August 2006, ten States have received waivers because they are administering an asbestos-in-schools program that is at least as stringent as the AHERA regulations. AHERA also required States to adopt and administer asbestos accreditation programs for asbestos professionals who perform work in schools. To assist the States in this effort, EPA was instructed to establish a uniform Model Accreditation Plan (MAP). The AHERA implementing regulations, as well as the MAP, are located at 40 CFR Part 763, Subpart E.

Also in 1986, EPA issued the Asbestos Worker Protection Rule, a TSCA §6 rule extending OSHA-like worker protection requirements to State and local government employees performing asbestos abatement projects not covered by an OSHA-approved State plan. In November 2000, EPA promulgated an amendment to the WPR that added coverage for State and local government employees performing building operations and maintenance projects and automotive brake and clutch repair. The 2000 amendment also cross-references the appropriate OSHA Standards so that future changes to the OSHA General Industry Standard for Asbestos and the Construction Standard for Asbestos become immediately effective for the State and local government employees covered by the WPR.

In 1989, the Asbestos Ban and Phase-Out Rule (ABPO) (http://www.epa.gov/asbestos/pubs/ban.html) under TSCA §6 banned most asbestos-containing products, such as pipeline wraps, vinyl tiles, and disc brake pads (54 FR 29460, July 12, 1989). The final rule, however, did not restrict mining or importation of bulk asbestos, nor did it regulate asbestos as a contaminant if the percentage of asbestos was below one percent. In 1991, the United States Court of Appeals for the Fifth Circuit Court overturned much of the ABPO. Today, only a few products remain banned, including roofing felt, rollboard, and commercial, corrugated paper, or specialty paper, and any new uses for asbestos. Spray-applied asbestos-containing materials and wet-applied or pre-applied asbestos pipe insulation (regulated under the CAA) are also banned. The Consumer Product Safety Commission has also banned asbestos in joint compound and artificial fireplace embers.

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may cause significant health problems, such as lung cancer, asbestosis (a lung disease), or mesothelioma (a type of cancer).

In 1990, Congress enacted the Asbestos School Hazard Abatement Reauthorization Act of 1990 (ASHARA). A large part of ASHARA was the reauthorization of the ASHAA loan and grant program. However, ASHARA also directed EPA to increase the number of training hours required for abatement worker accreditation under the MAP and to expand the accreditation requirements to cover asbestos abatement projects in all public and commercial buildings in addition to schools.

In May of 2003, EPA issued the results of a "Pilot Study to Estimate Asbestos Exposure from Vermiculite Attic Insulation (VAI)," (http://www.epa.gov/asbestos/pubs/verm.html) which found that disturbed VAI can release contaminant asbestos fibers and create a potential risk to consumers. EPA also launched a consumer awareness campaign in May about the dangers of VAI, along with the Agency for Toxic Substances and Disease Registry (ATSDR).

In November 2005, EPA released the Asbestos Project Plan (http://www.epa.gov/asbestos/pubs/asbprojplan.html). The plan brings together all of EPA's current actions relating to asbestos. It provides a framework for a coordinated Agency-wide approach to identify, evaluate and reduce risk to human health from asbestos exposure. EPA has identified three key areas where it will focus its asbestos research, program, and funding activities:

1) Improving the state of the science for asbestos. This involves activities to advance EPA's understanding of asbestos toxicology, asbestos-related exposures, sample collection and analysis and applied science in the field.
2) Identifying and addressing ways people are exposed to asbestos in products, schools and buildings, and potential ways to reduce exposure; and
3) Assessing and reducing risks associated with areas that require asbestos cleanup.

Dioxin

The term “dioxin” refers to a group of chemical compounds that share certain similar chemical structures and affect organisms in a similar way. A total of 30 of these dioxin-like compounds exist and are members of three closely related families: the chlorinated dibenzo-p-dioxins (CDDs), chlorinated dibenzofurans (CDFs) and certain PCBs. CDDs and CDFs are not created intentionally, but can be produced inadvertantly in nature and by a number of human activities.

In order to obtain additional information on the presence of CDDs and CDFs as impurities of concern in commercial chemical substances, EPA promulgated a TSCA §4 “Dioxin/Furans (D/F) Test Rule” in 1987 (see 52 FR 21437 and 40 CFR Part 766). The final rule requires each company that produces or imports a chemical listed at 40 CFR 766.25(a)(1) and (2) to: develop and submit an analytical protocol and sampling plan; submit the results of the sampling for EPA review to determine whether further actions are appropriate; and immediately submit to EPA all existing D/F data for the listed chemicals pursuant to TSCA §§ 8(c) and 8(d) (see section 1.4.2).

EPA continues to further evaluate the exposure of Americans to dioxin and related compounds through its dioxin research and assessment efforts. Additional information on EPA's dioxin activities can be found at www.epa.gov/ncea/dioxin.

Mercury

EPA has developed numerous programs to reduce risk from mercury releases. Traditionally, many of these activities have been directed at reducing industrial air and water releases, and management of mercury in products to reduce potential release into the environment from use and disposal. OPPT led the development of EPA's Mercury Roadmap (http://www.epa.gov/mercury/roadmap.htm), published in July 2006, which describes the Agency's progress to date in dealing with mercury issues domestically and internationally, and outlines EPA's major ongoing and planned actions to address risks associated with mercury. The Roadmap focuses on six key areas: addressing mercury releases to the environment; addressing mercury uses in products and industrial processes; managing commodity-grade mercury supplies; communicating risks to the public; addressing international mercury sources; and conducting mercury research and monitoring.

OPPT continues to play an important policy coordination role for domestic and international mercury issues. EPA continues to pursue reductions of mercury uses and releases through voluntary programs and partnerships, regulatory programs, and international programs and agreements, such as the Great Lakes Binational Toxics Strategy (BTS); the Commission for Environmental Cooperation (CEC) North American Regional Action Plan (NARAP) for Mercury; the Protocol on Heavy Metals under the Convention on Long-Range Transboundary Air Pollution (LRTAP) developed under the United Nations Economic Commission for Europe (UNECE); and the new global mercury program under the United Nations Environmental Program (UNEP). The common goal for these domestic and international programs is reductions in mercury uses, releases, and exposure.

At the 23rd session of the United Nations Environment Program (UNEP) Governing Council in February 2005, governments agreed to the development and implementation of partnerships as one approach to reducing the risks to human health and the environment from the release of mercury and its compounds to the environment. The ultimate goals of these partnerships is to show actual reductions in mercury releases to the environment, to facilitate the use of alternate substances and to promote best management practices that result in decreased exposure to mercury.

Current partnerships include pilot projects in five key sectors that can achieve reductions: Chlor-alkali facilities, mercury products, artinsanal and small-scale gold mining, coal combustion, and fate and transport research. OPPT has provided leadership, support and resources to support the UNEP Partnerships, and OPPT is managing the Mercury Products Partnership.

POLLUTION PREVENTION

When OPPT was established in 1977 to implement TSCA, EPA was primarily concerned with control of current sources of pollution using "end-of-pipe command and control" approaches. Over the next two decades, this approach to addressing environmental pollution evolved to include a stronger emphasis on prevention of pollution or source reduction.

Although pollution prevention (P2) at EPA in the 1980s was largely limited to the TSCA new chemical review, waste minimization activities and a few facility-specific projects, P2 gained additional momentum in 1990 with the implementation of a series of EPA prevention-focused programs and the passage of the Pollution Prevention Act (PPA) (http://www.access.gpo.gov/uscode/title42/chapter133_.html). In the mid-1990s, the Agency incorporated more formalized prevention practices into its mainstream activities, through regulations, permitting, technical assistance, and enforcement. New objectives for partnerships, public information policies, technological innovation priorities, and regulations were established, which encouraged the government to continually renew its commitment to P2 efforts.

Pollution Prevention Act

The PPA definition of P2 includes “source reduction” and other practices that reduce or eliminate the creation of pollutants through: increased efficiency in the use of raw materials, energy, water, or other resources; or protection of natural resources by conservation. The PPA defines "source reduction" specifically to include any practice that:

- reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and
- reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants.

The term “source reduction” also includes: equipment or technology modifications; process or procedure modifications; reformulation or redesign of products; substitution of raw materials; and improvements in housekeeping, maintenance, training, or inventory control.

The PPA establishes pollution prevention as a national policy through the following environmental management hierarchy:

- Pollution should be prevented or reduced at the source whenever feasible;
- Pollution that cannot be prevented should be recycled in an environmentally safe manner;
- Pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and
- Disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner.

The PPA includes authorities for EPA to facilitate the adoption of source reduction techniques by businesses and by EPA and other Federal agencies; to identify opportunities to use federal procurement policies to encourage source reduction; to ensure that the Agency considers the effect of its regulations and its existing and proposed programs on source reduction; to develop improved methods of coordinating, streamlining, and assuring public access to data collected under federal environmental statutes; and to provide grants to States for programs to promote the use of source reduction techniques by businesses. Additional information on PPA is provided in Appendix B, section B-3.1.

Two Executive Orders Integrating P2 Approaches within the Federal Government

In 1998, Executive Order 13101: *Greening the Government through Waste Prevention, Recycling and Federal Acquisition*, mandated that Executive agencies adopt environmentally preferable purchasing. This order required that EPA develop guidance to "address environmentally preferable purchasing." The EPA's Final Guidance on Environmentally Preferable Purchasing, (64 FR 45810, August 20, 1999, http://www.epa.gov/fedrgstr/EPA-GENERAL/1999/August/Day-20/g21664.htm) outlines the Federal government's approach for incorporating environmental considerations into its purchasing decisions.

In 2000, Executive Order 13148: *Greening the Government through Leadership in Environmental Management*, required federal agencies to incorporate environmental management systems into agency day-to-day decision-making and long term planning processes. Pollution Prevention is highlighted as a key aspect to the environmental management system process.

Pollution Prevention Stewardship Programs

At the same time the approach to environmental policy was expanding to include greater emphasis on P2 with the passage of the PPA, the methods of working with industry and stakeholders were also evolving. EPA and OPPT typically use a combination of command-and-control and voluntary programs to ensure compliance and encourage pollution prevention. P2 has been primarily implemented and encouraged through voluntary measures, such as:

- Technical assistance
- Technology evaluation
- Cost benefit analysis
- Waste assessment
- Product standards/certifications
- Environmental management systems
- Public reporting

The basic principle behind this approach is that the prevention of pollution at its source and the efficient use of resources usually result in significant cost savings, risk reduction, and improved public relations for the industry or organization involved. By promoting voluntary efforts, OPPT will be encouraging industry and other organizations to implement P2 (http://www.epa.gov/p2/) initiatives at their facilities in an environmentally beneficial and cost-effective manner. Currently, P2 is a key element of new EPA initiatives such as reducing risks from PBT pollutants in the air, in water, and on land; and empowering state and tribal programs (http://www.epa.gov/p2/).

Key OPPT voluntary pollution prevention activities include:

Design for the Environment (DfE) (http://www.epa.gov/dfe/): a voluntary partnership program that helps businesses design or redesign products, processes, and management systems that are cleaner, more cost-effective, and safer for workers and the public.

Environmental Labeling (http://www.epa.gov/oppt/epp/pubs/envlab/report.htm): covers a broad range of activities from business-to-business transfers of product-specific environmental information to environmental labeling in retail markets; provides an opportunity to inform consumers about product characteristics that may not be readily apparent and guide their use in an environmentally beneficial manner.

Environmentally Preferable Purchasing (EPP) (http://www.epa.gov/epp/): a federal government-wide program managed by OPPT that requires and assists Executive agencies in the purchasing of environmentally preferable products and services.

Electronic Product Environmental Assessment Tool (EPEAT) (http://www.epa.gov/epp/pubs/products/epeat.htm): a procurement tool to help institutional purchasers in the public and private sectors evaluate, compare and select desktop computers, notebooks and monitors based on their environmental attributes.

Green Chemistry (http://www.epa.gov/greenchemistry/): an initiative under OPPT's DfE Program that focuses on P2 through the environmentally conscious design of chemical products and processes.

Green Engineering (http://www.epa.gov/oppt/greenengineering/): an initiative under the DfE program designed to promote the development and commercialization of environmentally beneficial design methods, risk-based design tools, and green technologies via education, outreach, and partnering with the academic, research, and industrial communities.

Green Suppliers Network (GSN) (http://www.epa.gov/greensuppliers/): a collaborative venture between industry and EPA that works with all levels of the manufacturing supply chain to achieve environmental and economic benefits; improve performance, minimize waste generation and remove institutional roadblocks through its innovative approach to leveraging a national network of manufacturing technical assistance resources.

Partnership for Sustainable Healthcare (http://www.epa.gov/p2/pubs/psh.htm): a voluntary program working with the healthcare industry to reduce its environmental impact -- became EPA's first voluntary program to become an independent non-profit organization in 2006.

Sustainable Futures (http://www.epa.gov/oppt/sf/): a pilot project designed to encourage industry to use EPA-developed chemical risk screening tools and P2 principles in making decisions about new chemicals at the R&D stage before submittal as PMNs.

Suppliers Partnership for the Environment (SP) (http://www.epa.gov/oppt/suppliers/): A trade association comprised of small, mid-sized and large automotive and vehicle suppliers who are working in partnership with the U.S. Environmental Protection Agency (EPA) to create new and innovative business-centered approaches to environmental protection that improve the environment while providing value to the participants.

Additional information on these voluntary pollution programs is provided in Appendix B, section B-3.2.

Pollution Prevention Grants

One of the ways EPA promotes pollution prevention is by supporting the development of a network of State and Tribal pollution prevention programs. OPPT sponsors specific grant programs to promote P2 activities. Specifically, EPA provides funding for: the P2 Grant Program, which supports development of state and tribal programs; the Pollution Prevention Resource Exchange (P2Rx) (http://www.p2rx.org), which supports eight regional P2 information centers; and the Source Reduction Assistance Grant Program, which supports consolidation of small P2 projects. OPPT believes State-based and Tribal-based environmental programs often have the best opportunity to promote P2 because States have closer, more direct contact with industry and States and Tribes are more aware of local needs. Additional information on OPPT's grant programs that promote P2 activities is provided in Appendix B, section B-3.1.1.

The P2 Grant Program (http://www.epa.gov/oppt/p2home/pubs/grants/ppis/ppis.htm), created under the authority of the PPA, provides matching funds to States and Tribes to support P2 activities and develop State programs. The majority of the P2 grants fund projects in the areas of technical assistance and training, education and outreach, regulatory integration, data collection and research, demonstration projects, and recognition programs.

INTERNATIONAL CHEMICAL INITIATIVES

Coordinated international action is critical for effectively managing chemicals at the global level. OPPT activities include efforts directed at the environmentally sound manufacture, use, management, and disposal of chemicals. Such activities range from participation in conferences and meetings related to chemical testing, assessment and/or management, to the development and implementation of international agreements. OPPT also supports capacity-building for developing countries and countries with economies in transition. These activities are complementary to, and contribute to, the accomplishment of OPPT's domestic mission.

For international activities, OPPT actively partners with other offices in EPA, the Department of State, and other U.S. agencies. Also, OPPT cooperates and consults with industry, non-governmental organizations, and other interested stakeholders.

OPPT also coordinates with foreign governments on an ad-hoc basis as issues and opportunities arise, recently, for example, with Canada and China on a variety of mutual interests.
Key organizations and agreements that OPPT coordinates with and/or otherwise participates in include:

Organization for Economic Cooperation and Development (OECD)

The OECD is an international organization consisting of 30 industrialized countries in Europe, North America, Asia, and the Pacific. (http://www.oecd.org/)

OPPTS participates actively in:

- The OECD Chemicals Committee, a comprehensive program of expert working groups and projects that includes activities such as the Screening Information Data Set (SIDS) to facilitate the coordinated investigation of high production volume (HPV) chemicals

- The Globally Harmonized System (GHS) of Classification and Labeling to promote better exchange of information on the hazards of chemicals and mixtures to human health and the environment (as well as to harmonize information on labels and safety data sheets for chemicals in commerce)
- A proposed Mutual Acceptance of Notifications (MAN) process in response to concerns over the need to better align new chemicals systems in the global market

In addition, OPPTS scientists have participated in the OECD Test Guidelines Program to develop protocols for studies to assess physicochemical properties, environmental fate, ecotoxicity, and health effects endpoints. A foundation of the OECD chemicals program is the Mutual Acceptance of Data (MAD) agreement among OECD countries to accept for review studies generated in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice regardless of where the study is performed in or among OECD countries.

Recent illustrative OECD accomplishments involving OPPT leadership include:
Test guidelines- In the past two years, OECD member countries have approved 10 test guidelines and 5 guidance documents (on, for example, vapor pressure, terrestrial plants, anaerobic biodegradation of organic compounds in digested sludge, and freshwater lentic field tests.). OPPT is currently leading the development of 16 new and updated test guidelines (to keep OECD test guidelines current with scientific developments). OPPT relies on test guidelines and Good Laboratory Practices to ensure the development of quality data under its regulatory testing programs and so that data generated in the U.S. is also acceptable to other regulatory authorities party to the MAD agreement.

Existing chemicals- Agreement was recently reached for building the eChemPortal (http://www.oecd.org/ehs/eChemPortal) within a shorter time frame and for a consolidated approach adaptable to more countries' information systems. The eChemPortal will be an integrated system providing a gateway that, when fully operational, will allow users to search for information contained in government-generated and/or review assessment reports, and datasets on properties of chemicals. It will enable users to simultaneously query multiple sources of information on health and environmental effects data without initially having to go to each site separately.

eChemPortal (http://www.oecd.org/ehs/eChemPortal), launched by the OECD in June 2007, is an Internet gateway that provides direct access to information contained in government-generated and/or reviewed hazard assessment reports and datasets on the properties of chemicals. It allows users to simultaneously search multiple sources of information on health and environmental effects data prepared for government chemical review programs around the world without initially having to go to each site separately. Eight databases, including the US High Production Volume Information System (HPVIS), currently participate in the first phase of eChemPortal, where users search the databases by chemical name or CAS Registry Number. An outreach effort to encourage other countries and databases to participate in eChemPortal is ongoing. Work to design Phase 2 of eChemPortal, which will offer additional functionalities and advanced search capabilities is now underway.

OPPT scientists and policy analysts benefit greatly from being able to access chemical hazard information collected across the world in one step. Further, the public has the assurance that

they can easily and without cost view quality data that have been reviewed by governments and international organizations. In addition, work continues in completing OECD screening assessments on HPV chemicals. The OECD's work in testing and screening HPV chemicals served as the starting point for the HPV Challenge Program in the U.S. and domestic work to develop the HPV Information System contributed directly to the conception and realization of the eChemPortal.

Quantitative structure-activity relationships- Significant progress has been made in the last year on a validation principles document. A guidance document on validation was recently initiated. There is good progress on the (Q)SAR application toolbox project. The U.S. is recognized as the leader worldwide in the development and use of (Q)SAR assessment approaches for regulatory purposes. This experience was gained over several decades on new chemical assessments in the U.S.

Manufactured Nanomaterials- The United States hosted an OECD workshop on the safety of manufactured nanomaterials resulting in better cooperation, coordination and communication among interested countries. On the basis of the results of the workshop, the OECD agreed to establish a Working Party to advance this issue and invited the United States to chair the work.

United Nations Environmental Program (UNEP): POPs, PIC, SAICM and Mercury Program.

UNEP was established in 1972 under the United Nations system, and includes a chemicals unit tasked with helping governments take actions for the sound management of chemicals. UNEP supports the Stockholm Convention on Persistent Organic Pollutants (POPs), which is a global treaty to protect the environment from POPs. UNEP also jointly manages the Rotterdam Convention on Prior Informed Consent (PIC) with the Food and Agriculture Organization (FAO) of the United Nations to prevent the export of harmful pesticides and industrial chemicals unless the importing country agrees to accept them.

UNEP also serves as the Secretariat for the Strategic Approach to International Chemicals Management (SAICM). SAICM was developed in the context of the Rio Declaration, Agenda 21 and the Johannesburg Plan of Implementation (JPOI). The overall objective of SAICM is to achieve the sound management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment. OPPT is currently working with its counterparts in Canada and Mexico to facilitate a regional approach to SAICM implementation.

In February, 2003, UNEP initiated a global mercury program which will help less developed countries to better characterize and address their mercury pollution problems. OPPT and other EPA programs have also played a major role in shaping the UNEP global strategy for mercury to reduce risks to human health and the environment from the release of mercury and its compounds to the environment.

A series of partnerships proposed by the United States, and agreed to by governments in the 2005 UNEP Governing Council Decision 23/9, enlists the support of public and private stakeholders in building the scientific, technical and institutional capacity to reduce mercury use

and releases. EPA leads four international mercury partnerships in the areas of chlor-alkali, products, artisanal and small scale gold mining, and coal combustion; and participates in a fifth partnership on mercury transport and fate research.

OPPT leads the development of the global partnership on reducing mercury use in products. In cooperation with the North American Commission for Environmental Cooperation (CEC) and the UNEP Mercury Program, OPPTS worked with Canada and Mexico on the CEC Mercury Task Force to plan and host a workshop on reducing mercury use in products in Mexico in February 2006. The CEC-Americas workshop was attended by sixteen countries from North, Central and South America and the Caribbean. The workshop was successful in sharing information on useful tools and best practices for reducing mercury use in products and in identifying developing country needs in the Americas.

United Nations Economic Commission for Europe's (ECE) Convention on Long-Range Transboundary Air Pollution (LRTAP).

OPPT has been an active participant in the preparations for implementing a legally binding regional protocols, one protocol is for the elimination and/or control of persistent organic pollutants (POPs), and another protocol is for heavy metals (cadmium, lead and mercury). The regional protocols were developed under the ECE's 1979 Geneva Convention on Long-Range Transboundary Air Pollution.

North American Commission for Environmental Cooperation (CEC).

OPPT is involved in a number of regional undertakings that stem from the North American Agreement for Environmental Cooperation among the governments of Canada, Mexico, and the U.S. By working through the CEC's Sound Management of Chemicals (SMOC) Work Group, OPPT has assisted in the development of North American Regional Action Plans for several substances of international concern, including PCBs, mercury and dioxin.

TOOLS AND MODELS

OPPT has developed many different tools and models both to support its own staff analyses in implementing OPPT programs and regulations, as well as to help external users assess and manage chemical risks. Many of OPPT's tools and models can be used to provide estimates and predictions of certain risk assessment information where empirical data are unavailable or insufficient. Some of these focus on hazard information, estimating the physical or chemical properties of a substance, its environmental fate, or its toxicity. Others focus on estimating the potential for human exposure or assessing risk by examining both hazard and exposure.

Assessing Chemical Risk

Within the set of models intended to be applied in assessing chemical risk, OPPT has developed models for different uses. Screening-level tools by design require minimal data entry, rely on conservative estimates, and quickly screen hazard, exposure, and/or other data to prioritize chemicals for future work. One example is the Exposure-Fate Assessment Screening Tool (E-FAST) (http://www.epa.gov/oppt/exposure/pubs/efast.htm). This tool provides screening-level

estimates of the concentrations of chemicals released to air, surface water, and landfills, and those found in consumer products. It estimates potential inhalation and ingestion dose rates resulting from these releases. The modeled estimates of concentrations and doses are designed to reasonably overestimate exposures, for use in screening-level assessment (also see Appendix B, section B-6.4).

Estimating Hazard

OPPT has also developed models to estimate hazard to humans and the environment. For example, OncoLogic™ (http://www.epa.gov/oppt/newchems/tools/oncologic.htm) estimates the potential for a chemical to cause cancer in humans using the known carcinogenicity of chemicals with similar chemical structures, information on mechanisms of action, short-term predictive tests, epidemiological studies, and expert judgment (see Appendix B, section B-6.9). ECOSAR (Ecological Structure Activity Relationships) (http://www.epa.gov/oppt/newchems/tools/21ecosar.htm) estimates the aquatic toxicity of a chemical based on the known aquatic toxicity of chemicals having similar chemical structures (see Appendix B, section B-6.5).

Higher Tier Tools

Higher tier tools use more detailed data and more sophisticated models to closely simulate exposure or risk and produce results with a higher level of accuracy. These are complex and often require substantial, detailed data as input to the model. Where possible, data sets and default values are included with the model. A solid, technical background in science, chemistry, engineering or related disciplines is needed to appropriately use these tools. Examples of higher tier tools are the Multi-Chamber Concentration and Exposure Model (MCCEM) (http://www.epa.gov/oppt/exposure/pubs/mccem.htm) and the Wall Paints Exposure Assessment Model (WPEM) (http://www.epa.gov/oppt/exposure/pubs/wpem.htm).

MCCEM estimates average and peak indoor air concentrations of chemicals released from products or materials in houses, apartments, townhouses, or other residences, adjusting emissions data for indoor area volumes, interzonal air flows, whole-house exchange rates, and "sinks" (materials such as carpeting or wallboard that can absorb chemicals from the air) (also see Appendix B, section B-6.8). WPEM estimates the potential exposure of consumers and workers to the chemicals emitted from wall paint which is applied using a roller or a brush, based on paint emissions test data, and detailed use, workload, and occupancy data (also see Appendix B, section B-6.13).

Risk and Prevention Tools

OPPT also develops risk and prevention tools and models to help both internal and external users in risk management decision-making and pollution prevention opportunity assessment. For example, the PBT Profiler (http://www.epa.gov/oppt/sf/tools/pbtprofiler.htm) is a model that helps incorporate pollution prevention principles in the design and development of chemicals and promotes the selection and application of safer chemicals and processes by estimating the environmental persistence, bioconcentration potential, and aquatic toxicity characteristics of a chemical based on its chemical structure (also see Appendix B, section B-6.10).

Additional information on tools developed and used by OPPT is provided in Appendix D and Appendix B, section B-6.

OUTREACH AND COORDINATION

Outreach to Public and Stakeholders

OPPT's outreach efforts are extensive and varied. They may be characterized in terms of the chosen medium or mechanism as well as the target audience.

Mechanisms that OPPT currently employs to reach out to stakeholders include:

- National Pollution Prevention and Toxics Advisory Committee (NPPTAC) (http://www.epa.gov/oppt/npptac/)
- Publications (both printed and electronic) (http://www.epa.gov/oppt/pubs/opptpubs2.htm)
- Interactive Web sites
- Public dockets, Hotlines, and Clearinghouses of information (http://www.epa.gov/oppt/pubs/opptloc.htm)
- Media notices and events
- Workshops
- Sector-based and other initiatives

EPA Regions conduct outreach to stakeholders regarding new or changed requirements, develop projects and pilot programs, as well as promote pollution prevention objectives. Primary target audiences include the general public, environmental, public interest and animal welfare organizations, industry, and small business.
Many examples of outreach to the general public can be found on the OPPT website:

- The Lead Awareness Program (http://www.epa.gov/oppt/lead/pubs/leadpbed.htm) designs outreach activities and educational materials, awards grants, and manages a toll-free hotline to help parents, home owners, and lead professionals learn what they can do to protect families, and themselves, from the dangers of exposure to lead.

- The TSCA Assistance Information Service (TSCA Hotline) (http://www.epa.gov/oppt/pubs/opptloc.htm) provides both general and technical information on TSCA regulations and policies to a broad range of stakeholders.

- The National Lead Information Center Information (http://www.epa.gov/lead/pubs/nlic.htm), which provides information on lead hazards to the public, is funded by EPA, HUD, and CDC.

- The Pollution Prevention Information Clearinghouse (http://www.epa.gov/oppt/ppic/) is a free, nonregulatory service of the EPA dedicated to reducing or eliminating industrial pollutants through technology transfer, education, and public awareness (see Appendix B, section B-3.1.2). The Clearinghouse provides access to selected EPA documents, pamphlets, and fact sheets on P2, can answer questions about P2, and suggests appropriate contacts for additional information.

- Design for the Environment (DfE) (http://www.epa.gov/oppt/dfe/) (see Appendix B, section B-3.2.1), a voluntary partnership focused on industry outreach. DfE consists of programs that work directly with specific industry sectors to integrate health and environmental considerations into business decisions.

- Small Business Programs and Initiatives under OPPT's Pollution Prevention Program (for example, see Appendix B, section B-7.1.2) aim to streamline and coordinate technical assistance from small business development centers and to provide small businesses a voice in EPA's rulemaking process.

Coordination with Other Federal Agencies

OPPT coordinates with other Federal agencies, and briefs Congress and Congressional staff on its goals and objectives. TSCA §9 includes procedures under which EPA can refer the regulation of chemicals to other agencies and requirements to coordinate actions taken under activities with other Federal agencies "for the purpose of achieving the maximum enforcement of this act [TSCA] while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes." TSCA Title IV (http://www.access.gpo.gov/uscode/title15/chapter53_subchapteriv_.html) also requires EPA to coordinate with other Federal Agencies on certain lead related activities.

Various Federal agencies may regulate chemicals at different stages of their life cycles, and the agencies often work together. For example, the Occupational Safety and Health Administration (OSHA) identifies and controls the risks to workers in many industries from exposure to chemicals. The Consumer Product Safety Commission (CPSC) determines and manages the risks from chemicals in consumer products. OPPT coordinates and consults on an as-needed basis with numerous agencies, including:

- Food and Drug Administration (FDA)
- National Institute for Occupational Safety and Health (NIOSH)
- U.S. Department of Housing and Urban Development (HUD)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- National Institute of Environmental Health Sciences (NIEHS)
- National Toxicology Program (NTP)
- Mine Safety and Health Administration (MSHA)
- Federal Environment Executive (FEE)
- U.S. Geological Survey (USGS)
- General Services Administration (GSA)
- U.S. Department of Defense (DOD)
- Fish and Wildlife Service (FWS)
- U.S. Department of State (DOS)
- U.S. Department of Commerce (DOC)
- Office of the U.S. Trade Representative (USTR).

OPPT is part of two interagency committees that consider issues of cross-agency interest:

- The OSHA, MSHA, NIOSH, and EPA (OMNE) Committee, and
- Toxics and Consumer Products Committee (TAC), formed by EPA and CPSC.

TSCA Title IV requires EPA to coordinate with other Federal Agencies on certain lead related activities. Title IV requires HUD and EPA to jointly promulgate regulations on lead-based paint disclosure at time of lease or property transfer. Additionally, lead-based paint training and certification activities must include "... consultation with the Secretary of Labor, the Secretary of Housing and Urban Development and the Secretary of Health and Human Services (acting through the Director of the National Institute for Occupational Safety and Health)..." Also, the requirements of Title IV on lead abatement and measurement calls for EPA to cooperate and/or consult with HHS, CDC, NEIHS, NIOSH, ATSDR, HUD, CPSC and other appropriate "Federal Agencies." There is an Interagency Task Force that is co-chaired by EPA and HUD that has been meeting since 1989, three years before Title IV was past.

Coordination with States and Tribes

OPPT has continued to strengthen its partnership with State and Tribal leaders to increase understanding and improve collaboration among the States, Tribes and EPA on toxics and pollution prevention issues. EPA Headquarters and Regions work together with States, local governments, and Tribes, leveraging resources and expertise, in order to implement solutions to prevent pollution and reduce environmental risk. States and Tribes address environmental issues differently, particularly in their technical and legal capabilities to facilitate the implementation of standards and regulations developed by EPA and OPPT. Given this, OPPT has been tailoring more of its efforts to fit the differences of States and Tribes.

States

OPPT has formed networks with a number of state agencies and organizations to develop state capacity and delegated/authorized programs, to encourage, initiate and share innovative approaches, and to partner on program direction and implementation. For the national chemicals of concern (i.e., asbestos, PCBs, lead, mercury), OPPT interacts mostly with the health and environmental state agencies while on pollution prevention OPPT works with a range of state and related non-profit organizations of the state and local level. Two state organizations OPPT has dealt with routinely are the Environmental Council of the States (ECOS) (http://www.ecos.org/) and the National Pollution Prevention Roundtable (NPPR) (http://www.p2.org/).

EPA Headquarters and the Regions continue to support the work in the States in several ways, including grants, model programs, national meetings, technical assistance and program implementation. An example is in the area of the training and certification of lead-based paint contractors, where EPA has promulgated a model State program that may be used by States in setting up their own training/certification programs (see section 2.2 and Appendix B, section B-2.1.3).

In the past OPPT has worked with States through a cooperative agreement entitled Forum on State and Tribal Toxics Action (FOSTTA) (http://www.epa.gov/oppt/tribal/pubs/fostta.htm). Initiated in 1991, (see Appendix B, section B-7.2.1). FOSTTA served as a forum to help identify, discuss, and address the needs of States and Tribes in their efforts to manage toxic-related and pollution prevention problems.

As the priorities within OPPT evolve to include more focused efforts relating to lead reduction, pollution prevention solution implementation and chemical information management, a new framework approach is being put into action. This new framework will seek individual input from State and Tribal leaders via a range of approaches, including issue specific meetings and utilization of national meetings, and give OPPT flexibility in targeting issues in a timely manner.

OPPT and EPA Regions also work with States to implement many voluntary initiatives and programs. For example, to achieve the U.S. voluntary PCB decommissioning goals supported by OPPT, the Region 5 (Chicago) PCB Phasedown Program has been used as a model for nationwide efforts by implementing cooperative agreements and consultations with States and Tribes.

EPA also provides grants to the states and supports a network of state and regional technical assistance programs. The funds are used for technical assistance/training, education and outreach, regulatory integration, data collection, demonstration projects, and recognition programs. In addition, there are two key activities for which OPPT provides support:

- State Technical Assistance Centers (TAPs) (http://www.epa.gov/p2/pubs/assist/index.htm) - funded with state and federal funds, these centers provide technical assistance to businesses, particularly small businesses
- P2 Resource Exchange Centers (P2Rx) (http://www.p2rx.org/P2InfoNexpert/TopicHubs_2.cfm) - a national network of eight regional centers which support the state TAPs by supplying high quality, web-based P2 resources

Other state technical assistance programs are discussed in Appendix B, section B-7.1.1.

Tribes

OPPT has established a tribal program to better communicate with Native American Indian Tribes and Alaska Native Villages to build more effective partnerships to protect and safeguard the environment. OPPT is continuing to build a stronger partnership with Tribal leaders to identify priority areas to more effectively implement toxics and pollution prevention (P2) programs in Indian Country.

OPPT has worked with the Office of Pesticide Programs (OPP) to develop the OPPTS Tribal Strategic Plan (2004-2008) (http://www.epa.gov/oppts/pubs/tribal/tribalplan_signsep804Final.pdf). This plan was developed with input from the Tribes through Tribal focus and listening sessions around the country, written communications with the federally recognized Tribes and through the EPA's Tribal Advisory groups (i.e., National Tribal Operations Committee). OPPT is currently in its

fourth year of implementing the Strategy and has in various stages checked back in with Tribes regarding the implementation of the Strategy goals.

OPPT. This commitment is evidenced in our work with the Tribal Operations Committee (TOC) and FOSTTA (http://www.epa.gov/oppt/tribal/pubs/fostta.htm) and will continue with the new framework. As noted above, FOSTTA served as a forum to help identify, discuss, and address the needs of States and Tribes in their efforts to manage toxic-related and pollution prevention problems. The new framework will focus on chemical and, prevention, issues including lead control and abatement, subsistence food and hazard communications, and outreach. Through the input received from this group, OPPT will obtain a better understanding of the Tribes' unique issues.

Activities of the OPPT Tribal program include the implementation of work activities under the Tribal Strategy, publication of a tribal newsletter (copies are available online at http://www.epa.gov/oppt/tribal/pubs/index.html), grants funding, training for OPPT staff and managers on Tribal issues, follow-up activities from EPA's Tribal Operations Council meetings, interagency coordination efforts, and stakeholder outreach. OPPT has also issued numerous lead and pollution prevention grants to Tribes.

OPPT develops regulations, policies, and guidance for national chemicals of concern, including lead, asbestos, PCBs, and mercury. A few examples of OPPT Headquarters and regional support for and/or collaboration with Tribes in these areas include the development of a Lead Community Tool Kit specifically for Native American communities, a lead poisoning prevention manual for Tribal day care centers and families, listening sessions with Tribal representatives regarding mercury as the Agency develops its action plan, tribal assessment of dioxin levels in Lake Superior, a workshop for Tribes in New Mexico on building PBT awareness.

Currently, Region 5 is conducting a pilot program to implement a tribal cooperative agreement with a Tribe in Wisconsin. One Tribe will provide outreach, inspections, and compliance assistance services for several neighboring Tribes. This pilot activity will serve as a model to be replicated by other Tribes in the future.

In 2006, the National Tribal Lead Workgroup was established to identify and work toward the elimination of lead hazards in Indian Country by creating effective partnerships with Tribal governments and communities, EPA Program Offices, and other federal agencies. The National Tribal Lead Workgroup developed a strategy document with activities such as promoting comprehensive data collection, evaluating and supporting pilot programs and methods, training, and information exchange. The intent of developing this document is to implement the OPPTS Tribal Strategy.

Pollution prevention is another key focus of OPPT's work with the Tribes. OPPT has worked with the Partnership for Environmental Technology Education (PETE) to recognize community and technical colleges as an important national resource for workforce development, small business outreach, and public information. Tribal colleges across the country are important members of the PETE network, adding new "tribal perspectives" to environmental curricula and building the capacity of Native American environmental professionals.

Another example of promoting P2 in Indian country is the effort to develop a Tribal sector hub in the Pollution Prevention Resource Exchange (http://www.p2rx.org/) to support Tribal pollution prevention collaboration and technical assistance. OPPT has enlisted the support of a Tribal 8A contracting firm that is working on a marketing strategy for P2 green building design. The framework document that is currently being produced will highlight economic advantages of green buildings. The document will contain geographic-specific information that will aid users in narrowing their choices of building materials. The document will also include case studies highlighting the construction of green buildings in Indian country. In addition, plans call for development of a software tool that will enable Tribes to integrate cost and geographic data to further facilitate green building decision making.

March 2008

Appendices To

Overview:
Office of Pollution Prevention and Toxics
Laws and Programs

Appendices

Appendix A:

Organizational Charts for EPA and OPPT

Appendix A: Organizational Charts for EPA and OPPT

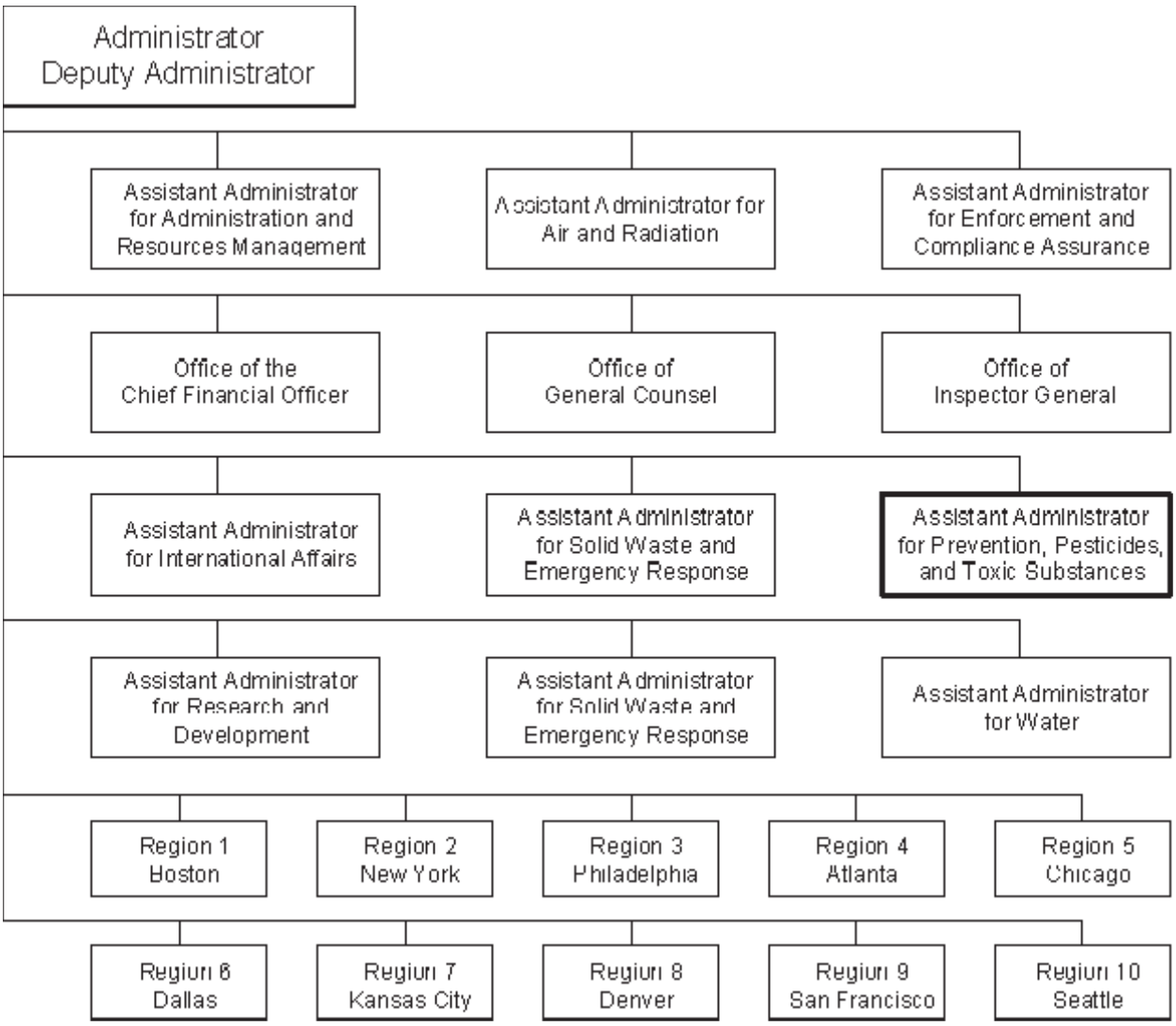
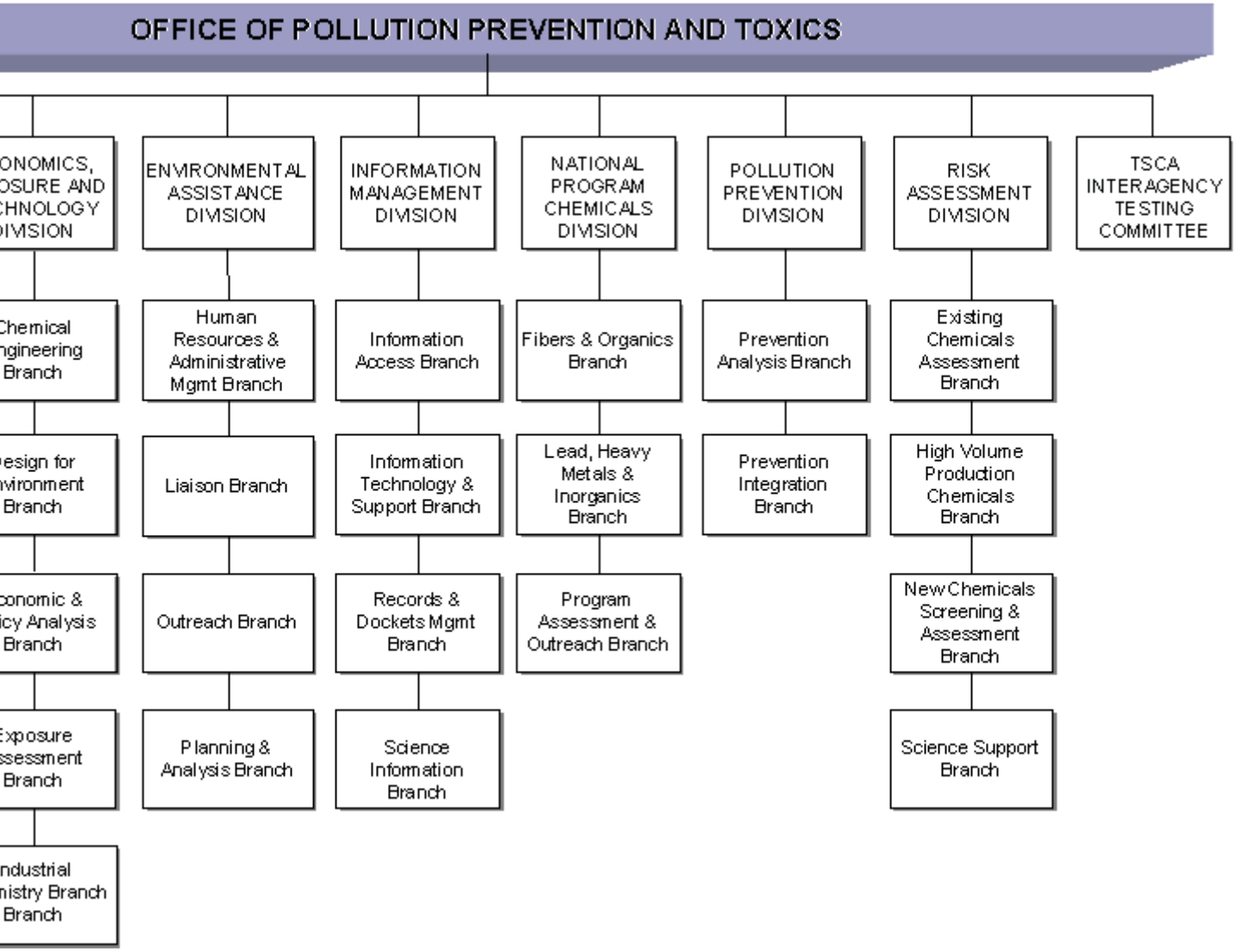


Figure A-1. U.S. EPA Organizational Chart

For more information about EPA's organizational structure, visit http://www.epa.gov/epahome/organization.htm.



Organizational Chart

rmation about OPPT's organizational structure, visit http://www.epa.gov/oppt/pubs/opptdiv.htm.

Appendix B:

Supplementary Information on OPPT Programs

Appendix B - Table of Contents

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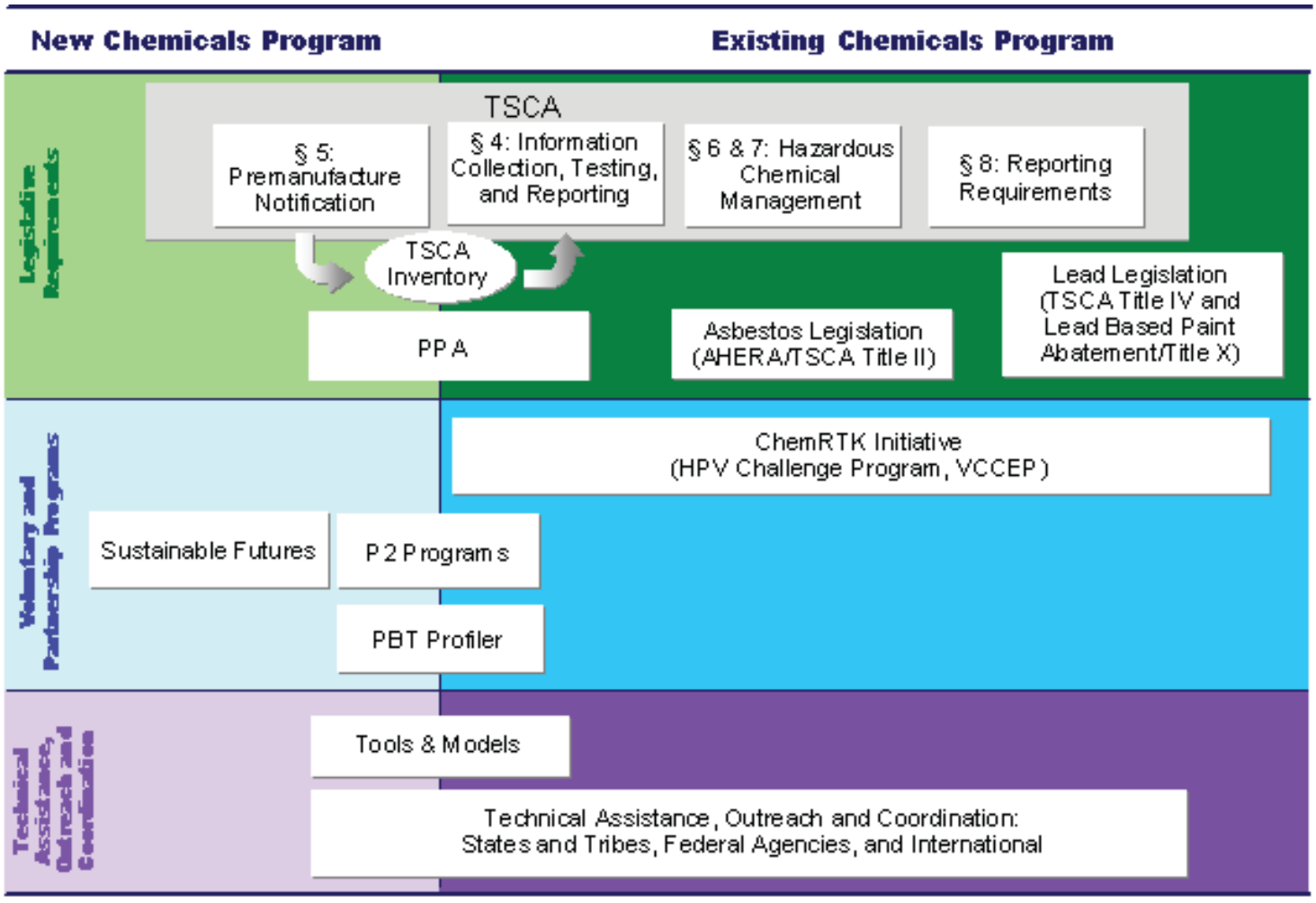
Appendix B: Supplementary Information on OPPT Programs

A table of links to EPA source information on a given topic, is included in Appendix D, "Source Information and Additional Web Resources."

B-INTRODUCTION

Appendix B provides supplementary information on selected OPPT policies and programs discussed in the preceding report. An overview of OPPT's framework for chemical management, within the context of the New and Existing chemicals programs, is illustrated in Figure B-1. OPPT's voluntary and partnership programs complement OPPT's legislative foundation. OPPT's technical assistance, coordination, and outreach efforts support both the voluntary and regulatory efforts.

Figure B-1. Overview of OPPT's Framework for Chemical Management: Legislative, Voluntary, Technical Assistance, Outreach, and Communication Efforts



B-1 THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

The best authority for information about TSCA is the Act itself and the regulations that are published by EPA at 40 CFR Part 700 through Part 799. Specific legislative citations for key provisions under TSCA are provided in Appendix C of this document. A copy of the Act is included in Appendix E.

B-1.1 THE TSCA CHEMICAL SUBSTANCE INVENTORY

The TSCA Inventory, available on CD-ROM, is updated every six months. EPA does not provide searches of the non-confidential TSCA Inventory, but there are a number of ways to research whether a chemical is listed on the non-confidential portion of the TSCA Inventory:

- Many public libraries and company libraries have copies of the TSCA Inventory. In addition, the Inventory is available at federal depository libraries. To find the closest federal depository library, call your local library or look in the Directory of U.S. Government Depository Libraries.

- Assistance in determining whether a chemical substance is on the TSCA Inventory is available on a fee basis from at least two organizations: the Chemical Abstracts Service (CAS) and Dialog. To request assistance, phone CAS at (800) 848-6538 or Dialog at (800) 334-2564. Other companies may offer similar services in the future; contact the TSCA Hotline at tsca-hotline@epa.gov or at (voice) 202-554-1404, (fax) 202-554-5603 for an up-to-date list.

- A copy of the TSCA Inventory can be purchased from the National Technical Information Service (NTIS):

  NTIS: (703) 487-4650 TSCA Inventory: searchable CD-ROM database, includes also SARA Title III; or through the NTIS Web site

- Cornell University has posted an extract of the Public Inventory at http://msds.pdc.cornell.edu/tscasrch.asp. Though the University's posting is not an official government version of the Inventory, it can be useful.

The identity of an existing chemical that has been claimed as confidential business information will not be listed on the public portion of the TSCA Inventory. Most TSCA Inventory substances are in the non-confidential version of the Inventory. A majority of the substances now being added through commenced PMNs, however, are confidential.

EPA will search the confidential portion of the TSCA Inventory if a bona fide intent to manufacture or import the chemical substance is demonstrated in writing (40 CFR 720.25).

B-1.2 NEW CHEMICALS PROGRAM (TSCA §5)

The TSCA New Chemicals Program (NCP) is responsible for reviewing new chemical substances prior to their entry into U.S. commerce.

B-1.2.1 Premanufacture Notification

There are many specific PMN requirements under TSCA §5 (40 CFR 700, 720, 723, 725, 747). There are several exclusions and exemptions from the PMN requirements (40 CFR 723). TSCA §3(b) specifically excludes certain substances including mixtures (individual substances comprising the mixtures are not exempted); substances manufactured solely for use as pesticides, food, food additives, drugs, or cosmetics; tobacco and tobacco products; nuclear source materials; firearms and ammunition; impurities; byproducts that have no commercial use; non-isolated intermediates; and chemical substances manufactured solely for export (40 CFR 720.3(e) and (u)). Many of these substances are covered under other regulations.

EPA provides industry with five possible exemptions under the new chemicals program. Each of these exemptions has specific reporting requirements which are unique to the exemption class. The five possible exemptions are:

1) The low volume exemption (LVE) applies to those who manufacture or import 10,000 kilograms or less a year of a chemical substance (40 CFR 723.50);
2) Manufacturers that meet certain criteria may be eligible for the low release and exposure exemption (LoREX), which is not dependent on production volume (40 CFR 723.50 (c));
3) The polymer exemption applies to polymers that meet specific criteria for composition, molecular weight, and degradation (40 CFR 723.250);
4) Chemicals produced in small quantities solely for experimental or research and development purposes (R&D) also qualify for an exemption if manufactured and distributed under certain conditions (40 CFR 720.36); or
5) Manufacturers that plan to produce a chemical solely for test marketing may qualify for an exemption (40 CFR 720.38).

An overview of the PMN process is provided in Figures B-2, B-3, and B-4 below.

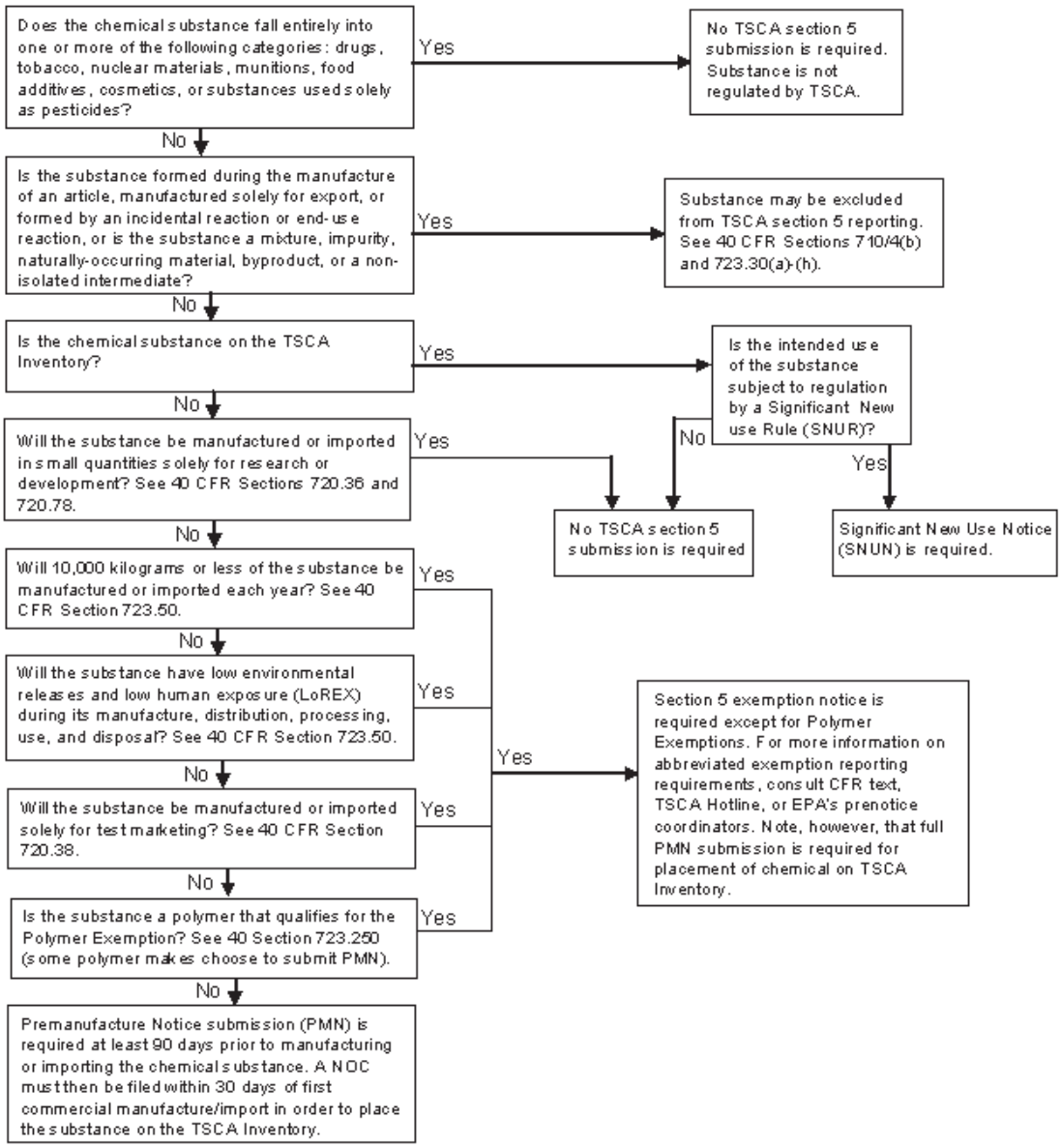


Figure B-2. Overview of New Chemical Handling under TSCA

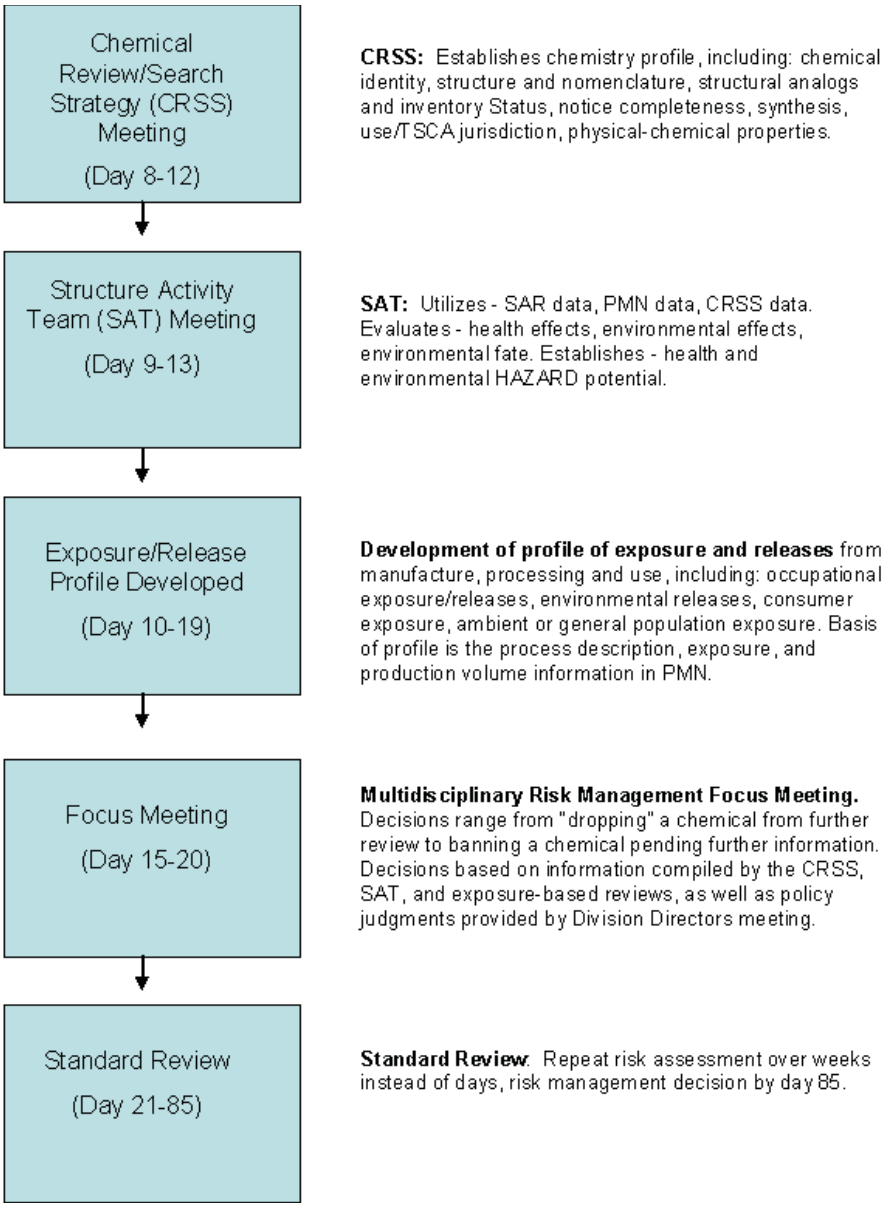


Figure B-3. Overview of the PMN 90-day Review Process

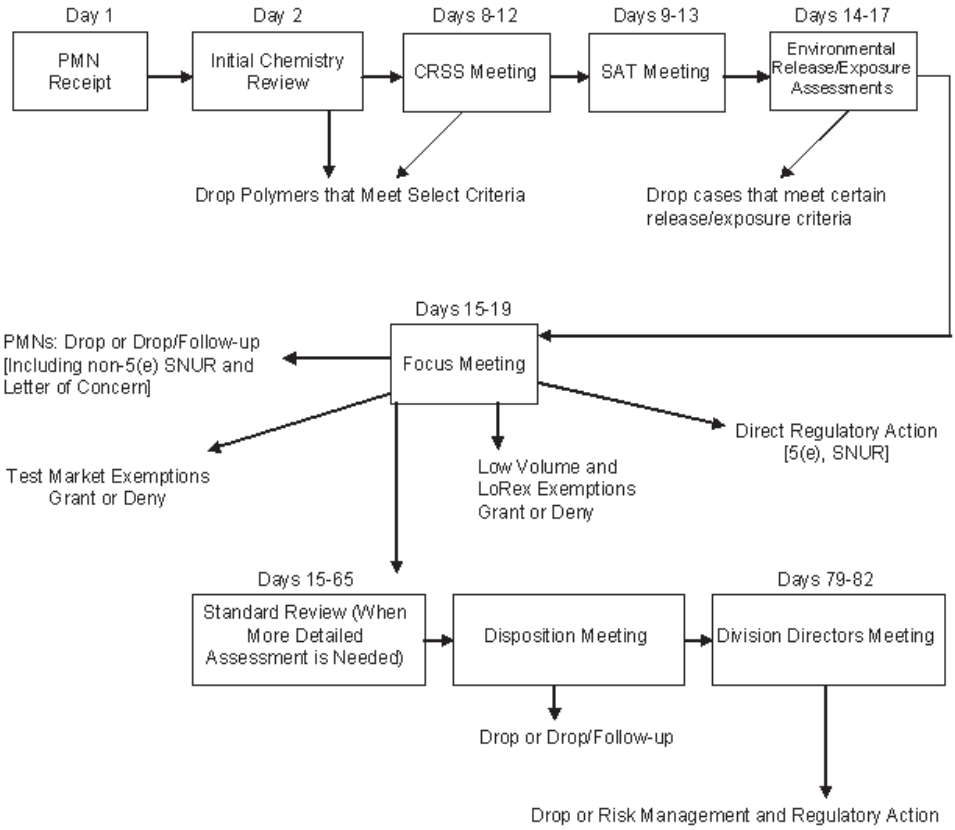


Figure B-4. Outcomes of the PMN 90-day Review Process (Source: USEPA, 1997. Chemistry Assistance Manual for Premanufacture Notification Submitters)

B-1.2.2 EPA/European Union (EU) Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships [(Q)SAR]

In October 1989, the Organization for Economic Cooperation and Development (OECD) organized, in the context of that organizations chemicals program, a workshop on notification schemes for new chemicals applied by the Member Countries of the OECD.

One of the most important recommendations from the OECD workshop was that an attempt be made to evaluate the predictive power of the (Q)SAR method, used by the EPA, in comparison to the results obtained by the EU in its minimum pre-marketing data set (MPD). It was also recommended that this evaluation be achieved by applying the (Q)SAR methods to chemicals for which screening level test data were already available and then comparing the properties predicted by SAR with the properties observed from experimental testing. This recommendation was the starting point for the collaborative project between the EU and EPA. The project was limited to evaluation of the predictive power of the (Q)SAR techniques used by EPA in the context of new chemicals, and was not designed to be an evaluation of (Q)SAR techniques in general.

Looking at the overall results of the study, EPA noted that the physical/chemical properties generally appear to be the most difficult to predict accurately, but are among the most inexpensive to measure. On the other hand, prediction of health hazards appears reasonably good, although there is an issue with the prediction of systemic toxicity, which the EPA systems tend to under-predict. Targeted

testing may offer a cost effective alternative to use of a standard test battery. EPA's ecotoxicity predictions appear to be reasonably accurate in assessing acute toxicity for fish and daphnia.

This project provided a unique opportunity to gain insight into the strengths and weaknesses of the SAR approach used by EPA versus the MPD approach of the EU in assessing the potential fate and effects of new chemicals. Analysis of the results of this study have shown that while the SAR approach has largely been successful in identifying chemicals of concern, the process could be improved by selectively incorporating specific testing schemes into the process. Results from such schemes would serve two purposes: to gain insight into chemical toxicities and to improve predictive capabilities. Improving predictive capabilities would result in better hazard assessment for new chemicals by providing richer data base upon which to base predictions as to their fate and effects. These enhanced capabilities would also serve to avoid questionable testing requirements and thus spare manufacturers the cost of such testing while not compromising worker, consumer or environmental safety. Such a focused effort would provide valuable data while not presenting large overall cost implications.

B-1.2.3 Managing Genetically Engineered Microorganisms as New Chemicals (TSCA Biotechnology Program)

Oversight of certain new microorganisms is implemented under TSCA §5 in accordance with the 1997 "Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act." The risks of these microorganisms are reviewed prior to their commercial use or importation, and weighed against potential benefits to society.

Microorganisms that are reviewed under TSCA must meet all of the following criteria:

- The microorganism is intended for commercial use
- The microorganism is not on the TSCA Inventory
- The microorganism is "intergeneric": it is the result of the deliberate introduction of genetic material from one organism into a microorganism from a different genus than that of the donor/source organism. For example, a *Pseudomonas* bacterium into which *Escherichia coli* DNA has been deliberately introduced would be considered intergeneric
- The microorganism is not subject to review by other Federal Agencies (e.g., FDA reviews pharmaceuticals, etc.). Microorganisms subject to TSCA review include those used in applications such as bioremediation, fuel production, biomass conversion, nitrogen fixation, biosensors, and closed system fermentation for the production of enzymes and specialty chemicals.

Prior to the manufacture or importation of an intergeneric microorganism subject to TSCA, OPPT must receive an appropriate submission. Within the specified statutory time frame, which varies according to the type of submission, staff in OPPT conduct a risk assessment on the microorganism. In order to obtain the correct information from submitters for the risk assessment, OPPT provides a "Points to Consider" document that addresses information needs such as: taxonomic identity of organisms used, genetic modifications, health effects, ecological effects, exposure to workers, releases to the environment, and fate of the microorganism in the environment (available at http://www.epa.gov/biotech_rule/pdf/ptcbio.pdf).

Microorganisms intended for intentional release to the environment for applications such as in agriculture often trigger more extensive information requests. However, there are several types of abbreviated submissions and exemptions for microbial products which are enumerated in the 1997 Rule that require little or no new risk assessment information from the submitter.

Examples of microorganisms reviewed include rhizobia (type of bacteria) for enhanced nitrogen fixation in alfalfa, pseudomonads (again, type of bacteria) for degradation of hazardous wastes, and many bacteria and fungi for closed system production of enzymes.

B-1.3 DATA DEVELOPMENT AND DATA COLLECTION ACTIVITIES FOR EXISTING CHEMICALS

B-1.3.1 TSCA Interagency Testing Committee

The TSCA Interagency Testing Committee (ITC) (http://www.epa.gov/oppt/itc/), established under TSCA §4(e), is an independent advisory committee to the EPA Administrator that was created to identify TSCA chemicals for which there are suspicions of toxicity or exposure and for which there are few, if any, ecological effects, environmental fate, or health effects testing data.

The ITC adds such chemicals to the TSCA §4(e) Priority Testing List and recommends them for testing or information reporting to the EPA Administrator to meet the data needs of its U.S. government member organizations. In response to ITC's recommendations, the EPA promulgates automatic final rules under TSCA §8 and the Administrator gives priority consideration to ITC's chemicals for the development of test rules under TSCA §4. The rules that EPA promulgates under TSCA §8 are unique to the ITC, because they are promulgated as automatic final rules for which data must be submitted within 90 days of their *Federal Register* publication date. At the ITC's request, the EPA adds chemicals to the TSCA §8(a) Preliminary Assessment Information Reporting (PAIR) rule to obtain production, processing and worker exposure information (see section B-1.3.3 for additional information on the PAIR Rule). In addition, at the ITC's request, the EPA adds chemicals to the TSCA §8(d) Health and Safety Data Reporting (HaSDR) rule to obtain unpublished studies on ecological effects, environmental fate and health effects (see section B-1.3.4 for additional information on TSCA §8(d)).

The ITC includes representatives from many U.S. Government organizations:

- Agency for Toxic Substances and Disease Registry (ATSDR),
- Presidents Council on Environmental Quality (CEQ),
- U.S. Consumer Products Safety Commission (CPSC),
- U.S. Department of Commerce (DOC),
- U.S. Department of Defense (DOD),
- U.S. Department of the Interior (DOI),
- U.S. Environmental Protection Agency (EPA),
- U.S. Food and Drug Administration (FDA),
- National Cancer Institute (NCI),
- National Institute of Environmental Health Sciences (NIEHS),

- National Institute for Occupational Safety and Health (NIOSH),
- National Science Foundation (NSF),
- National Toxicology Program (NTP),
- Occupational Safety and Health Administration (OSHA), and
- U.S. Department of Agriculture (USDA).

B-1.3.2 Master Testing List

The Master Testing List (MTL) presents a consolidated listing of OPPT's existing chemical testing priorities under TSCA, as well as those brought forward to OPPT by other EPA Program Offices, other Federal agencies, the Organization for Economic Cooperation and Development (OECD), and the TSCA Interagency Testing Committee (ITC). In addition to identifying chemical testing needs of the Federal government (including EPA) and international programs of interest to the U.S. (e.g., the OECD HPV SIDS Program), and focus limited EPA resources on the highest priority chemical testing needs, OPPT also uses the MTL to: (1) identify and publicize EPA's testing priorities for industrial chemicals, (2) obtain broad public comment on EPA's Chemical Testing Program and its priorities, and (3) encourage voluntary initiatives by members of the U.S. chemical industry to provide EPA with the priority data identified in the MTL. The MTL also includes information about EPA's TSCA New Chemicals Program (NCP). Additional information about the contributions of the TSCA NCP to the EPA's overall TSCA Chemical Testing Program are expected to appear in future iterations of the MTL.

B-1.3.3 TSCA §4(a)(1)(B) Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure

On April 12, 1990, the Fifth Circuit Court of Appeals remanded to EPA the TSCA §4 test rule for the cheminal cumene, based on a challenge to this rule by the Chemical Manufacturers Association (CMA), *Chemical Manufacturers Association v. Environmental Protection Agency* 899. F.2d 344 (5th Cir. 1990). The Fifth Circuit Court of Appeals required EPA to articulate criteria for the findings EPA made in the cumene test rule (53 FR 28195, July 27, 1988). That is to say, the Court required the Agency to "articulate the standards or criteria on the basis of which it found the quantities of cumene entering the environment the environment from the facilities in question to be 'substantial'." EPA decided to use this opportunity to articulate criteria for all findings under §4(a)(1)(B)(I) of TSCA.

In May of 1993, EPA articulated standards and criteria for making findings it would use in implementing its authority under TSCA §4(a)(1)(B)(I). Under this policy, EPA will use as guidance threshold amounts to make "substantial" production, release, and human exposure findings under TSCA §4(a)(1)(B). However, EPA may also make such findings in situations where the quantitative numerical thresholds are not met if additional factors exist. EPA will continue to develop and refine the criteria as its experience with chemical substances and mixtures (chemicals) considered for testing evolves, particularly with regards to the findings of "significant" human exposure, for which EPA has not established a minimum numerical threshold.

The "B" Policy. Section 4(a)(1)(B)(I) requires the Administrator to find that 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," to impose testing requirements. However, TSCA does not define the criteria or standards to be used, or the meanings of the words "significant" or "substantial." Additionally, the legislative history of TSCA provides no elucidation of these terms.

EPA received written comments on the criteria and standards it intended to use in implementing the "B" policy from a majority of the chemical industries trade groups and from other Federal agencies. On the policy as a whole, the Chemical Manufacturers Association (now American Chemistry Council), commented that EPA's proposed criteria under TSCA §4(a)(1)(B)(I) are reasonable as a basis for requiring screening tests such as the Screening Information Data Set (SIDS) utilized by the Organization for Economic Cooperation and Development (OECD) for high production volume (HPV) chemicals. The U.S. Department of Labor's Occupational Safety and Health Administration (DOL/OSHA), and the U.S. Department of Health and Human Services's National Institute for Occupational Safety and Health (HHS/NIOSH), argued that the thresholds for "substantial human exposure" should be lower than those proposed by EPA.

Findings.

- ***Substantial Production.*** EPA established a threshold value of 1 million pounds, aggregate production volume of the substance per year of all manufacturers, as the substantial production threshold.

- ***Substantial Release.*** EPA established a threshold value of 1 million pounds of release to the environment from all sources per year, or release equal to or greater than 10 percent of production volume per year, whichever is lower, as the threshold for substantial release.

  The percentage threshold reflects EPA's concern about chemical releases that are a sizeable percentage of the production volume of that chemical. EPA believes that when such a sizeable percentage of a chemical's production volume is released, that release should be considered "substantial" for that chemical substance.

- ***Substantial or Significant Human Exposure.*** It is EPA's belief that TSCA §4(a)(1)(B) was intended to address situations where large numbers of people may be exposed to a chemical substance and where little or no hazard data exists to indicate whether or not that chemical substance may present an unreasonable risk. EPA based its thresholds for workers on experience gained through case-by-case analysis of existing chemicals:

  - General population:
    substantial: 100,000 people
    significant: <100,000 people exposed more directly or on a routine or episodic basis
  - Consumers:
    substantial: 10,000 people
    significant: <10,000 people exposed more directly or on a routine or episodic basis

- Workers:
  substantial: 1,000 workers
  significant: <1,000 workers exposed more directly or on a routine or episodic basis.

The different numeric thresholds for workers, consumers, and general population are EPA's attempt to reflect the inherent differences in the probable exposure scenarios for particular categories of individuals. EPA decided to apply a differential equal to one order of magnitude between the worker, consumer, and general population thresholds. EPA believes that these criteria are a reasonable interpretation of the phrase "significant or substantial human exposure" in TSCA section 4(a)(1)(B)(i)(II).

- ***Additional Factors.*** EPA applies these generic thresholds for most substances considered for testing under TSCA §4(a)(1)(B). In some cases, however, where the thresholds are not met, it may be more appropriate to use a case-by-case approach for making findings by applying other considerations. EPA may consider "additional factors" (i.e., bioconcentration) for making findings for substances which do not meet the numerical thresholds for evaluating existing chemicals under TSCA §4(a)(1)(B).

B-1.3.4 Collecting Information to Evaluate Potential Risks of Existing Chemicals (TSCA §8)

Preliminary Assessment Information Reporting (PAIR) Rule. Under PAIR (40 CFR 712), producers and importers of a listed chemical are required to report the following site-specific information on a two-page form:

- Quantity of chemical produced and/or imported;
- Amount of chemical lost to the environment during production or importation;
- Quantity of enclosed, controlled, and open releases of the chemical;
- Per release, the number of workers exposed and the number of hours exposed.

Exemptions for such reporting are as follows:

- Production or importation for the sole purpose of research and development (R&D);
- Production or importation of less than 500 kilograms during the reporting period at a single plant site;
- Companies whose total annual sales from all sites owned by the domestic or foreign parent company are below $30 million for the reporting period and who produced or imported less than 45,400 kilograms of the chemical;
- Production or importation of the listed chemical solely as an impurity, a non-isolated intermediate, and under certain circumstances as a by-product.

The PAIR Rule is generally used to meet the information needs of the Interagency Testing Committee (ITC).

Allegations of Significant Adverse Reactions Rule (TSCA §8(c)). EPA's TSCA §8(c) rule requires producers, importers, and certain processors of chemical substances and mixtures to keep records concerning allegations of significant adverse reaction to health or the environment, and to report those records to EPA upon notice in the Federal Register or upon notice by letter (40 CFR 717). An "allegation" is defined as "a statement, made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment." "Significant adverse reactions" are defined as "reactions that may indicate a substantial impairment of normal activities, or long lasting or irreversible damage to health or the environment."

Any person can make a written or verbal allegation. Verbal allegations must be transcribed either by the company or the individual making the allegation (if transcribed by the individual, they must be signed). To be recordable, allegations must implicate a substance that caused the reaction by naming either the specific substance, a mixture or article containing the substance, or a company process in which substances are involved, or identifying a discharge from a site of manufacture, processing, or distribution of the substance.

Examples of significant adverse reactions include:

- Long-lasting or irreversible damage to human health;
- Partial or complete impairment of bodily functions;
- Impairment of normal activity by all/most persons exposed at one time/each time an individual is exposed;
- Gradual or sudden changes to animal or plant life in a given geographic area;
- Abnormal numbers of deaths/changes in behavior or distribution of organisms;
- Long lasting or irreversible contamination of the physical environment.

Allegations that are "exempt" from the requirements of the TSCA §8(c) rule include:

- Those alleging "known human effects;"
- Allegations involving adverse reactions to the environment if the alleged cause can be directly attributable to an incident of environmental contamination that has already been reported to the U.S. government under any applicable authority; and
- Anonymous allegations.

TSCA §8(c) records must be filed by alleged cause and kept at a company's headquarters or at a site central to their chemical operations. An allegation made by an employee must be kept by the company for 30 years, while all other allegations (e.g., those made by plant site neighbors or customers) must be kept by the company for 5 years. The record must contain the following information:

- The original allegation as received;
- An abstract of the allegation;
- The results of any self-initiated investigation regarding the allegation; and

- Copies of any further required information regarding the allegations (e.g., copies of any reports required to be made to the U.S. Occupational Safety and Health Administration).

Unpublished Health and Safety Studies Rule (TSCA §8(d)). Under TSCA §8(d), EPA has the authority to promulgate rules to require producers, importers, and processors to submit lists and/or copies of ongoing and completed, unpublished health and safety studies. EPA has identified in 40 CFR Part 716 many chemical substances and categories subject to these requirements. Chemicals that have been added to the TSCA §4(e) Priority List by the TSCA Interagency Testing Committee (ITC) may be added to the §8(d) rule within 30 days' notice to that effect in the Federal Register (up to 50 substances/year). Non-ITC chemicals can be added to the §8(d) rule via notice and comment rulemaking.

The term "health and safety study" is intended to be interpreted broadly and means "any study of any effect of a chemical substance or mixture on health or the environment or on both," including but not limited to:

- Epidemiological or clinical studies;
- Studies of occupational exposure;
- Toxicological and clinical studies; and
- Ecological studies.

EPA will specify in the rule: the specific type(s) of health and safety data needed; the chemical grade/purity of the test material; and any specifics concerning mixtures covered by the rule.

Persons who must report under the TSCA §8(d) rule include:

- Manufacturers (including importers) who are classified in the "chemical manufacturing and allied products" subsection of the North American Industry Classification System, who either proposed to manufacture (including importing), or did/does manufacture the listed substance or mixture: (a) in the ten years preceding the effective date that a substance or mixture is added to the rule, (b) as of the effective date of the rule, or (c) after the effective date of the rule, and
- Other manufacturers and processors who may be specifically identified by EPA rule.

Once a chemical substance or mixture is added to the rule, reporting obligations terminate (i.e., sunset) no later than 2 years after the effective date of the listing of the substance or mixture, or on the removal of the substance or mixture from the rule.

Unpublished studies on listed substances or mixtures are potentially reportable (i.e., studies may be subject to either copy submission requirements or listing requirements). Generally, copies of studies possessed at the time a person becomes subject to the rule must be submitted, and the following categories of studies must be listed:

- Studies ongoing as of the date a person becomes subject to the rule (copies must be submitted when completed);

- Studies initiated during the 60-day reporting period (copies must be submitted when completed);
- Studies that are known as of the date a person becomes subject to the TSCA §8(d) rule, but not possessed; and
- Studies previously sent to U.S. government agencies without confidentiality claims.

Substantial-risk Information Requirement (TSCA §8(e)). The term "substantial risk" information refers to that information which reasonably supports a conclusion that the subject chemical or mixture presents a substantial risk of injury to health or the environment; however, such information need not and most typically does not establish conclusively that a substantial risk exists. TSCA §8(e) states that "any person who manufactures [including imports], processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information" (90 Stat. 2029, 15 U.S.C. 2607(e)). EPA has issued guidance under §8(e) stating that anyone covered under the above reporting requirement must report that information to EPA within 30 calendar days of obtaining it. The information may include toxicity and/or exposure data and need not be complete or definitive. Limited studies (e.g., range finding studies), preliminary results, and draft reports may constitute sufficient evidence for §8(e) reporting. Under EPA's guidance, information that has been published or submitted to EPA under other authorities is exempt from §8(e) reporting.

In deciding whether information is "substantial risk" information, one should consider 1) the seriousness of the adverse effect, and 2) the fact or probability of the effect's occurrence. In determining TSCA §8(e)-applicability/reportability, these two criteria should be weighted differently depending upon the seriousness of the effect or the extent of the exposure, i.e., the more serious the effect, the less heavily one should weigh actual or potential exposure, and vice versa. For example, in cases where serious effects such as birth defects or cancer (as evidenced by benign and/or malignant tumors) are observed, the mere fact that the implicated chemical is in commerce (including chemicals at the research and development stage) constitutes sufficient evidence of exposure to submit the new-found toxicity data.

The decision-making process for §8(e)-reportability should focus primarily on whether the toxicity or exposure information offers reasonable support for a conclusion of substantial risk under the criteria described above, but should not focus at all on whether the information is conclusive regarding the risk. A decision to report information to the Agency under §8(e) should not involve exhaustive health and/or environmental risk assessments of the subject chemical(s). Further, determining reasonable support for a conclusion of substantial risk should not include any evaluation of either the economic or social benefits of the use(s) of the subject chemical substance(s). Finally, determining whether reasonable support exists for "substantial risk" is not synonymous with the determination of an "unreasonable risk" as that term is used elsewhere in TSCA.

EPA has received §8(e) submissions alerting the Agency that chemical substances already known to be capable of causing serious health and/or environmental effects were detected in significant amounts in environmental media (e.g., soil, surface waters, groundwater, air (including workplace

air)) or in products not known previously by the Agency to contain such chemicals. In such cases, the discovery of previously unknown and significant human and/or environmental exposure, when combined with knowledge that the subject chemical is already recognized as or suspected of being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity) or serious environmental effects (e.g., non-trivial aquatic species toxicity), can provide a sufficient basis to report the new-found exposure data to EPA under §8(e) of TSCA.

B-1.3.5 Overview of the OPPT Existing Chemical Review and Assessment Process

Following is a description of the OPPT existing chemical review and assessment process, which is also shown in Figures B-5 and B-6.

Initial Steps. The process is illustrated with a description of assessment activities that begin with the submission of materials from companies participating in a voluntary program (Figure B-5) or following TSCA §8(e) reporting requirements (Figure B-6), or identification of chemicals of interest by EPA. Company submissions may include test plans, summaries of existing data, or reports of potential hazard. Flow diagrams for the HPV Challenge Program and the TSCA §8(e) submission review process are included.

Receipt. Logging in and distribution, following CBI requirements as necessary.

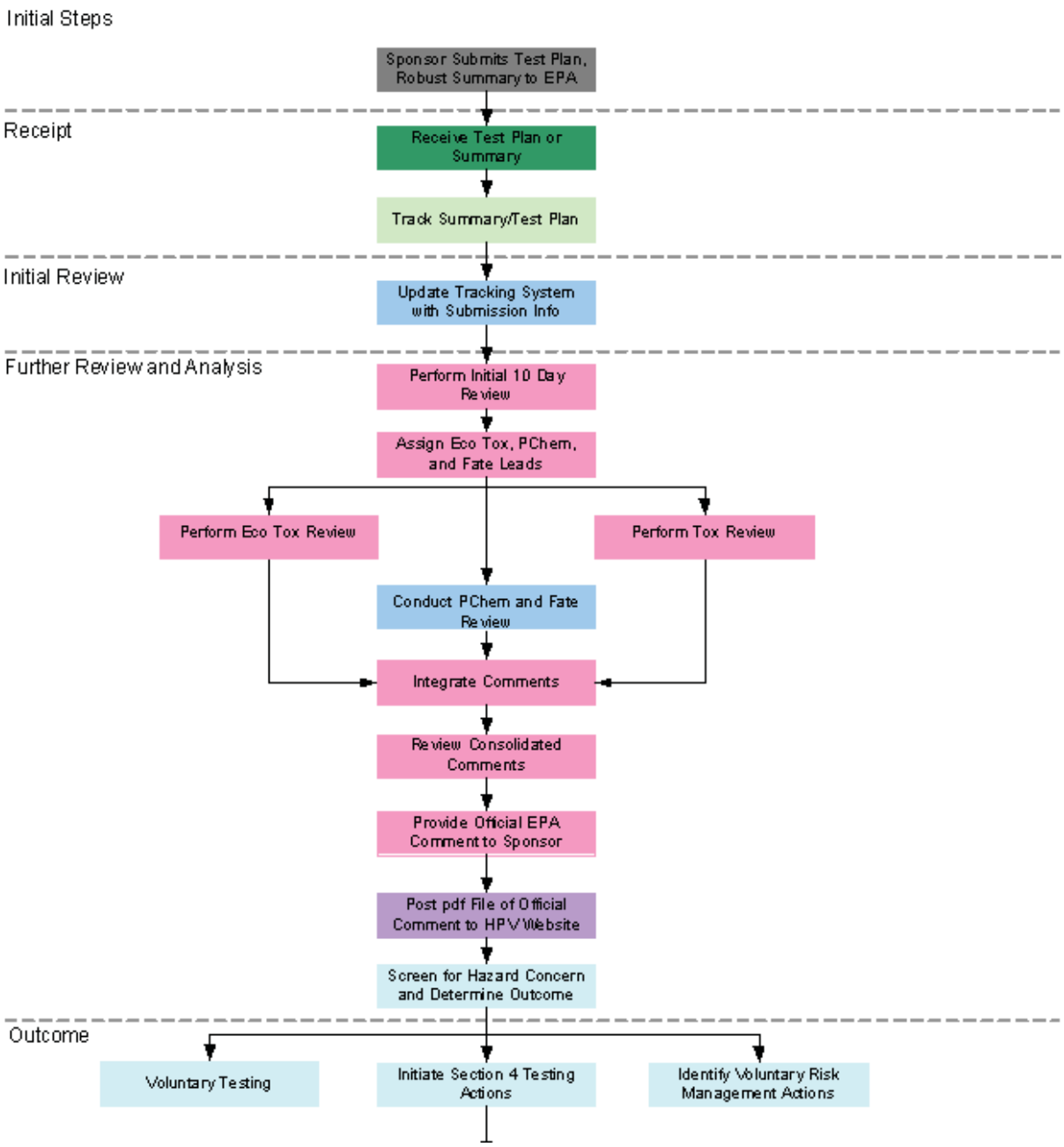


Figure B-5. Flow Sheet for HPV Challenge Program Reviews

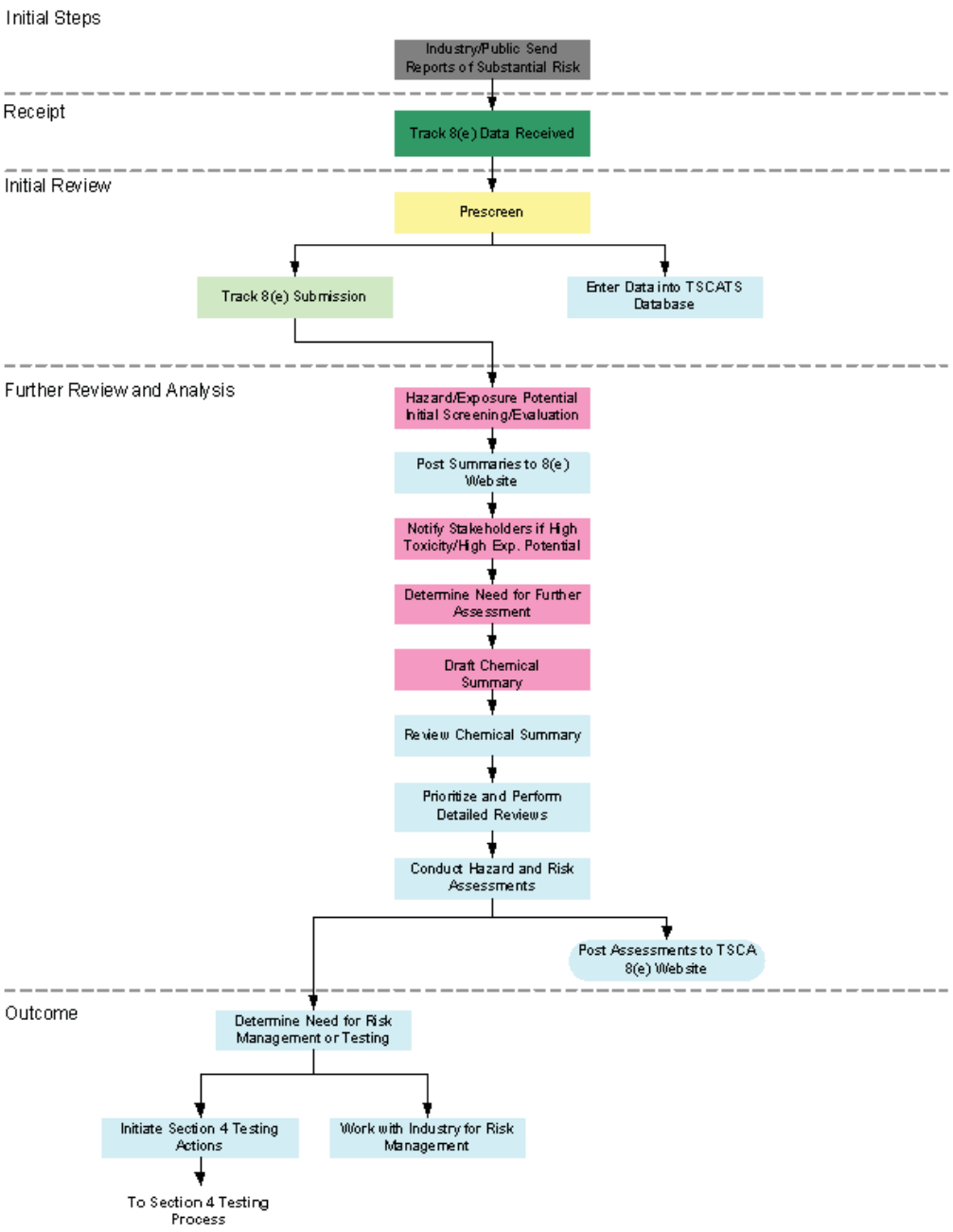


Figure B-6. Flow Sheet for TSCA §8(e) Reviews.

Initial Review. A preliminary review may be necessary to prioritize for further review or to determine whether to contact the submitter for clarification or further details.

Further Review and Analysis. The next step of review involves the analysis, by EPA staff or by a support contractor, of the submitted information for mammalian toxicity, ecotoxicity, physicochemical properties, and fate. If a Challenge submission is for a category, a Category Expert Review Team (CERT) provides initial review and comment on the proposed category's adequacy. Some kinds of assessments include an exposure review.

A coordinator integrates all comments, and the integrated comments are reviewed by a Team Leader, other senior staff, and more widely as appropriate. Often, the report is forwarded to other divisions within OPPT or other offices within EPA for comment. Other possibilities are an outside peer consultation panel, or public meetings to discuss the assessment.

TSCA §8(e) submissions. Because a §8(e) submission involves the identification of a potential substantial risk, a significant amount of additional review and analysis takes place with §8(e) data. If there is a need to notify other stakeholders of a concern associated with the particular chemical, a *Chemical Advisory* is issued to notify unions, trade associations, consumer groups, etc. EPA then prioritizes the chemical for further review on the basis of hazard potential, exposure potential, and current risk management status. Specialists may engage in detailed reviews of the chemical, including hazard and risk assessments.

Generally, the process ends with the posting of a final report to an EPA Web site, a docket, and/or other publicly accessible repository. The report may also be provided to the original submitter.

Outcomes. Possible review outcomes when a concern is verified:

- The chemical may need additional testing to fully determine hazard or risk. This can result in voluntary testing actions by industry or the development and issuance of a TSCA §4 Chemical Testing Rule.

- EPA may initiate regulatory consideration or, alternatively, may work with industry/the various stakeholders to identify and implement risk management strategies for the chemical (for example, refer to the discussion of PFOS/PFOA in Section 1.4.3 of the Overview in the main part of this document).

B-1.4 OTHER TSCA PROVISIONS

B-1.4.1 TSCA §12(b) Export Notification (40 CFR 707)

Any person who exports or intends to export a chemical substance or mixture must notify the EPA Administrator, prior to exporting that chemical substance or mixture, if:

- The submission of data is required under §4 or 5(b);
- An order has been issued under §5;
- A rule has been proposed or promulgated under §5 or 6; or

- Action is pending, or relief has been granted under §5 or 7.

A current List of Chemical Substances Subject to TSCA §12(b) Export Notification Requirements is available on EPA's website at http://www.epa.gov/oppt/chemtest/main12b.htm.

The following additional provisions are included in the Agency's regulations implementing §12(b) of TSCA (40 CFR part 707, subpart D):

(a) No notice of export is required for articles, except PCB articles, unless the Agency so requires in the context of individual TSCA §5, 6, or 7 actions.
(b) Any person who exports or intends to export polychlorinated biphenyls (PCBs) or PCB articles, for any purpose other than disposal, shall notify EPA of such intent or exportation under TSCA §12(b). PCBs and PCB articles have their definitions published in 40 CFR 761.3.
(c) Any person who would be prohibited by a TSCA §5 or 6 regulation from exporting a chemical substance or mixture, but who is granted an exemption by EPA to export that chemical substance or mixture, shall notify EPA under §12(b) of such intent to export or exportation.
(d) An exporter will be subject to possible enforcement action (including penalties) for not complying with §12(b).

B-1.4.2 Import Certifications (TSCA §13)

TSCA §13 directs the U.S. Customs Service to refuse entry into U.S. territory of chemical substances, mixtures, and articles not in compliance with TSCA. Regulations promulgated by the Customs Service to implement TSCA §13 require importers of chemical substances and mixtures to certify at the port of entry that either:

- The shipment is subject to TSCA and complies with all applicable (i.e., TSCA §5, 6 or 7) rules and orders thereunder; or
- The shipment is not subject to TSCA (19 CFR 12.118-12.127, 127.28).

EPA issued a policy statement addressing the Customs regulation (40 CFR 707.20) on December 13, 1983. The policy notes that, in addition to §13 import certification requirements, imports may be subject to additional requirements under rules issued under TSCA §§4, 5, 6, 7, 8, and 12.

Certification for chemical substances/mixtures imported as part of articles is not presently required. A shipment may be detained or refused entry if certification is not made or if the shipment is believed not to be in compliance with TSCA. Certification is required for substances that are imported and are received by mail or commercial carrier, including those intended for research and development.

"Blanket" certification may be requested from the Customs District Director on an annual basis to cover several shipments of the same chemical over a one-year period.

B-2 NATIONAL PROGRAM CHEMICALS

B-2.1 THE LEAD PROGRAM: LEAD EXPOSURE REDUCTION (TSCA TITLE IV) AND THE RESIDENTIAL LEAD-BASED PAINT HAZARD REDUCTION ACT OF 1992 (TITLE X OF THE HOUSING AND COMMUNITY DEVELOPMENT ACT)

B-2.1.1 Setting Health-Based Standards for Lead (Title X and TSCA §403)

TSCA §403 (15 U.S.C. § 2683) requires EPA to develop standards for identifying lead-based paint hazards, lead-contaminated household dust, and lead-contaminated residential soil. In January 2001, OPPT issued Residential Lead Hazard Standards (40 CFR 745 Subpart D), under TSCA §403. The new standards provide Federal agencies, as well as State, local, and Tribal governments with new uniform benchmarks on which to base remedial actions taken to safeguard children and the public from the dangers of lead. These standards also apply to other federal lead provisions, such as EPA's real estate disclosure requirements presently in place for people selling or renting a home or apartment (see Section B-2.1.2). In addition, these standards provide landlords, parents, and childcare providers, as well as inspectors and risk assessors, with specific levels on which to make informed decisions on how to address problems regarding lead found in homes, yards, or play areas.

B-2.1.2 Lead Disclosure Upon Sale or Lease of Housing (Title X, §1018) and The Lead-Based Paint Pre-Renovation Education Rule (TSCA §406)

Disclosure of Information Concerning Lead Upon Transfer of Residential Property (Title X, §1018). Recognizing that families have a right to know about lead-based paint and potential lead hazards in their homes, Congress directed EPA and the U.S. Department of Housing and Urban Development (HUD) to work together to develop disclosure requirements for sales and leases of older housing. Before selling or leasing most pre-1978 housing, §1018 (42 U.S.C. § 4852(d)) requires that sellers and lessors disclose all known information on lead-based paint hazards in the dwelling, provide the purchaser or lessee with the Lead Hazard Information Pamphlet, and include a specific Lead Warning Statement in each contract. In addition, sellers must allow purchasers a ten-day opportunity to inspect the dwelling for lead-based paint hazards. EPA rules implementing these requirements were promulgated on March 6, 1996, at 40 CFR §§ 745.100-745.119.

Pre-Renovation Lead Information Rule (PLIR) (TSCA §406(b)). If conducted improperly, renovations in housing with lead-based paint can create serious health hazards to workers and occupants by releasing large amounts of lead dust and debris. Thus, TSCA §406(b) (15 U.S.C. § 2686(b)) requires renovators, prior to beginning renovations in pre-1978 homes, to distribute a Lead Hazard Informational Pamphlet (see Section B-2.1.4) to educate their customers on lead hazards and how they can be minimized. EPA published a final rule, "Requirements for Hazard Education Before Renovation of Target Housing" in June 1998 (63 FR 29908, June 1, 1998).

B-2.1.3 Training and Certification for Lead-Based Paint Activities (TSCA §§402 and 404)

Training Programs and Certification of Contractors and Renovation and Remodeling (R&R) Workers (TSCA §§402(a) and 402(c)(1),(2),(3)). TSCA §402(a) (15 U.S.C. § 2682) required EPA to establish a regulatory framework governing the certification and training of lead-based paint abatement professionals to ensure that individuals engaged in risk assessments, inspections, and abatement are properly trained, that contractors are certified (licensed), and that training programs are accredited. The Agency published its Lead-based Paint Activities Training and Certification Rule in 1996 (61 FR 45778, August 29, 1996). TSCA §402(c) required EPA to prepare renovation and remodeling (R&R) guidelines to reduce the exposure to lead when conducting R&R activities (HUD, 1997). TSCA §402(c)(2) required EPA to conduct a study to determine the extent to which persons engaged in various types of renovation and remodeling activities create a lead-based paint exposure hazard for workers, themselves, or occupants where the work is being conducted. EPA will use the information from the study to revise the R&R guidelines and to assess the degree to which different categories of R&R workers will require training or certification for activities that disturb lead-based paint, as required by §402(c)(3).

Developing a Model State Program and EPA Grants (TSCA §404). TSCA §404 provides for EPA authorization of state programs for training and certification of lead-based paint contractors and for performing the education and outreach requirements of §406 (see Section B-2.1.4). TSCA §404(d) requires EPA to promulgate a model state program that may be used by States seeking to administer programs. All state programs must be at least as protective as the Federal program and must provide adequate enforcement. In those States lacking their own programs, EPA must establish, administer, and enforce Federal programs. TSCA §404(g) authorizes EPA to make grants to States to develop and carry out authorized programs (HUD, 1997). Figure B-7 illustrates the Status of EPA Lead Programs.

B-2.1.4 Lead Outreach and Education

Lead Hazard Information Pamphlet (TSCA §406(a)). Recognizing that many families might be unaware that their homes might contain lead-based paint, TSCA §406(a) (53 U.S.C. § 2686) required EPA to develop and publish, after notice and comment, a lead hazard information pamphlet. As a result, EPA developed "Protect Your Family From Lead in Your Home" (EPA 747-K-99-001), a pamphlet that provides comprehensive information to the general public on lead-based paint in housing, the risks of exposure, and the precautions for avoiding exposure. In addition to being used to educate families about lead hazards, the pamphlet must be given to home buyers and renters for most pre-1978 housing. Information on lead hazards, including this pamphlet, is available through the National Lead Information Center (1-800-424-5323) or online at http://www.epa.gov/oppt/lead/.

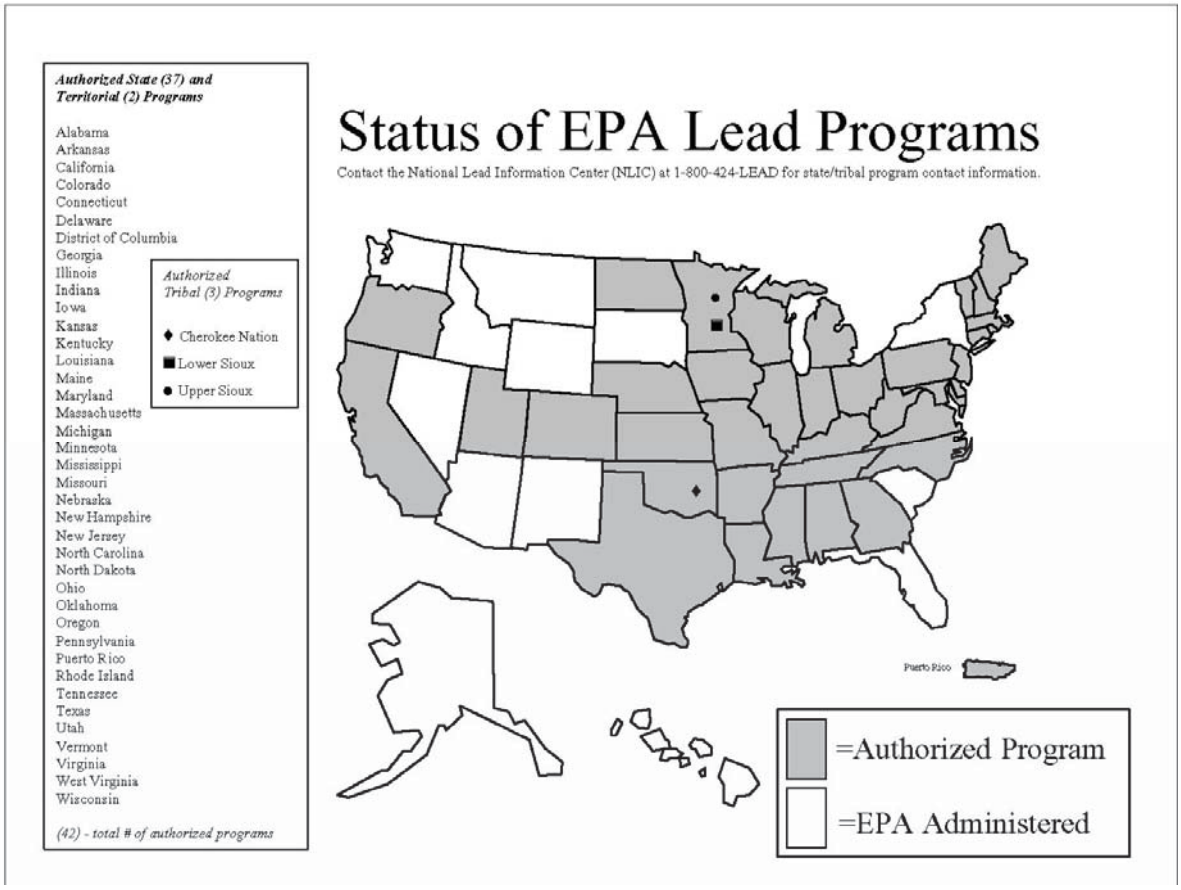


Figure B-7. Status of EPA Lead Programs.

B-2.1.5 Supporting Research

TSCA §405. This section requires EPA and other appropriate agencies to: (1) conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection, and abatement of lead-based paint and other lead exposure hazards; (2) to establish protocols, criteria, and minimum performance standards for laboratory analysis of lead in paint films, soil, and dust; and (3) to determine whether an effective voluntary accreditation program exists to certify laboratories that test for lead, and if not, to establish a Federal program for such certification. Under TSCA §405(b), EPA has established the National Lead Laboratory Accreditation Program to recognize laboratories that demonstrate lead analysis proficiency.

Research and Development (Title X, Subtitle D). This subtitle requires HUD, in cooperation with other Federal agencies, to conduct research on: (1) strategies to reduce the risk of lead exposure from such non-paint sources, and (2) testing technologies, including improved methods

for evaluation of lead-based paint hazards in housing and assessments of the effectiveness of hazard evaluation and reduction activities. EPA has cooperated with HUD on several research projects (HUD, 1997).

B-2.1.6 Coordination with Other Federal and Non-Federal Agencies (Title X, §1015, 1016 and 1032)

Task Force on Lead-Based Paint Hazard Reduction and Financing (Title X, §1015). TSCA §1015 directs the Secretary of HUD, in consultation with the Administrator of EPA, to establish a Task Force comprised of Federal agencies and a broad range of non-governmental organizations (42 U.S.C. § 4852a). The Task Force on Lead-Based Paint Hazard Reduction and Financing was created in October 1993 and their final report, *Putting the Pieces Together: Controlling Lead Hazards in the Nation's Housing*, was published in 1995 (available through the National Lead Information Center; http://www.epa.gov/lead/nlic.htm).

National Consultation on Lead-Based Paint Hazard Reduction (Title X, §1016). This section of the Act calls for Federal interagency consultation on lead-based paint activities (42 U.S.C. § 4852b). Government-wide coordination is achieved through the Federal Interagency Lead-Based Paint Task Force, which has met regularly since April 1989. In addition to staff from EPA and HUD, the Task Force includes members from 15 other agencies (HUD, 1997).

Coordination Between Environmental Protection Agency and OSHA / Department of Labor (Title X, §1032). Close coordination is mandated between EPA and OSHA because OSHA worker protection requirements are an integral element of training and certification programs (42 U.S.C. § 4853a). This coordination has been accomplished by two methods: (1) an ongoing committee, which is known as the OMNE Committee (for OSHA, MSHA, NIOSH and EPA); and (2) detailed consultation with OSHA in the development of the training requirements (HUD, 1997).

President's Task Force on Environmental Health Risks and Safety Risks to Children (Executive Order 13045). A panel co-chaired by the Department of Health and Human Services and the EPA, and including members from HUD, the Department of Justice, and other agencies, issued a Federal Strategy in February 2000, titled Eliminating Childhood Lead Poisoning (USEPA, 2000a). The report is available at www.epa.gov/lead/fedstrategy2000.pdf.

B-2.2 ASBESTOS: FEDERAL REQUIREMENTS FOR ASBESTOS MANAGEMENT IN SCHOOLS

The Asbestos-Containing Materials in Schools regulation (40 CFR Part 763), in effect since 1986, require that public and non-for-profit non-public, elementary and secondary schools be inspected to determine the presence of asbestos-containing building materials and that asbestos management plans be developed as a result of those inspections. The following is a guidance of those regulatory requirements; however, State requirements may vary.

Designated Person. The Local Education Agency (LEA) must designate a person (designated person) to ensure that the responsibilities of the LEA, as detailed in the regulations, are properly implemented. Other requirements include:

- The LEA must verify that this individual has received proper training. The individual is not required to be a licensed asbestos consultant. There is no specific training course for the designated person; however, the EPA has developed a "Designated Person's Self-Study Guide" that details the required specific background knowledge the designated person must have (information about ordering at http://www.epa.gov/asbestos/schools.html).
- The Asbestos Management Plan (AMP) for schools must include a true and correct statement signed by the designated person certifying that the general responsibilities of the LEA have been or will be met.
- In the event that the designated person leaves his or her position, the LEA must ensure that a new individual is identified and appropriately trained to serve as the designated person. The newly identified designated person must then sign the aforementioned statement of certification. The designated person must have a basic knowledge of the health effects of asbestos, the detection, identification and assessment of asbestos-containing material, options for controlling asbestos-containing material, asbestos management programs, and relevant federal and state regulations concerning asbestos.

Reinspection. The LEA must retain the services of a licensed asbestos inspector or management planner to conduct a reinspection every three years subsequent to implementation of a management plan. Other requirements are:

- Triennial reinspections must include an inspection of each area of every building that is leased, owned, or otherwise used as a school building.

Written Notification Regarding Availability of the AMP. At least once each school year, the LEA must provide written notification to parent, teacher, and employee organizations regarding the availability of the Asbestos Management Plan and any response actions taken or planned. Other requirements include:

- This notice must be dated and a copy placed in the AMP.
- The AMP must describe the steps taken to notify parents, teachers and employee organizations. Acceptable methods of notification include placing a notice in the school handbook, mailing a letter to each household, or placing an add in a local paper.

Periodic Surveillance. After the AMP has been implemented, the LEA must conduct periodic surveillance in each building that it leases, owns, or otherwise uses as a school building at least once every six months. The purpose of surveillance is to look at all known or suspect asbestos-containing building materials (ACBM) and note any changes in the material. Periodic surveillance does not need to be conducted by a licensed consultant. It is often conducted by custodial or maintenance personnel.

Custodial & Maintenance Training and Short-Term Worker. All maintenance and custodial staff who may work in a building that contains asbestos-containing building materials (ACBM) must

receive at least two hours of asbestos awareness training whether or not they are required to work with ACBM. Other requirements include:

- Maintenance and custodial staff conducting any activities that will result in the disturbance to ACBM must receive an additional fourteen hours of training.
- The LEA must ensure that new custodial and maintenance employees are trained within sixty days after commencement of employment.
- The LEA must ensure that short-term workers who may come in contact with asbestos (e.g. utility repair workers) are informed of the location of ACBM.

Record-Keeping Requirement. The LEA must maintain records required by the regulations to be included in the Asbestos Management Plan. This includes:

- a copy of prior inspection and/or reinspection reports;
- documentation related to the training provided to custodial and maintenance employees;
- periodic surveillance forms;
- dated statements regarding operations and maintenance activities;
- a copy of the annual notice of the management plan availability;
- a copy of all reports on response actions taken; and
- a copy of the updated management plan in each school.

Compliance/Enforcement. EPA is committed to providing assistance to LEAs to ensure compliance with regulatory requirements. While it is the goal of EPA to provide LEAs with assistance in achieving regulatory compliance voluntarily, LEAs that fail to comply with existing regulatory requirements will be subject to enforcement action. The Regional Asbestos Coordinator can provide more information.

B-3 POLLUTION PREVENTION

B-3.1 POLLUTION PREVENTION ACT (PPA)

The major provisions of the PPA include:

- Defining pollution prevention as source reduction and establishing the pollution prevention hierarchy (see Figure B-8);
- Providing matching funds for state and local P2 programs through the Pollution Prevention Incentives for States (PPIS) grant program to promote P2 techniques by businesses (42 U.S.C. §13104);
- Establishing a P2 strategy outlining the Agency's intent to promote source reduction and collect data on source reduction and recycling (42 U.S.C. §13106); and

- Operating a source reduction clearinghouse, the Pollution Prevention Information Clearinghouse, dedicated to reducing or eliminating industrial pollutants through technology transfer, education, and public awareness (42 U.S.C. §13105).

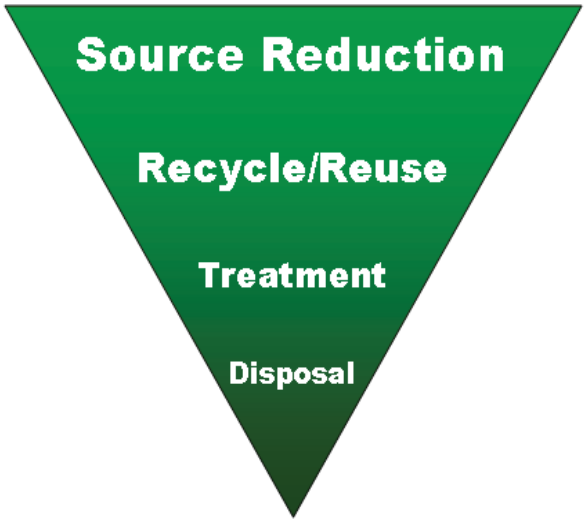


Figure B-8. Pollution Prevention Environmental Management Hierarchy

B-3.1.1 Grant Programs

OPPT sponsors three grant programs that specifically promote P2 activities.

Pollution Prevention (P2) Grant Program. The P2 grant program (42 U.S.C. §13104), created under the authority of the PPA, provides matching funds to States to support P2 activities and develop state programs. OPPT believes state-based environmental programs often have the best opportunity to promote P2 because States have closer, more direct contact with industry and are more aware of local needs.

The goal of the P2 grant program is to assist businesses and industries in identifying better environmental strategies and solutions for reducing waste at the source. The majority of the P2 grants fund state-based projects in the areas of technical assistance and training, education and outreach, regulatory integration, data collection and research, demonstration projects, and recognition programs.

Since the program began in 1989, more than $75 million has been awarded and almost every State has established a P2 program (67 FR 18611). State agencies (including state universities), the District of Columbia, territories and possessions of the United States, and Federally recognized Indian tribes are eligible for funding. To date, States are the primary recipients of PPIS funding although EPA has funded more than 25 Tribal P2 grant projects.

Pollution Prevention Information Network Grant Program. The Pollution Prevention Information Network grants have funded the establishment of the Pollution Prevention Resource Exchange (P2Rx). This grant program was created in 1997 by the EPA to lay the groundwork for a seamless national network of easily accessible, high-quality P2 information. The objectives for the P2Rx included:

- To provide information that is easily accessible and easy to search;
- To collect, synthesize, and update technical information; and
- To identify experts and/or other sources of information.

Currently, P2Rx is a consortium of eight regional P2 information centers, funded in part through EPA grants. These centers collect, synthesize, and update technical information. They provide P2 information, networking opportunities, and contact information for experts. The centers represent a broad constituency, including state and local P2 programs, manufacturing extension partnerships, cooperative extension, and nonprofit organizations.

Source Reduction Assistance Grant Program. The Source Reduction Assistance grant program was created to serve two distinct functions: 1) comply with EPA's policy on small grant competition, and 2) to consolidate several source reduction/pollution prevention small grant initiatives supported EPA Regional offices. The grant funds support project activities dealing with - Design for the Environment, Environmentally Preferable Purchasing, Pollution Prevention projects of general interest, Pollution Prevention projects of interest to States, regions, and/or Tribes and Reducing Persistent, Bioaccumulative, and Toxic chemicals. Grant recipients may include State and local governments, federally recognized Tribal governments, nonprofit organizations and public and private universities.

B-3.1.2 Pollution Prevention Information Clearinghouse (PPIC)

As mandated by the PPA (42 U.S.C. §13105), EPA established the Pollution Prevention Information Clearinghouse (PPIC) to serve as a free, nonregulatory service dedicated to reducing or eliminating industrial pollutants through technology transfer, education, and public awareness. This is accomplished through EPA's P2 website, PPIC's P2 Information Products (EPA documents, pamphlets, and fact sheets, which can be ordered through the Clearinghouse) and PPIC's Reference and Referral Service (the Clearinghouse can answer questions about P2 or refer appropriate contacts). The PPIC public interface is accessible online at http://www.epa.gov/oppt/ppic/

B-3.2 HIGHLIGHTS OF VOLUNTARY POLLUTION PREVENTION PROGRAMS

B-3.2.1 Design for the Environment (DfE) Program

The Design for the Environment (DfE) Program is a voluntary partnership program that helps businesses design or redesign products, processes, and management systems that are cleaner, more cost-effective, and safer for workers and the public. A business can "design for the environment" by:

- Evaluating the human health and environmental impacts of its processes and products;
- Conducting an assessment of alternatives;
- Reducing the use and release of toxic chemicals through the innovation of cleaner technologies that use safer chemicals;
- Making products that can be reused, refurbished, remanufactured, or recycled; and
- Monitoring the environmental impacts and costs associated with each product or process.

DfE provides decision-makers with information, tools, and incentives to make informed decisions that integrate risk, performance, and cost concerns. The DfE process systematically promotes

continuous environmental improvement by first identifying the array of technologies, products, and processes that can be used to perform a particular function within an industry and related P2 opportunities. The next step is evaluating and comparing the relative risks, performance, and costs of the alternatives. The final step is disseminating this information to the entire industry community and encouraging use of this information by providing mechanisms and incentives to institutionalize the alternatives.

The DfE Program partners with industry sectors, usually through industry leaders and trade association representatives. DfE's partnerships have focused on garment and textile care, printed wiring boards used in computers and other electronics, commercial printing, industrial and institutional cleaning formulations, auto refinishing, adhesives used in foam furniture and sleep products, computer displays, lead-free solders used in electronics, and automobile suppliers.

B-3.2.2 Environmentally Preferable Purchasing

EPA's Environmentally Preferable Purchasing (EPP) is a federal-wide program that encourages and assists Executive agencies in the purchasing of environmentally preferable products and services. Specifically, the program seeks to help Executive agencies prevent waste and pollution by considering environmental impacts along with price and performance and other traditional factors when deciding what to buy. The Federal government is the single largest consumer in the U.S., spending over $200 billion annually on a wide variety of products and services. The government's purchase and use of products and services leave a large environmental footprint. Through its purchasing decisions, the Federal government can minimize environmental impacts while giving a boost to manufacturers that produce environmentally preferable products and services.

The EPP Program serves as a clearinghouse of information and tools to facilitate Executive agencies to purchase environmentally preferable products and services. However, EPP's audience is not limited to the Federal government. Businesses, non-profit organizations, and State and local government agencies have also found to the program to be of interest and value.

Executive Orders. On September 14, 1998, President Clinton signed Executive Order 13101: *Greening the Government through Waste Prevention, Recycling and Federal Acquisition*, which mandates that Executive agencies adopt environmentally preferable purchasing. Executive Order 13101 defines "environmentally preferable purchasing" as the purchase of "products and services [that] have a lesser or reduced effect on human health and the environment when compared to other products and services that serve the same purpose."

Executive Order 13101 includes a requirement for EPA to develop a guidance to "address environmentally preferable purchasing." The EPA's Final Guidance on Environmentally Preferable Purchasing (64 FR 45810, August 20, 1999) outlines the Federal government's approach for incorporating environmental considerations into its purchasing decisions. The guidance helps Executive agencies systematically integrate environmental preferability principles into their buying decision with specific requirements for implementing EPP, and provides a list of available resources, a glossary, and a list of environmental attributes to help Federal agencies compare products and services. More recently, OPPT's EPP program has focused its efforts on providing guidance to

federal purchasers in particular product categories, notably electronics, building products, and cleaning products.

On April 21, 2000, President Clinton signed Executive Order 13148: *Greening the Government through Leadership in Environmental Management* which requires federal agencies to incorporate environmental management systems into agency day-to-day decision-making and long term planning processes. Pollution Prevention is highlighted as a key aspect to the environmental management system process.

B-3.2.3 Green Chemistry

Green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances. EPA's Green Chemistry Program, an initiative under EPA's DfE Program, focuses on P2 through the environmentally conscious design of chemical products and processes. The Program promotes the research, development, and implementation of innovative chemical technologies that accomplish P2 in both a scientifically sound and cost-effective manner. To accomplish these goals, the Green Chemistry Program recognizes and supports chemical technologies that reduce or eliminate the use or generation of hazardous substances during the design, manufacture, and use of chemical products and processes. The Program is composed of four major areas:

- **Green Chemistry Research:** Supports basic research in green chemistry in order to provide the chemical tools and methods necessary to design and develop products and processes that are more environmentally benign.
- **Presidential Green Chemistry Challenge:** Recognizes outstanding accomplishments in green chemistry through an annual awards program.
- **Green Chemistry Education Activities:** Supports a variety of educational efforts that include the development of materials and courses to assist in the training of professional chemists in industry and the education of students in academia.
- **Scientific Outreach:** Supports a number of outreach projects that include organizing and participating in prominent meeting and conferences, publishing in scientific journals and books, and developing and disseminating computational tools and databases.

The Program works with many partners to promote P2 through green chemistry. Partnering organizations represent academia, industry, other government agencies, scientific societies, trade organizations, national laboratories, and research centers.

B-3.2.4 Green Engineering Program

Green Engineering is the design, commercialization, and use of processes and products that are technically sound and economically viable while minimizing generation of pollution at the source and environmental impact to human health and the environment.

The goals of the Green Engineering Program are:

- To incorporate green engineering approaches in academic and industrial communities, and
- To promote and foster development of commercialization of Green Engineering approaches and technologies. Primary targeted audiences of the Green Engineering Program include engineers in academia and practicing engineers.

The focus of the Green Engineering Program in the past few years has been on the academic community. The aim is to develop future chemical engineers with Green Engineering knowledge. To accomplish its goals, the Green Engineering Program first developed a standardized textbook and modules that can be used by universities for Green Engineering courses and provide starting references for practicing engineers. The textbook, titled "Green Engineering: Environmentally Conscious Design of Chemical Processes and Products," was completed and published via Prentice Hall in September 2001. This textbook is being used and/or incorporated into a number of chemical engineering departments domestically and abroad. In addition, engineers from other engineering disciplines (e.g., civil and environmental engineering) have expressed interest in incorporating Green Engineering principles into their curricula.

The Green Engineering Program, over the next few years, will continue its academic effort in institutionalizing Green Engineering in engineering curricula. The program will be working with the American Institute of Chemical Engineers (AIChE) to convert the Green Engineering textbook and other materials into industrial format for practicing engineers. The program will also partner with other interested organizations to incorporate Green Engineering into their activities. For example, the AIChE's Chemical Center for Process Safety (CCPS) has agreed to incorporate Green Engineering into process safety training. CCPS activities are supported by industry and its members include most chemical engineering departments.

The Green Engineering Program also partners with the EPA's Office of Research and Development to provide grants to researchers to develop innovative Green Engineering technologies. In addition, EPA has planned to partner with interested companies to pilot application of green engineering approaches in designing greener and safer processes and technologies.

B-3.2.5 Green Suppliers Network

The Green Suppliers Network is a collaborative venture among industry, the U.S. Environmental Protection Agency (EPA), and the US Department of Commerce's Manufacturing Extension Partnership (MEP). Green Suppliers works with all levels of the manufacturing supply chain to improve processes and minimize waste generation. Through on-site Green Supplier reviews, suppliers continuously learn ways to increase energy efficiency, identify cost-saving opportunities, and optimize resources and technologies to eliminate waste. The result - more effective processes and products with higher profits and fewer environmental impacts.

The program launched an initial pilot in February of 2001 with General Motors Corporation and its subsidiary, Saturn Corporation. In 2003, the program was officially launched and has been steadily expanding into new sectors.

The Green Suppliers Network is aimed at enhancing the competitiveness of US manufacturers in the global market while improving their material and resource efficiency. By combining lean manufacturing and pollution prevention (P2) techniques, the Green Suppliers Network focuses on improving supplier productivity, capacity building, efficiency, and environmental performance.
Key Green Suppliers Features:

- **Technical Reviews.** A team composed of lean manufacturing experts from the local National Institute of Standards and Technology Manufacturing Extension Partnership (NIST MEP) and state environmental experts perform industry-specific, one-on-one reviews at manufacturing facilities. Green Suppliers Network reviews provide custom solutions to fit a company's needs.
- **Lean and Clean.** Using *Lean and Clean* manufacturing practices, Green Suppliers Reviews combine environmental considerations and lean manufacturing techniques to enhance process efficiencies, which can lead to substantial environmental and economic benefits.
- **Supply Chain Relationships.** Green Suppliers also provides a forum for all members of the supply chain to work together to identify options for change.
- **Metrics.** MEP centers will aggregate and quantify economic and environmental benefits identified during Green Suppliers reviews.
- **Continuous Improvement.** Green Suppliers establishes a delivery mechanism to engage manufacturers and their suppliers in continuous environmental/economic improvement.
- **Implementation.** Green Suppliers can form partnerships with state, local and other federal agencies to bring the best technical, financial and research assistance to participating companies

The Green Supplier Network (GSN), a collaborative venture between industry and EPA, works with all levels of the manufacturing supply chain to achieve environmental and economic benefits. GSN improves performance, minimizes waste generation and removes institutional roadblocks through its innovative approach to leveraging a national network of manufacturing technical assistance resources. Through GSN, suppliers are able to continuously improve products and processes, increase energy efficiency, identify cost-saving opportunities, and optimize resources and technologies with the aim of eliminating waste.

B-3.2.6 Sustainable Futures

In December 2002, EPA announced the launch of Sustainable Futures, a new voluntary pilot project under the TSCA New Chemicals Program (67 FR 76282, December 11, 2002). Sustainable Futures is a pilot project designed to encourage the application of P2 principles during the development of new chemicals submitted as PMNs under TSCA §5. The goal of this pilot project is to encourage P2 and the development of inherently low-hazard chemicals. Furthermore, OPPT seeks to gain additional data and experience regarding the P2, risk reduction, and source reduction benefits of the use of hazard, exposure, and risk screening methodologies in new product development efforts. Companies participating in Sustainable Futures will be encouraged to use pollution prevention-based

screening techniques to reduce the toxicity of new chemicals. One approach is the EPA's Pollution Prevention Framework, which is implemented by means of a set of computer models that predict risk-related properties of chemicals using structure activity relationships (SARs) and standard (default) scenarios. These models have been developed by EPA's Office of Pollution and Toxics (OPPT) to screen new chemicals by capturing the expertise of multiple EPA scientists, grantees, and support contractors working for 20+ years screening chemicals in the absence of data. The Pollution Prevention 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 (R&D) process. EPA will consider providing regulatory flexibility in the form of certain expedited review to participants in the pilot project.

OPPT may use the experience from the Sustainable Futures pilot project to potentially modify its process for PMN review. For example, EPA may develop an exemption under TSCA §5(h)(4) to provide expedited review for PMNs for low-hazard/low-risk chemicals that have been subjected to hazard, exposure, and risk screening by industry prior to submission.

B-4 HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM

B-4.1 CATEGORIES

The HPV Challenge Program allows the use of categories, where scientifically justified, in generating and making publicly available a minimum hazard data set for the sponsored HPV chemicals. A chemical category, for the purposes of the HPV Challenge Program, is a group of chemicals whose physicochemical and toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity. These structural similarities may create a predictable pattern in any or all of the following parameters: physicochemical properties, environmental fate and environmental effects, and human health effects. The similarities may be based on the following:

- a common functional group (e.g., aldehyde, epoxide, ester, etc.); or
- the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (e.g., the "family approach" of examining related chemicals such as acid/ester/salt); and
- an incremental and constant change across the category (e.g., the dimethylene group difference between adjacent members of the alpha-olefins)

Categories can sometimes apply to series of chemical reaction products or chemical mixtures that are, again, related in some regular fashion. Analogous to the basic "discrete chemical" category model, in a mixture category some, but not all, of the individual mixtures may undergo testing. Categories accomplish the goal of the HPV Challenge Program to obtain screening level hazard information through the strategic application of testing to some, but not all, members of a category. If these test results show that the chemicals in the category behave in a similar or predictable manner, then interpolation and/or extrapolation can be used to assess the non-tested chemicals in lieu of conducting additional screening-level testing.

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 data for every chemical in the category has been judged sufficient for screening purposes. This alternative helps to reduce burden on industry, as well as minimize animal testing concerns. Guidance on the development and implementation of categories in the HPV Challenge Program is provided on the website at http://www.epa.gov/hpv/pubs/general/categuid.htm.

The category approach has been applied for the majority of the HPV chemicals to date. As of December, 2006, 1,125 chemicals were submitted as part of the 125 category submissions. These 1,125 chemicals represent 80% of the total 1,406 chemicals that have been submitted. The number of chemicals in a given category range from 2 to as many as 161 HPV chemicals. The different approaches used by sponsors have varied widely and have a variety of complicating factors. For example, in some cases, public comments on a category have raised questions about the technical soundness of a category proposal. Also, some category proposals – whether they were questioned in terms of their technical soundness or not – did not propose any additional testing. In such cases, the submission is simply a proposal that the members of the category belong together, without an analysis showing how each category member should be "treated" in terms of a hazard analysis. This is important for understanding how "untested"
category members should be characterized in a hazard screening exercise. The HPV Challenge Program has reached the point where most of the early category proposals have completed their proposed testing, yet, some of the sponsors are still in the process of reviewing the data to determine whether their original category hypothesis holds. OPPT has recently begun receiving these analyses.

B-4.2 DATA ADEQUACY

The purpose of the HPV Challenge Program is to provide screening-level hazard information on all HPV chemicals manufactured or imported into the U.S. Therefore, it is not important whether this information comes from existing data or newly conducted studies – as long as the information is judged adequate and is available for public review.

The guidance for assessing adequacy of existing data describes how to determine whether existing data are sufficient to meet the SIDS program requirements, and is provided on the website at http://www.epa.gov/pubs/general/datadfin.htm.
In its guidance document, EPA proposes that submitters consider a two-tiered system to evaluate existing data. In Tier I, criteria are used to assess the overall scientific integrity of the information. Any data or information that do not meet the Tier I criteria would be rejected from further consideration in the HPV Challenge Program. In Tier II, a more rigorous evaluation of existing data that has passed Tier I occurs (existing data generated via OECD or equivalent guidelines can enter directly into Tier II evaluation). However, some Tier I studies that do not advance to Tier II may still be useful in a weight-of -the-evidence analysis. Whether used or not, it is prudent to make publicly available all of the studies that have been reviewed, possibly in the form of a bibliography.

Other methods are available for assessing "data adequacy", and one in particular has been recently proposed for use in Europe in developing the International Uniform Chemical Information Database (IUCLID). Klimisch et al. (1997) describe the method and propose that data evaluation be done systematically and that it include consideration of reliability, relevance, and adequacy. Klimisch et

al. define adequacy as "the usefulness of data for risk assessment purposes", whereas in the document "Determining the Adequacy of Existing Data" EPA uses the term to mean usefulness for hazard identification purposes.

The method described in Klimisch et al. (1997) is similar in principle to EPA's tiered approach in that both methods present specific criteria for evaluating existing data. In fact, the data reliability criteria presented by Klimisch and by EPA (in Tier I) are remarkably similar. The difference between the two approaches is in how the criteria are used.

Klimisch et al. use their criteria in the following scoring system for evaluating data reliability, which is proposed for use with ecotoxicology and health effect studies and is not applicable to physicochemical and environmental fate studies: 1 = reliable without restrictions; 2 = reliable with restrictions; 3 = not reliable; and 4 = not assignable. The Klimisch ranking system does not conflict with the EPA approach. Assigning a numerical value to each study is both useful and comprehensive; however, EPA believes that using the same criteria as a screen (Tier I as described below) results in the appropriate "weeding out" of data/studies not useful in describing an endpoint. For example, studies assigned Klimisch reliability codes "3" or "4" would not advance to Tier II in the EPA approach, except for those cases in which a weight-of-evidence analysis might be used.

B-4.3 NON-SIDS DATA

SIDS was developed as a minimum hazard data set. In order to assess the hazard of a chemical, there are other types of information – including other hazard information and use/exposure information – that would be useful. Since SIDS is a minimum hazard data set, by definition, it does not include use/exposure information. However, since its inception, the HPV Challenge Program recognized the need for minimal use information to "put the hazard in context".

Non-SIDS Hazard Information. Here are some examples of information that is generally used to assess the hazard of a chemical, but are not part of SIDS, presented under each of the four main SIDS subject areas:

- Physicochemical properties: include information on flash point, flammability and explosivity. Other types that are usually not presented but are of interest include the Henry's Law Constant (a measure of a substance's tendency to stay in water or volatilize into air) and K_d (partition coefficient between soil/sediment and water).

- Environmental fate: bioconcentration (which is often presented in an HPV submission) and waste water treatability information (which is not usually submitted but is useful to determine whether a substance would degrade or be altered by conventional wastewater treatment technologies)

- Ecological effects: SIDS for ecological effects focuses on acute effects on aquatic vertebrates, invertebrates, and plants and on chronic aquatic toxicity if certain criteria are met (substances with estimated log $K_{ow} > 4.2$ are not likely to be acutely toxic but may be toxic under prolonged exposure periods). Occasionally, non-SIDS information on effects on either microorganisms or terrestrial organisms (plants, birds, mammals) is presented.

- Human health effects (laboratory animal studies): there are many types of animal studies performed (as well as *in vitro* studies) to assess potential effects on organisms, including humans. Some examples include: skin/eye irritation, skin/respiratory sensitization, carcinogenicity, specific toxicities (e.g. neurological, immunological, and endocrine effects), and metabolism data.

Non-SIDS Use/Exposure Information. Understanding the difficulty of presenting hazard data, OPPT recently issued guidance on how to submit information on use/exposure information for HPV submissions for those submitters who wish to do so (http://www.epa.gov/hpv/pubs/general/expinfo.htm).

Examples of "non-SIDS" use/exposure information include:

- whether the substance is a closed-system intermediate, is used in industrial or commercial applications only, or has consumer uses
- occupational monitoring data
- environmental monitoring data

It should be noted that some HPV submissions have included some or all of these types of information.

B-4.4 INTERNATIONAL HPV

The International Council of Chemical Associations (ICCA) consists of representatives of chemical industry trade associations from Argentina, Australia, Brazil, Canada, Europe, Japan, Mexico, New Zealand, and the United States.

Companies can meet the requirements of the HPV Challenge Program either directly through the HPV Challenge Program or indirectly through the OECD HPV SIDS Program and/or the ICCA HPV Initiative. Also, U.S. companies deciding to sponsor chemicals under the HPV Challenge Program can also identify those chemicals as U.S. contributions to the OECD HPV SIDS Program and/or the ICCA HPV Initiative.

The ICCA HPV Initiative called for the testing and screening-level assessment of approximately 1,000 "high priority" chemicals by the end of the year 2004. Most of the chemicals on the ICCA working list are also HPV chemicals. The assessments and testing will be directly tied in with the Organization for Economic Cooperation and Development (OECD) HPV Screening Information Data Set (SIDS) Program. There is considerable consistency amongst the OECD HPV SIDS Program, the ICCA HPV Initiative, and the U.S. HPV Challenge Program. All three programs have the following components:

- focus on HPV chemicals;
- are based on the OECD SIDS test battery;
- include the steps of information gathering, test plan development, and conducting SIDS testing as needed to provide a complete set of screening level hazard data;

- allow the use of category approaches to group chemicals and the use of Structure Activity Relationship (SAR) analysis as an alternative to testing where scientifically appropriate.

B-4.5 VCCEP PROCESS

The flow chart (Figure B-9) depicts the sequence of events that comprise the VCCEP pilot. Each event is briefly described here, more detail can be found in the December 26, 2000 Voluntary Children's Chemical Evaluation Program Federal Register notice (65 FR 81700, December 26, 2000).

1. Chemical selection. After receiving feedback on the draft Framework for a Voluntary Children's Chemical Evaluation Program (USEPA, 2000b) from various individuals at the April 26–27, 2000, stakeholder meeting and considering the written comments submitted to the docket and other communications, EPA identified candidate chemicals for the VCCEP and the pilot program. These chemicals are those judged by EPA to present, given the data at hand, the relatively greatest potential for exposures that may impact children. The Voluntary Children's Chemical Evaluation Program Federal Register notice (65 FR 81700, December 26, 2000) initiated the voluntary program by identifying the test battery, outlining the program, and soliciting Tier 1 sponsorship of the pilot chemicals by their manufacturers and importers.

2. Tier 1 commitment. To sponsor a chemical at Tier 1, a company (or consortium) would send a letter to EPA indicating their commitment to handling a chemical under the VCCEP pilot. The commitment letter must provide the name and Chemical Abstract Service Registry Number (CAS No.) of the chemical being sponsored, a commitment to start the development of the information no later than 6 months after the end of the sign up period, and an anticipated start date and submission date to EPA. The commitment letter must also identify the entity (company or consortium of companies) sponsoring the chemical and provide the name, address, e-mail address, telephone, and fax numbers of a technical contact. Sponsors or consortia making a Tier 1 commitment for a specific chemical would agree, among other things, to:

- Develop a Hazard Assessment of Tier 1 (existing and new studies as needed) studies and existing higher tier hazard studies.
- Develop an Exposure Assessment, Risk Assessment, and a Data Needs Assessment.
- Make all hazard and exposure data developed for this program publicly available.
- Judge existing hazard studies not conducted per Good Laboratory Practices (GLPs) guidelines based on their merits.
- Generate any new hazard data using GLPs and test guidelines listed in the December 26, 2000 Voluntary Children's Chemical Evaluation Program Federal Register notice.
- Develop exposure data that is representative of known exposure scenarios and is of known quality.

Tier 1 commitments were requested between January 25, 2001 and June 25, 2001.

3. Submission of Tier 1 data. Sponsors (or consortium) would subsequently submit to EPA a Tier 1 Hazard Assessment, a Tier I Exposure Assessment, and a Tier 1 Risk Assessment. A Data Needs

Assessment would also be submitted to EPA and would describe additional hazard testing and/or exposure data needed to fully evaluate the risks of a chemical to children and, where relevant, prospective parents.

4. Peer Consultation regarding Tier 2 data needs. At EPA's request, a third party would periodically convene a Peer Consultation to evaluate the Tier 1 information with emphasis on the Data Needs Assessment. The Peer Consultation would evaluate whether Tier 1 data needs were met by the sponsor's submission and whether the Tier 1 submission fully characterized the chemical's potential risk to children and whether there are remaining Tier 2 data needs. A possible conclusion of the Peer Consultation is that no more work is needed. Results and comments from the Peer Consultation Process will be compiled by the third party and submitted to EPA.

5. EPA review of Peer Consultation results. EPA would review the sponsor's submission and the third party report and announce the Tier 2 Data Needs Decision. The sponsor will be informed by mail and the public by the VCCEP web site. If EPA's approach differs substantially from that indicated by the third party report, sponsors and other stakeholders will have 60 days to comment on EPA's determination regarding Tier 2 data needs. EPA, following consideration of comments, will mail its final decision on Tier 2 data needs to the sponsor and announce it on the VCCEP web site.

6. Tier 2 commitment. The sponsor would have a period of 4 months after the issuance of EPA's final Tier 2 Data Needs Decision to commit to Tier 2 of the pilot program. To sponsor a chemical at Tier 2, a company (or consortium) would forward a letter to EPA indicating their commitment to handling the chemical under Tier 2 of the VCCEP pilot. The commitment letter must identify the chemical by name and CAS No., include a technical contact (and member companies for consortia), commit to starting development of Tier 2 hazard and exposure data no later than 6 months after the end of the sign up period, and include the anticipated start date and submission date to EPA of Tier 2 information. Tier 2 commitments should be made by sponsor companies within 4 months of the issuance of EPA's Tier 2 Data Needs Decision. Sponsors or consortia making a Tier 2 commitment for a specific chemical would agree to comply with the guidance given under Tier 1 as well as the following:

- Develop a Hazard Assessment of Tier 2 (existing and new studies as needed) studies and existing higher tier hazard studies.
- Develop an Exposure Assessment, Risk Assessment, and a Data Needs Assessment.

7. Development and submission of Tier 2 data. The sponsor will develop and submit to EPA Tier 2 hazard and exposure data in the form of a revised Hazard Assessment, revised Exposure Assessment, and revised Risk Assessment. The sponsor will also submit a Data Needs Assessment which addresses the need for Tier 3 information. The time allowed for this effort would be based on the time needed to conduct specific tests or exposure studies for each chemical using the guidance provided in the December 26, 2000 Voluntary Children's Chemical Evaluation Program Federal Register notice.

Steps 4, 5 and 6 are repeated for Tier 2 and Tier 3 submissions and analyses.

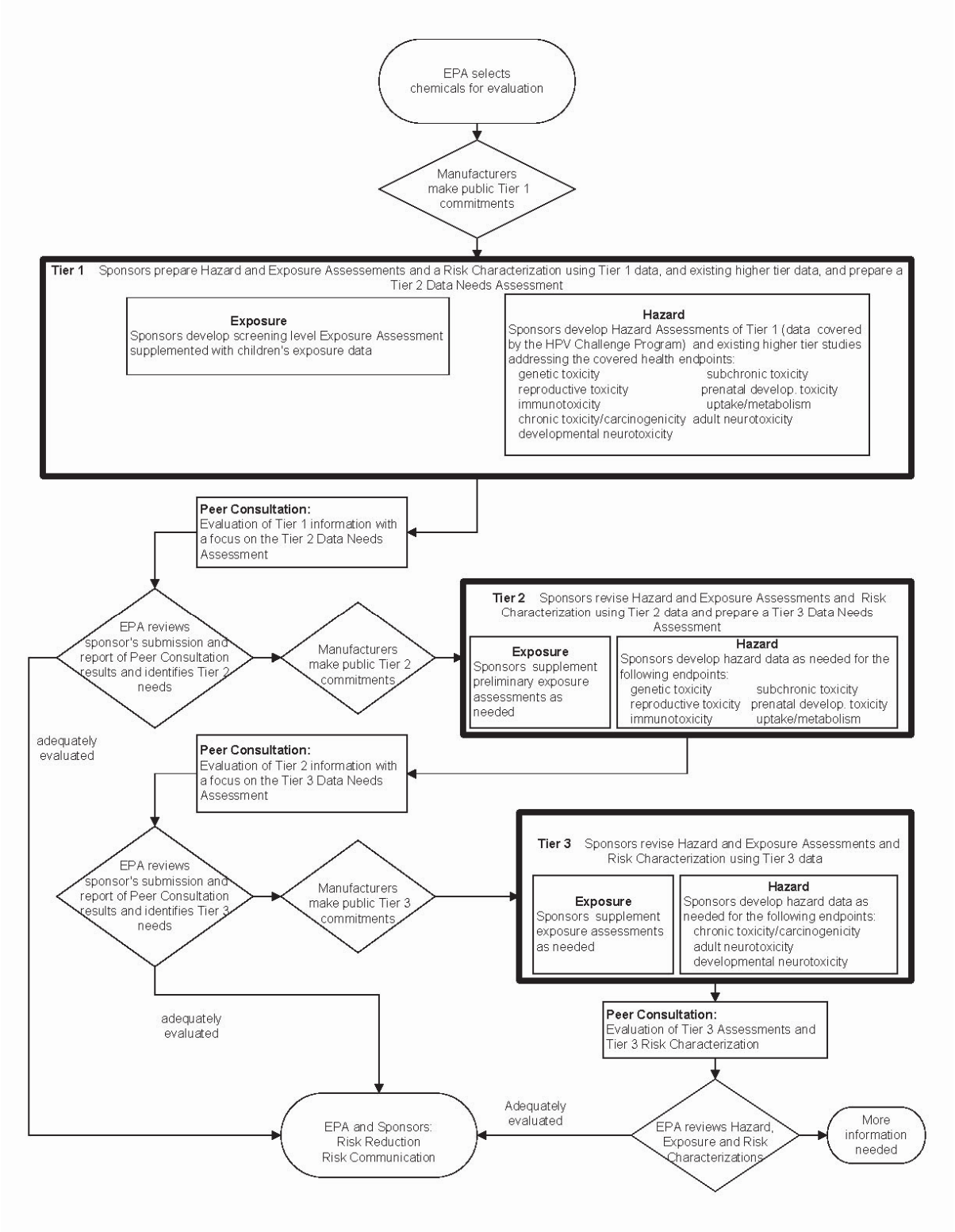


Figure B-9. Voluntary Children's Chemical Evaluation Program Pilot

B-5 GLOBAL ISSUES AND INTERNATIONAL COORDINATION

B-5.1 ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

The OECD is an international organization consisting of 30 industrialized countries in Europe, North America, Asia, and the Pacific. OPPT participates actively in the OECD's Chemicals Program, a comprehensive program of expert working groups and projects that includes activities such as the Screening Information Data Set (SIDS) to facilitate the coordinated investigation of HPV Chemicals; the Globally Harmonized System (GHS) of Classification and Labeling to promote better exchange of information on the hazards of chemicals and mixtures to human health and the environment (as well as to harmonize information on labels and safety data sheets for chemicals in commerce); and a proposed Mutual Acceptance of Notifications (MAN) process in response to concerns over the need to better align new chemicals systems in the global market. In addition, OPPT scientists have participated in the OECD Test Guidelines Program to develop protocols for studies to assess physicochemical properties, environmental fate, ecotoxicity, and health toxicity endpoints. A foundation of the OECD's chemicals program is the Mutual Acceptance of Data (MAD) agreement among OECD countries to accept studies generated in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice for review regardless of where the study is performed.

Benefits of OPPT Participation in OECD Work. In 1998, the OECD issued a report that addressed the costs and benefits to Member country governments and to industry of the Environmental Health and Safety Program (OECD, 1998). The report assessed quantifiable and non-quantifiable benefits. Importantly, environmental and public health benefits associated with improved chemical management were not taken into account in the report (OECD, 1998). Quantifiable savings included "costs saved by having an [Environmental Health and Safety] Program product (test guideline, chemical assessment report, etc.) that reduces duplicative testing and evaluation of chemicals." (OECD, 1998) Non-quantifiable benefits included "benefits accrued especially by governments, but also by industry, from the exchange of technical information and policy experience in the OECD forum." (OECD, 1998)

The OECD estimated that the savings to Member country governments and industry associated with programs pertaining to new industrial chemicals and high production volume industrial chemicals were more than $11 million per year (OECD, 1998).[1]

[1] These figures do not take into account estimated savings associated with pesticide and pharmaceutical chemical management programs, which accounted for the majority of the total estimated savings of $81 million. The figures were reported in French Francs. The conversion rate of francs to dollars is approximately 4-to-1.

Non-quantifiable benefits were identified as follows (OECD, 1998):

Benefits for governments	Benefits for industry
Creation of networks among government and industry experts in the OECD countries.	Reduction in non-tariff trade barriers.
Forum to develop new policies with a view to harmonization OECD-wide (8 Council Decisions, 12 Council Recommendations).	Reduction in delays for marketing new products.
Development of technical instruments that improve the quality of chemical evaluations and regulations.	Creation of a level playing field regarding regulations in OECD countries.
Access to information and advice from countries with different policy experience.	Harmonized classification and labeling systems for chemical products.
Harmonized classification and labeling systems for chemical products.	Creation of networks among government and industry experts from the OECD countries.
Much increased availability of safety data on high production volume chemicals	Opportunity to obtain information about OECD countries' policies and regulations.

As reflected above, the benefits to the U.S. and to other OECD Member countries participating in the work of the OECD are substantial. Member countries, and participating non-Member countries, benefit as a result of resource savings resulting from the sharing of data on chemicals. Where additional data must be generated, as in the high production volume chemicals program and the Endocrine Disruptor Program, governments benefit by sharing the burden of work. "By working together in tackling chemicals management issues, countries can share the burden associated with this work which they might otherwise have to face alone. Such sharing of the burden saves valuable government and industry resources and gets more work done faster." (OECD, 2000)

The international chemical industry also benefits by reducing the need to make duplicative submissions to countries in order to manufacture or market chemicals in those countries. Consistency in regulatory oversight mechanisms also reduces non-tariff barriers to trade. "The chemical industry...recognises [sic] the considerable benefits derived from the OECD-wide harmonization and it appreciates the cost-savings resulting from the limitation of non-tariff barriers to trade and avoidance of duplicative testing." (OECD, 2000)

In 2001, the OECD published the *Environmental Outlook for the Chemicals Industry* (OECD, 2001a). The OECD report predicts that the chemical industry will continue to expand over the next 20 years, with faster growth rates in non-OECD countries, while chemical companies in OECD countries will shift production to life science and specialty chemicals, and more companies will merge to form larger and fewer multinationals. The OECD recognizes that over the last three decades many essential elements of good chemical safety policy have been developed and used both

by countries and through international co-operation. At the same time, the OECD expects three main approaches to evolve to address the future development of the industry and some of the shortcomings of current policies:

- a greater focus on chemical products
- more involvement of all stakeholders; with full responsibility for industry in generating data and bigger role in assessing data and managing chemicals; more participation of workers and the public in chemical safety discussions and wider dissemination of data
- a greater focus on the chemical safety infrastructure in non-OECD countries.

In the 2001 *OECD Environmental Outlook* (OECD, 2001b), Chemicals Industry chapter, the OECD indicates that priority should be given to filling the immense knowledge gap about chemicals on the market. The OECD also identifies a variety of instruments to encourage the development of better chemicals information, including economic incentives, voluntary approaches, and regulations.

B-5.2 CHEMICAL REGULATIONS IN OTHER COUNTRIES

There are various approaches to addressing new and existing chemicals across the globe. For example, new chemicals programs may differ in terms of data required to be submitted with the premanufacture or premarketing application and approaches to the hazard and risk assessment. While the U.S. does not require data to be submitted with the premanufacture notice unless it already exists, other countries such as Australia, Canada, Switzerland, the EU, and Japan all have requirements for submission of certain types of data at the time of notification. The U.S., in the absence of data, uses (Quantitative) Structure-Activity Relationships ((Q)SARs), predictive methods which estimate the properties of a chemical (e.g., melting point, vapor pressure, human toxicity, and ecotoxicity) on the basis of its structure and test data on analogous chemicals. The EU currently requires a minimum premarketing data set (MPD) which includes physiochemical properties, biodegradation information, ecotoxicity, and health effects data. In Japan biodegradation and bioaccumulation data are requested prior to commercialization; in addition, all chemicals are classified as to whether they are mutagens by a government hazard and risk assessment committee. The number of new chemical notices submitted between 1983 and 1996 in the EU, U.S., and Japan were 4,514, 25,545, and 2,895, respectively. The far greater number of notices submitted in the U.S. is likely because there is no requirement to perform laboratory tests in the introductory phase of the new chemical review, resulting in reduced "upfront" pre-notification costs as compared to other countries

There are also various approaches to existing chemical programs across the globe. The U.S. collects information on existing chemicals under TSCA §§4 and 8. The Inventory Update Rule, under TSCA §8, enables the Agency to collect data on production volume, plant site and site-limited status if the substance is produced at levels of 10,000 pounds or more per site. Currently, the U.S. is focusing on collecting test data on a subset of 3,000 high production volume (HPV) chemicals, which are produced and/or imported in annual volumes of 1 million pounds or more across all U.S. companies. The EU has a requirement that manufacturers of existing substances provide data to the EC once they reach certain production volumes. Information requirements include production volume, classification, information on reasonable foreseeable uses, and physico-chemical data. Within the

Canadian existing chemicals process, there is a Characterization and Screening of the Domestic Substances List (DSL) process, in which all substances on the DSL that have not been subject to notification and assessment as new substances need to be characterized and screened based on potential toxicity, bioaccumulation and persistence, and exposure potential.

B-6 TOOLS AND MODELS

OPPT has developed many different tools and models both to support its own staff analyses in implementing OPPT programs and regulations as well as to help external users assess and manage chemical risks. Many of OPPT's tools and models can be used to provide estimates and predictions of certain risk assessment information where empirical data are insufficient. Some of these focus on hazard information, estimating the physical or chemical properties of a substance, its environmental fate, or its toxicity. Others focus on estimating the potential for human exposure or assessing risk by examining both hazard and exposure.

To support the Sustainable Futures pilot program, OPPT is using the Pollution Prevention Framework to predict risk-related properties of chemicals using structure activity relationships (SARs) and standard (default) scenarios. The Pollution Prevention Framework combines several of OPPT's models to estimate physical and chemical properties, chemical fate in the environment (EPI SUITE), models to estimate hazards to humans and the environment (OncoLogic, ECOSAR, PBT Profiler), and models to estimate exposure and/or risk (E-FAST and ChemSTEER).

Several models developed and used by OPPT are summarized briefly below. Additional information on OPPT's exposure tools and models is available at http://www.epa.gov/oppt/software.htm#model. OPPT is also making its models available through the OPPTS International Toolbox. The International Toolbox is a collection of Internet "tools" (data, computer models and valuable information about the safe use and disposal of chemicals) that is designed to provide easy access of health and environmental information to government and private managers around the world. OPPTS expects that the Toolbox will provide an opportunity to better understand chemical hazards and risks, to responsibly approve, use and dispose of chemicals more safely.

B-6.1 403 EMPIRICAL MODEL

The §403 Empirical Model was developed by OPPT specifically to support the risk analysis for the Title X §403 rulemaking that sets health-based standards for levels of lead in a residential environment. The purpose of the model is to serve as a basis for predicting a national distribution of children's blood-lead concentrations as a function of environmental lead-levels observed in the HUD National Survey. The model was used on the §403 risk analysis to help assess different options for health-based standards by estimating the reduction in average blood-lead concentrations and the reduction in the number of children with elevated blood-lead concentrations that would be associated with selection of a given set of health-based standards.

B-6.2 AMEM

The Arthur D. Little Migration Exposure Model (AMEM) was developed to estimate the migration of chemicals from polymeric materials used in home environments where these chemicals could

become sources of indoor air pollution or potable water contamination. AMEM is primarily used for screening purposes and requires physical/chemical use information input that is then used to estimate releases from polymers (based on diffusion coefficients for six types of polymers). An exposure assessment model can then be used to estimate exposure.

B-6.3 CHEMSTEER

The Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) is a PC-based software program that generates screening-level estimates of environmental releases from and worker exposures to a chemical manufactured, processed, and/or used in industrial and commercial workplaces. The tool contains data and estimation methods and models to assess chemical use in certain common industrial/commercial sectors (e.g., automotive refinishing), as well as for certain chemical functional uses (e.g., tackifier in adhesives).

B-6.4 E-FAST

The Exposure, Fate Assessment Screening Tool (E-FAST) provides screening-level estimates of the concentrations of chemicals released to air, surface water, and landfills, as well as from consumer products. E-FAST Version 2 is being designed to support both the new chemicals and existing chemical programs. Estimates provided by the tool are potential inhalation, dermal, and ingestion dose rates resulting from chemical releases. Modeled estimates of concentrations and doses are designed to reasonably overestimate exposures, for use in screening-level assessment.

B-6.5 ECOSAR

Ecological Structure Activity Relationships (ECOSAR) is a personal computer software program that is used to estimate the aquatic toxicity of chemicals. The program predicts the toxicity of industrial chemicals to aquatic organisms such as fish, invertebrates, and algae by using Structure Activity Relationships (SARs). SARs predict the aquatic toxicity of chemicals based on their structural similarity to chemicals for which aquatic toxicity data is available. SARs measured for one compound can be used to predict the toxicity of similar compounds belonging to the same chemical class. ECOSAR also allows access to over 100 SARs developed for 42 chemical classes. ECOSAR makes EPA's SAR methods for aquatic toxicity conveniently available through an easy-to-use computer program.

B-6.6 EFDB

The Environmental Fate Data Base (EFDB), developed and maintained by Syracuse Research Corporation (SRC), is an excellent source of extracted data as well as pointers (references) to data on environmental chemistry, fate, and properties of chemicals. EFDB has been funded for many years by EPA/OPPT and is now available free to users via SRC's website. This computerized database serves the following purposes:

- to allow rapid access to all available fate data on a given chemical without having to resort to expensive, time consuming, and inefficient primary literature searches;

- to identify critical gaps in the available information to facilitate planning of research needs; and
- to provide a data source for constructing structure-activity correlations for degradability and transport of chemicals in the environment.

The EFDB is a tremendous aid in identifying persistent chemical classes, as well as physical or chemical properties that may correlate to particular behavior in the environment. The EFDB is comprised of several interrelated files: DATALOG (contains eighteen types of environmental fate data), CHEMFATE (contains 25 categories of environmental fate and physical/chemical property information), BIOLOG (provides sources of microbial toxicity and biodegradation data), and BIODEG (contains experimental values as in CHEMFATE, but only relating to biodegradation subjects and evaluation codes that can be used for structure/biodegradability correlations). These databases share a CAS# file containing over 20,000 chemicals with preferred name and formula, and a bibliographic file containing full references on over 36,000 articles cited.

B-6.7 EPI SUITE

The Estimation Program Interface (EPI) Suite™ is a screening-level tool designed to provide users with estimations of physical/chemical properties and environmental fate properties, which are the building blocks of exposure assessment. EPI Suite is a suite of physical/chemical property and environmental fate estimation models developed by OPPT and the Syracuse Research Corporation (SRC). EPI Suite (previously called EPIWIN) uses a single input (chemical structure) to run a series of estimation models for $LogK_{OW}$, K_{OC}, atmospheric oxidation potential, Henry's Law constant, water solubility, melting point, boiling point, vapor pressure, biodegradation, Bioconcentration Factor, hydrolysis, sewage treatment plant removal, fugacity modeling, and multimedia modeling.

B-6.8 MCCEM

The Multi-Chamber Concentration and Exposure Model (MCCEM) estimates average and peak indoor air concentrations of chemicals released from products or materials in houses, apartments, townhouses, or other residences. The data libraries contained in MCCEM are limited to residential settings. However, the model can be used to assess other indoor environments (e.g. schools, offices) if the user can supply the necessary inputs. MCCEM estimates inhalation exposures to these chemicals, calculated as single day doses, chronic average daily doses, or lifetime average daily doses. (All dose estimates are potential doses; they do not account for actual absorption into the body.)

MCCEM maintains a library of residences, containing data on zone or area volumes, interzonal air flows, and whole-house exchange rates. MCCEM allows the user to:

- Tailor an analysis to a particular location, and to model air concentrations in as many as four zones for a given residence.
- Estimate exposure for periods ranging from 1 hour to 1 year.
- Choose from several different options for dealing with 'sinks.' A sink is a material (e.g., carpeting, wallboard) that can absorb chemicals from the air; the absorption can be either reversible or irreversible.

B-6.9 ONCOLOGIC

The Cancer Expert System is a personal computer software program developed under a cooperative agreement between EPA's Office of Pollution Prevention and Toxics (OPPT) and LogiChem, Inc. The IBM-compatible DOS (non-Windows) program is registered under the trademark OncoLogic®®. The Cancer Expert System or OncoLogic®® can analyze a chemical structure to determine the likelihood that it may cause cancer. This is done by applying the rules of structure activity relationship (SAR) analysis and incorporating knowledge of how chemicals cause cancer in animals and humans. The Cancer Expert System is comprised of four subsystems that evaluate fibers, metals, polymers, and organic chemicals of diverse chemical structures. The program applies SAR analysis to predict the potential cancer-causing effects of a chemical. In addition to SAR analysis, the Cancer Expert System applies the knowledge gained from studies of how chemicals cause cancer in animals and humans.

B-6.10 PBT PROFILER

The PBT Profiler is an online (http://www.pbtprofiler.net/) PBT screening and priority-setting tool that estimates environmental persistence (P), bioconcentration potential (B), and aquatic toxicity (T) of discrete chemicals based on their molecular structure when test data is not available. The PBT Profiler includes a subset of methods included in the P2 Framework, an approach to risk screening that incorporates P2 principles in the design and development of chemicals.

To use the PBT Profiler online, the user enters a chemical using the CAS number. The PBT Profiler is linked to a database containing the CAS numbers and the associated chemical structures for over 100,000 discrete chemical substances. If the CAS number is in the database, the structure is retrieved and entered into the model. The PBT Profiler then predicts the PBT characteristics and provides a PBT Profile in an easy to understand format. A drawing program is also available so that the user can draw and enter the structure or the structure can be entered as a line notation using the Simplified Molecular Input Line Entry System. In addition, the PBT Profiler compares the results of a profile with the PBT criteria established for PMNs submitted under TSCA §5 and the final rule for reporting chemicals to TRI (EPCRA §313).

B-6.11 RSEI

The Risk-Screening Environmental Indicator (RSEI) is a screening-level tool that compares toxic chemicals released to the environment from industrial sources. Although not a formal risk assessment, RSEI provides a full risk-related perspective for air and water releases, and hazard-based and pounds-based perspectives for releases to air, water, and land. The full risk-related perspective covers over 400 chemicals and chemical categories, and approximately 38,000 reporting facilities. RSEI calculates hazard- and risk-related results for every facility, every chemical released, each release pathway and each exposure pathway for each of the 13 years of TRI reporting data (1988 to 2000). RSEI also contains information databases (chemical, facility, census, etc.) that are fully accessible within and outside the model. RSEI has multi-faceted outputs including geographic information system (GIS) mapping, graphs, sorted lists, and tables, etc. RSEI can be used for examining trends to measure change, ranking and prioritizing chemicals and industry sectors for strategic planning, conducting risk-related targeting, supporting community-based projects, and

investigating environmental justice issues. Additional information is available at http://www.epa.gov/oppt/rsei.

B-6.12 UCSS

The Use Clusters Scoring System (UCSS) identifies and screens clusters of chemicals ("use clusters"). A use cluster is a set of chemicals that may be substituted for one another in performing a given task. UCSS identifies clusters of potential concern and provides an initial ranking of chemicals using human and environmental hazard and exposure data from a number of sources. For each chemical in a cluster, UCSS allows the user to enter data indicating the potential for human and ecological exposure and hazard, and the level of U.S. EPA interest. The UCSS team calculates health and ecological risk or toxicity rating scores for each chemical within a cluster using the information entered and preprogrammed scoring algorithms. It also uses individual chemical scores to calculate an overall cluster score, which is an indicator of potential risk for the use cluster. UCSS contains data on nearly 400 use clusters and 4,700 chemicals.

OPPT uses risk scores generated by UCSS to prioritize chemicals and clusters for further investigation. Scientists and engineers in private industry or academics can use the system as a preliminary decision-making tool in comparing the toxicity of similar chemicals used to perform a particular task. The system can also assist public or private sector organizations in identifying clusters of potential concern.

B-6.13 WPEM

The Wall Paints Exposure Assessment Model (WPEM) estimates the potential exposure of consumers and workers to the chemicals emitted from wall paint which is applied using a roller or a brush. WPEM is a user-friendly, flexible software product that uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. This is then combined with detailed use, workload, and occupancy data (e.g., amount of time spent in the painted room, etc,) to estimate exposure. WPEM provides exposure estimates such as Lifetime and Average Daily Doses, Lifetime and Average Daily Concentrations, and peak concentrations.

B-7 OUTREACH AND COORDINATION

B-7.1 TECHNICAL ASSISTANCE EFFORTS

B-7.1.1 State Technical Assistance Programs

OPPT believes that a strong partnership with the States is key to successful national P2 efforts. Therefore, the office has developed many resources to assist States in their P2 efforts.

State Technical Assistance Programs (State TAPs) strive to promote sustainable development and resource efficiency by providing services to help State agencies enhance the effectiveness of their P2 programs. State TAPs benefit state officials responsible for implementing state regulatory programs by providing the following services:

- **Providing P2 Materials.** State TAPs have developed extensive libraries of resources including case studies, tip sheets, and P2 checklists for specific industries.
- **Helping Reduce Waste Generated by State Agencies.** TAPs help State regulatory agencies use P2 strategies within their own operations.
- **Assisting With Regulatory Integration.** State TAPs provide technical information to help integrate P2 into regulatory activities such as enforcement settlements, permitting, compliance inspections, and rules.
- **Reducing the Regulated Universe Through Prevention.** By implementing P2 techniques, businesses can sometimes become exempt from regulations, as the requirements no longer apply given their new level of waste generation.
- **Training Regulatory Staff.** State TAPs provide training to inspectors on how to conduct multimedia inspections for specific industrial sectors or for all facilities.

B-7.1.2 Business Technical Assistance Programs

EPA promotes environmental stewardship to the business community via several programs that encourage businesses to incorporate environmental concerns into their standard financial and accounting practices.

Business Technical Assistance Programs (Business TAPs). Business TAPs provide businesses with cutting edge environmental management assistance and help identify and implement measures that reduce or eliminate pollution at its source. Business TAPs offer a variety of services, most of which are free, nonregulatory, and confidential. These services include:

- Voluntary onsite audits;
- Information clearinghouses;
- Planning assistance;
- Hotlines;
- Research; and
- Workshops, seminars, and training.

Pollution Prevention Business Development and Finance Project. In the normal course of their operations, most firms by necessity work with, and rely upon, various members of the financial community. The overall goal of the Pollution Prevention Business Development and Finance Program is to utilize the financial community, along with various business development organizations, as a method of reaching individual businesses with EPA's P2 message.

Through the Pollution Prevention Finance Project, OPPT has conducted research on how commercial bank loan officers view the P2 aspects of capital improvement projects, what are the key features investors look for in seeking out prevention-oriented companies, and what is the potential utility of information on environmental management systems such as ISO 14001 (a series of comprehensive guidelines for incorporating environmental protection and P2 objectives into industrial activity worldwide) to the financial community.

Environmental Assistance to Small Businesses. Small business programs and initiatives aim to coordinate technical assistance provided by small business development centers and to provide small businesses a voice in EPA's rulemaking process. Small businesses are an important target for P2 outreach because they typically lack resources to fund their own environmental personnel, but collectively are responsible for a large percentage of waste. Developed by OPPT, the *Small Business Guide* (USEPA, 2001) is a resource provided by EPA Technical Assistance Programs targeted at small businesses to explain P2 approaches and innovative technologies. In addition to cost savings, it can help improve worker safety, reduce liability, and enhance a business's image in the community. The guide is available online at http://www.epa.gov/oppt/p2home/assist/sbg.htm.

B-7.2 COORDINATION WITH STATES AND TRIBES

B-7.2.1 The Forum on State and Tribal Toxics Action (FOSTTA)

FOSTTA is a mechanism by which State and Tribal officials jointly, and in cooperation with OPPT, address toxics-related issues. FOSTTA is a partnership between OPPT and state and tribal leaders to increase understanding and improve collaboration on toxics and P2 issues among States, Tribes, and EPA. Created in 1991, FOSTTA is currently operated under a cooperative agreement with the Environmental Council of the States (ECOS) and the National Tribal Environmental Council (NTEC). In the past, FOSTTA committees or "projects" addressed chemical management, the Agency's TRI, lead, P2, community-based activities, and tribal affairs (USEPA, 2002a). At this time, FOSTTA is composed of the Chemical Information and Management Project, Pollution Prevention Project, and the Tribal Affairs Project.

ECOS is the national non-profit, non-partisan association of state and territorial environmental commissioners. For more information on ECOS, see http://www.sso.org/ecos/.

NTEC was formed in 1991 as a membership organization dedicated to working with and assisting Tribes in the protection and preservation of the reservation environment. NTEC membership is open to Federally recognized tribes throughout the United States and currently has 108 member tribes. Although NTEC is a membership organization, its services are provided to all Federally recognized tribes. For more information on the NTEC, see http://www.ntec.org/.

B-7.2.2 The National Conference of State Legislators (NCSL)

NCSL was founded in 1975 to provide an open, bipartisan, national forum for the lawmakers and staffs of the nation's 50 states and its commonwealths and territories to communicate with one another and share ideas. With a focus on service, NCSL is a source for research, publications, consulting assistance, meetings, and seminars. One example of a NCSL project related to OPPT efforts is the NCSL Lead Hazards Project. This project assists States on the issue of lead poisoning prevention by facilitating information exchange among the States and by promoting improved coordination between the States and OPPT. Additional information on NCSL environmental health projects is available at http://www.ncsl.org/programs/esnr/toxics.htm.

B-8 AGENCY-WIDE INITIATIVES

B-8.1 RELEVANT GPRA GOALS

The Government Performance and Results Act of 1993 (GPRA) requires that federally funded agencies develop and implement an accountability system based on performance measurement, including setting goals and objectives and measuring progress toward achieving them. Specifically, GPRA requires agencies to develop a five-year Strategic Plan that includes a mission statement and sets out long-term goals and objectives, as well as Annual Performance Plans describing commitments toward achieving the goals and objectives presented in the Strategic Plan. Annual Performance Reports are also required to evaluate progress toward achieving performance commitments. In accordance with these requirements, EPA has published Strategic Plans in 2000 and 2003 to establish the framework the Agency uses to plan programs, set priorities, and allocate resources.

In September 2000, EPA presented its Strategic Plan for Fiscal Years 2000 through 2005 (USEPA, 2000c). The Plan included its mission statement and the ten long-term goals around which EPA intended to focus its efforts:

- Clean air;
- Clean and safe water;
- Safe food;
- Preventing pollution and reducing risk in communities, homes, workplaces, and ecosystems;
- Better waste management, restoration of contaminated waste sites, and emergency response;
- Reduction of global and cross-border environmental risks;
- Quality environmental information;
- Sound science, improved understanding of environmental risk, and greater innovation to address environmental problems;
- A credible deterrent to pollution and greater compliance with the law; and
- Effective management.

Then, in 2003, EPA released a draft Strategic Plan for Fiscal Years 2003 through 2008 (USEPA, 2003a). This version of EPA's Strategic Plan includes five long-term goals around which EPA will focus its efforts:

- Clean air;
- Clean and safe water;
- Preserving and restoring the land;
- Healthy communities and ecosystems; and
- Compliance and environmental stewardship.

Each of these goals apply to all of EPA's programs and projects, and therefore encompass OPPT programs and projects. For example, pollution prevention principles are woven through all five

goals in order to effectively reduce impacts on the air, water, land, and people. The last two 2003 GPRA goals have elements that focus specifically on OPPT's activities.

B-8.2 HOMELAND SECURITY

In October 2002, EPA announced its Homeland Security Strategic Plan (USEPA Press Release, 2002). Based on EPA's core mission of protecting public health and safeguarding the environment, the plan identified an initial set of activities for the Agency to assist in protecting and responding to future terrorist attacks. EPA is currently revising this strategic plan to reflect both lessons learned over the past two years and the creation of the Department of Homeland Security.
OPPT will continue its work in the Acute Exposure Guidelines Levels Program. This program establishes short-term, peer reviewed, exposure levels for chemicals agents. These values are used extensively for emergency planning and response. OPPT is also working with other offices in the Agency to assess the Agency's overall role in chemical preparedness, response and site security.

B-8.3 INFORMATION QUALITY GUIDELINES

Section 515 of the Treasury and General Government Appropriations Act for FY2001 (Public Law 106-554) directed the Office of Management and Budget (OMB) to issue guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies." OMB issued this guidance in February 2002 (67 FR 8452, February 22, 2002).

In response, EPA developed "Guidelines to Ensure and Maximize the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency" (USEPA, 2002b), which define EPA's policy and procedures for collecting, using, and disseminating information to the public. The specific guidelines reference existing EPA requirements for senior management review, peer review, communication product review, web guidance, error correction processes, and public review. The guidelines define "information" and "influential information," applying a graded approach for ensuring information quality. The guidelines were created in an open collaborative process between EPA and EPA stakeholders. OPPT uses these guidelines when issuing information about chemicals and regulations, and when developing new rules.

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USEPA. 2000b. Framework for a Voluntary Children's Chemical Evaluation Program. U.S. EPA, April 12, 2000. Available online at: http://www.epa.gov/chemrtk/vccep/kdsfr410.htm

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USEPA. 1997. United States National Profile on Management of Chemicals. USEPA Office of Prevention, Pesticides, and Toxic Substances, January 1997.

USEPA Press Release. 2002. EPA Announces Homeland Security Strategic Plan, One of Many Efforts to Ensure Agency's Ability to Protect, Respond and Recover. October 2, 2002.

Appendix C:

Legislative and Regulatory Citations

Table C-1. Legislative and Regulatory Citations

Legislation/Regulation	Citation
TSCA	
The Toxic Substances Control Act (TSCA)	15 U.S.C. § 2601 et seq.
TSCA §2(b) – general purposes of TSCA	15 U.S.C. § 2601(b)
Testing	
TSCA §4 Testing of Chemical Substances and Mixtures	15 U.S.C. § 2603
TSCA §4 Test Rules (including Enforceable Consent Agreements and the TSCA Interagency Testing Committee)	40 CFR 790 - 799
New Chemicals and Significant New Uses	
TSCA §5 Manufacturing and Processing Notices	15 U.S.C. § 2604
Premanufacture Notification (PMN) Regulations	40 CFR 720
Significant New Use Regulations	40 CFR 721
TSCA §5 exemptions for research and development	40 CFR 720.36
TSCA §5 exemptions for test marketing	40 CFR 720.38
TSCA §5 exemptions for low volume/low release/low exposure	40 CFR 723.50
TSCA §5 polymer exemption	40 CFR 723.250
TSCA §5(e) Consent Orders	15 U.S.C. § 2604(e)
Biotechnology	
Biotechnology Policy Statement (1986)	51 FR 23302
TSCA Biotechnology Rule	62 FR 17909, April 11, 1997
TSCA Reporting Requirements and Review Processes for Microorganisms	40 CFR 725
Hazardous Chemicals	
TSCA §6 Regulation of hazardous chemical substances and mixtures; procedural rules	15 U.S.C. § 2605; 40 CFR 750
TSCA §6(e) PCBs	15 U.S.C. § 2605(e); 40 CFR 761
TSCA §7 Imminent hazards	15 U.S.C. § 2606
Also see Lead and Asbestos	

Legislation/Regulation	Citation
Information Reporting	
TSCA §8 Reporting and Retention of Information (including TSCA Chemical Inventory authority)	15 U.S.C. § 2607
TSCA Chemical Inventory Regulations and the Inventory Update Rule (IUR) / Amendments	40 CFR 710 64 FR 847, January 7, 2003
TSCA §8(a) General Information Gathering Authority and the Preliminary Assessment Information Rule (PAIR)	40 CFR 712
TSCA §8(c) Allegations of Significant Adverse Reactions	40 CFR 717
TSCA §8(d) Unpublished Health and Safety Studies	40CFR 716
TSCA §8(e) Substantial Risk Information	43 FR 11110, March 16, 1978 (Policy Statement)
Other TSCA Provisions	
TSCA §9 Coordination with Other Federal Lawy	15 U.S.C. § 2608
TSCA §12(b) Export Notification	15 U.S.C. § 2611; 40 CFR 707, Subpart D
TSCA §13 Import Certification	15 U.S.C. § 2612; 19 CFR 12.118 - 12.127, and 127.28; 40 CFR 707.20
TSCA §14 Regulations on the Confidentiality of Business Information	15 U.S.C. § 2613; 40 CFR 2, 704.7, 707.75, 710.38, 712.15, 716.55, 717.19
TSCA §21 Citizen Petitions	15 U.S.C. § 2620
Lead	
Ban on residential leaded paint by the Consumer Product Safety Commission	16 CFR 1303
The Residential Lead-Based Paint Hazard Reduction Act	42 U.S.C. § 4851 et seq.; 40 CFR 745
TSCA Title IV Lead Exposure Reduction	15 U.S.C. § 2681 et seq.; 40 CFR 745
TSCA Title IV regulation for training and certification system for lead-based paint professionals	40 CFR 745, Subpart L
TSCA Title IV regulation for training and certification system for renovation contractors	64 FR 6073, February 8, 1999

Legislation/Regulation	Citation
TSCA Title IV regulation to establish hazardous levels or conditions of lead in paint, dust and soil	40 CFR 745, Subpart D
TSCA Title IV requirements for individuals who conduct renovation to distribute lead-hazard information	40 CFR 745, Subpart E
Requirements for the disclosure of lead-based paint hazards in housing being offered for sale or lease	40 CFR 745, Subpart F
Asbestos	
TSCA §6 Asbestos Requirements	15 U.S.C. § 2641-2656; 40 CFR 763
Asbestos Ban and Phase-Out Rules (ABPO)	54 FR 29460, July 12, 1989; 58 FR 58964, November 5, 1993; 59 FR 33208, June 28, 1994
Asbestos Hazard Emergency Response Act (AHERA): TSCA Title II	15 U.S.C. § 2641 et seq.
The Asbestos School Hazard Abatement Act of 1984 (ASHAA)	20 U.S.C. § 4011 et seq.
The Asbestos School Hazard Abatement and Reauthorization Act of 1990 (ASHARA)	20 U.S.C. § 4011 et seq.
Chemical Right-to-Know	
High Production Volume (HPV) Challenge Program	65 FR 81686, December 26, 2000
Proposed TSCA §4 rulemaking for unsponsored HPV chemicals	65 FR 81658, December 26, 2000
Voluntary Children's Chemical Evaluation Program (VCCEP)	65 FR 81700, December 26, 2000
Other Legislation	
Clean Air Act (CAA)	42 U.S.C. § 7401 et seq.
The Government Performance and Results Act (GPRA)	Pub Law No. 103-62
The Pollution Prevention Act (PPA)	42 U.S.C. § 13101 et seq.

Appendix D:

Source Information and Additional Web Resources

Table D-1. Source Information and Additional Web Resources

Topic	Web Links for Source Information
TSCA	
TSCA Inventory / Inventory Update Rule (IUR) / Preliminary Assessment Information Rule (PAIR)	http://www.epa.gov/oppt/chemtest/index.htm http://www.epa.gov/oppt/chemtest/sect8a.htm
Allegations of Significant Adverse Reactions Rule	http://www.epa.gov/oppt/chemtest/sect8c.htm
Substantial-risk Information Requirement	http://www.epa.gov/oppt/tsca8e/index.htm
Unpublished Health and Safety Studies Rule	http://www.epa.gov/oppt/chemtest/sect8d.htm
Master Testing List (TSCA §4 Test Rules) / TSCA Interagency Testing Committee Activities (Priority Testing List)	http://www.epa.gov/oppt/chemtest/whatitc.htm http://www.epa.gov/oppt/chemtest/mtlintro.htm
Data Development Requirements for Evaluation of Potential Health and Environmental Hazards or Exposures	http://www.epa.gov/oppt/chemtest/data.htm
Import Certifications	http://www.epa.gov/oppt/chemtest/sect13.htm
Export Notification Rule	http://www.epa.gov/oppt/chemtest/sect12b.htm
Premanufacture Notification	http://www.epa.gov/oppt/newchems/index.htm http://www.epa.gov/oppt/newchems/cnosnurs.htm
Significant New Uses	http://www.epa.gov/oppt/newchems/cnosnurs.htm
TSCA Biotechnology Program	http://www.epa.gov/oppt/biotech/index.html http://www.epa.gov/oppt/biotech/presstxt.htm
Confidential Business Information	http://www.epa.gov/oppt/tsca8e/doc/cbi.htm http://www.epa.gov/oppt/tsca8e/doc/facts8e.htm http://www.epa.gov/oppt/tsca8e/doc/informationconfidential.htm
NATIONAL PROGRAM CHEMICALS	
Asbestos	http://www.epa.gov/asbestos/ http://www.epa.gov/asbestos/opptrole.pdf ATSDR, 2001 Toxicological Profile http://www.atsdr.cdc.gov/toxprofiles/
Asbestos Ban and Phase-Out Rules (ABPO)	http://www.epa.gov/asbestos/ban.html
Asbestos Hazardous Emergency Response Act (AHERA)	http://www.epa.gov/asbestos/asbreg.html
Setting Health-Based Standards for Lead	http://www.epa.gov/oppt/lead/leadhaz.htm http://www.hud.gov/offices/lead/

Topic	Web Links for Source Information
Lead Disclosure Upon Sale of Housing and Pre-Renovation Lead Information Rule	http://www.epa.gov/oppt/lead/leadrenf.htm http://www.epa.gov/oppt/lead/leadbase.htm http://www.hud.gov/offices/lead/
Training and Certification for Lead-Based Paint Activities	http://www.epa.gov/oppt/lead/leadcert.htm http://www.hud.gov/offices/lead/
Lead Hazard Information Pamphlet	http://www.epa.gov/oppt/lead/leadpbed.htm#Brochures
Supporting Research	http://www.hud.gov/offices/lead/
Dioxin	http://cfpub.epa.gov/ncea/cfm/dioxin.cfm http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=15239&ActType=default
Mercury	http://www.epa.gov/mercury/ http://www.epa.gov/Region5/air/mercury/mercury.html
POLLUTION PREVENTION	
Overview of the PPA	http://www.epa.gov/oppt/p2home/index.htm http://www.epa.gov/p2/p2policy/index.htm
Pollution Prevention Incentives for States (PPIS) and Tribes Grant Program	http://www.epa.gov/p2/pubs/ppisbro.pdf http://www.epa.gov/p2/grants/ppis/2002p2guidance.htm http://www.epa.gov/oppt/p2home/grants/ppis/ppis.htm
Environmental Justice through Pollution Prevention (EJP2) Grant Program	http://www.epa.gov/oppt/ejp2/
Pollution Prevention Resource Exchange (P2RX) Grant Program	http://www.epa.gov/oppt/p2home/grants/ppin/ppin.htm http://www.epa.gov/oppt/p2home/grants/ppin/factsheet.htm
Pollution Prevention Information Clearinghouse (PPIC)	http://www.epa.gov/oppt/library/ppicindex.htm
Design for the Environment (DfE) Program	http://www.epa.gov/dfe/ http://www.epa.gov/dfe/pubs/tools/DfEBrochure.pdf http://www.epa.gov/dfe/pubs/tools/dfefactsheet/dfefacts3-02.pdf
Green Chemistry	http://www.epa.gov/oppt/greenchemistry/whats_gc.html http://www.epa.gov/oppt/greenchemistry/docs/general_fact_sheet.pdf
Green Engineering Program	http://www.epa.gov/oppt/greenengineering/whats_ge.html
Environmentally Preferable Purchasing - Greening the Government Through Waste Prevention, Recycling and Federal Acquisition	http://www.epa.gov/oppt/epp/about/about.htm http://www.epa.gov/oppt/epp/documents/docback.htm http://www.epa.gov/oppt/epp/documents/eppbro.htm http://www.epa.gov/cpg/index.htm
Environmental Labeling Program	http://www.epa.gov/oppt/labeling/articles.htm http://www.epa.gov/oppt/labeling/factshts.htm
Sustainable Futures	http://www.epa.gov/oppt/newchems/sustainablefutures.htm

Topic	Web Links for Source Information
HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM	
Chemical Hazard Availability Study	http://www.epa.gov/oppt/chemtest/hazchem.htm
High Production Volume (HPV) Challenge Program	http://www.epa.gov/chemrtk/hpvvol2.pdf http://www.epa.gov/chemrtk/hpvfaqs.htm
Voluntary Children's Chemical Evaluation Program (VCCEP)	http://www.epa.gov/chemrtk/vccep/index.htm
GLOBAL CHEMICAL ISSUES	
Organization for Economic Cooperation and Development (OECD) and Screening Information Data Sets (SIDS)	http://www.epa.gov/oppt/sids/overview.htm http://www.chem.unep.ch/irptc/sids/sidspub.html
The International Organization for Standardization (ISO)	http://www.epa.gov/p2/programs/voluntary.htm
UNEP/UNECE Persistent Organic Pollutants (POPs) Negotiations	http://www.chem.unep.ch/pops/
TOOLS AND MODELS	
OPPT Exposure Assessment Tools and Models	http://www.epa.gov/oppt/exposure/
PBT Profiler	http://www.epa.gov/oppt/pbtprofiler/
Information about ADL Migration Exposure Model (AMEM)	http://www.epa.gov/epahome/models.htm
Chemical Screening Tool For Exposures & Environmental Releases (ChemSTEER)	http://www.epa.gov/oppt/exposure/docs/chemsteer.htm
Exposure, Fate Assessment Screening Tool (E-FAST)	http://www.epa.gov/oppt/exposure/docs/efast.htm
Ecological Structure Activity Relationships (ECOSAR)	http://www.epa.gov/oppt/newchems/21ecosar.htm
Estimation Program Interface (EPI) Suite	http://www.epa.gov/oppt/exposure/docs/episuite.htm
Multi- Chamber Concentration and Exposure Model (MCCEM)	http://www.epa.gov/oppt/exposure/docs/mccem.htm
Risk-Screening Environmental Indicators (RSEI)	http://www.epa.gov/oppt/rsei/
Use Clusters Scoring System (UCSS)	http://www.epa.gov/oppt/exposure/docs/ucss.htm
Wall Paint Exposure Assessment Model (WPEM)	http://www.epa.gov/oppt/exposure/docs/wpem.htm
OUTREACH AND COORDINATION	

Topic	Web Links for Source Information
State Technical Assistance Programs (Taps)	http://www.epa.gov/oppt/p2home/assist/state.htm
Business Technical Assistance Programs (Taps)	http://www.epa.gov/oppt/p2home/assist/business.htm
Pollution Prevention Business Development and Finance Project	http://www.epa.gov/oppt/p2home/programs/finance.htm
Environmental Assistance to Small Businesses	http://www.epa.gov/oppt/p2home/programs/busprac.htm http://www.epa.gov/sbrefa/statute.htm http://www.epa.gov/oppt/p2home/programs/smallbus.htm
Other State Organizations/ The National Conference of State Legislators (NCSL)	http://www.ncsl.org/programs/esnr/leaddes.htm
Tribes / OPPT and Tribal Environmental Network	http://www.epa.gov/oppt/tribal/
Region 8 Tribal Assistance Program (TAP)	http://www.epa.gov/region8/tribes/index.html
Tribal Operations Committee (TOC)	http://www.epa.gov/indian/overtoc.htm
OTHER	
Data Development Efforts on PFOA and PFOS	http://www.epa.gov/oppt/pfoa/
Information Quality Guidelines	http://www.epa.gov/oei/qualityguidelines/index.html

Appendix E:

Copies of Legislation and Related Documents

Table E-1. Legislation Web Resources

Legislation	Web Links
Toxic Substance Control Act (TSCA)	http://www.access.gpo.gov/uscode/title15/chapter53_.html
Pollution Prevention Act (PPA)	http://www.access.gpo.gov/uscode/title42/chapter133_.html