December 24, 2003

OVERVIEW:
OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS

Prepared for
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Office of Pollution Prevention and Toxics

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Table of Contents

Tables

Appendices

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
- 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 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] 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], 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 and Voluntary Children's Chemical Evaluation Program (VCCEP); the New and Existing Chemicals programs; the lead, asbestos, 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;

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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.

- 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.

OPPT's primary responsibility is to administer the Toxic Substances Control Act (TSCA) of 1976, and amendments, and the Pollution Prevention Act (PPA) 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 81,600 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) 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 81,600 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,

[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.

lead, 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.

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). Concurrently, EPA/OPPT has recognized that a broader program of integrated voluntary and regulatory actions, with greater emphasis on stakeholder involvement, 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.[4]

1.0 THE TOXIC SUBSTANCES CONTROL ACT (TSCA TITLE I)

1.1 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

[4] The Government Performance and Results Act (GPRA) of 1993, provides further focus to OPPT's office goals. The 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 the 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, section B-8.1.

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.

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 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 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 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.

1.2 THE TSCA CHEMICAL SUBSTANCE INVENTORY (TSCA §8 AND IUR)

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), for the partial updating of the production volume data reported to the Inventory. The rule required manufacturers of nonpolymeric organic chemical substances[5] 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* 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 81,600 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:

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

[5] Inorganic chemicals are defined as any chemical substance thatdoes 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 1.2-1. Approximate Number of Substances by Type in TSCA Inventory (October, 2003)

Class 1 Substances	34,000
Class 2 Substances	20,000
Polymers	27,600
TOTAL	81,600

Table 1.2-2. Approximate Number of Existing Chemicals in TSCA Inventory (October, 2003)[1]

Number of non-polymeric organics > 10,000 pounds/year[2]	9,000
Number of non-polymeric organics < 10,000 pounds/year	41,800
Number of inorganic substances	3,200
Polymers	27,600
Number of new chemicals added to original Inventory via commenced PMNs[1]	18,100

[1] Total of 81,600 = 9,000 + 41,800 + 3,200 + 27,600. The 18,100 chemicals added to the Inventory via commenced PMNs are distributed among these numbers.
[2] Based on an average over the first four IUR reporting cycles (1986, 1990, 1994, 1998).

Table 1.2-3. Approximate Number of New Substances Added to Inventory (As of October, 2003)

	New Substances Added to the Inventory
Class 1 Substances	4,200
Class 2 Substances	3,300
Polymers	10,600
TOTALS	18,100

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

1.3 OPPT'S 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 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.

1.3.1 The Premanufacture Notification Process and Significant New Uses (TSCA §5)

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) 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.[6]

Every PMN that is submitted to OPPT goes through a streamlined initial review process. The first of four review phases is a chemistry review. 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

[6] 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.

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. 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).

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.

Other possible outcomes of the PMN review process may include one or more of the following:

- 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").[7] TSCA §5(e) orders typically include: exposure or release mitigation,

[7] 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):

- substantial production: 100,000 kg/yr
- 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
- substantial release to the environment: greater than or equal to 1,000 kg/year total release to surface water calculated after wastewater treatment.

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 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, 2002

Regulatory Action	Number
§5(e) Consent Orders without SNURs	743
§5(e) Consent Orders with SNURs	500
Non-§5(e) SNURs	437
§5(f) Actions	4
PMNs withdrawn often in face of action	1,552
Approximate Voluntary Testing Actions	300
TOTAL ACTIONS	3,536

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, 2002

Type of Exemption	Number
Test Marketing Exemptions	662
Low Volume Exemptions	6,238
Low Release/Low Exposure Exemptions	25
Polymer Exemptions	2,127[1]
TOTALS[2]	9,052

[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).

1.3.2 Managing Genetically Engineered Microorganisms as New Chemicals (TSCA Biotechnology Program)

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. 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

1.3.3 Encouraging the Development and Introduction of Safer or "Green" 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.** 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. 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 companies free software to use in evaluating their new chemicals for PBT characteristics.

Green Chemistry. 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.[8]

Design for the Environment. EPA's Design for the Environment (DfE) Program works with industry to incorporate environmental considerations into traditional business decisions. DfE has partnered with over 200 trade associations, companies, academic organizations, and public interest groups to achieve environmental stewardship and risk reduction through improved design of products, processes, technologies and management systems. Rather than rely on end-of-pipe controls, DfE encourages pollution prevention through the redesign of formulations, technologies, and management processes.

1.4 OPPT'S EXISTING CHEMICALS DATA DEVELOPMENT AND DATA COLLECTION ACTIVITIES

The current TSCA Inventory contains approximately 81,600 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.[9] Currently, OPPT is focusing

[8] 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.

[9] 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 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.

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.

1.4.1 REQUIREMENTS FOR COMPANIES TO DEVELOP HAZARD AND EXPOSURE DATA (TSCA §4)

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.[10] TSCA §4 has

[10] EPA must make statutory findings under either §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 §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 §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)

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 voluntary 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.

1.4.2 Collecting Information to Evaluate Potential Risks of Existing Chemicals (TSCA §8)

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 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:

- General Information Gathering Authority (§8(a))
- Allegations of Significant Adverse Reactions (§8(c))
- Unpublished Health and Safety Studies (§8(d))
- 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 (see section 1.2), 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 November 2003, approximately 31 PAIR rules have been issued for about 1,100 chemicals.

Under TSCA §8(c) 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 (about a half a dozen times).

Under TSCA §8(d), 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. To date, EPA has issued about 50 TSCA §8(d) "unpublished health and safety data" reporting rules covering approximately 1,000 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://esc.syrres.com/efdb/TSCATS.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) 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 October 28, 2003, EPA has received 15,445 initial §8(e) submissions and approximately 7,725 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 October 29, 2003, EPA received 1,471 FYI (voluntary) submissions, averaging about 30 per year.

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.

1.4.3 Data Development Efforts on Perfluorooctyl Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

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 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 April 2003, EPA released a Preliminary Draft Risk Assessment on developmental toxicity concerns indicating potential nationwide human exposure to low levels of PFOA. However, this assessment also reflects considerable scientific uncertainty about the interpretation of the risk. In an effort to obtain additional information to address the uncertainty regarding the risk, OPPT stated its interest in developing one or more enforceable consent agreements (ECAs) with interested parties to obtain additional information to be used in making regulatory or voluntary risk management decisions.

1.5 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.

1.6 ADDRESSING RISK (TSCA §§6 AND 7)

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 (section 2.0) 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	Proposal Date	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.

1.6.1 Imminent Hazards (TSCA §7)

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.

1.7 CONFIDENTIAL BUSINESS INFORMATION (TSCA §14(A))

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.

1.8 OTHER TSCA PROVISIONS

1.8.1 Relationship to Other Federal Laws (TSCA §9)

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."

1.8.2 Export Notification (TSCA §12(b)) and Import Certification (TSCA §13)

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).

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).

1.8.3 Citizen Petitions (TSCA §21)

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*.

2.0 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).

2.1 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 around the reduction and elimination of the use of PCBs and encouraging cleanup and safe disposal of PCBs.

2.2 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. 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. 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 October 2003, 37 States, 3 Tribes and 2 Territories administer their own program. TSCA

§404(g) also authorizes EPA to make grants to States to develop and carry out authorized programs.

2.3 ASBESTOS/FIBERS

EPA's major asbestos[11] 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 Radiation. OPPT has the responsibility for various asbestos programs implemented under TSCA, as described below.

The Asbestos School Hazard Abatement Act (ASHAA) of 1984 (20 USC 4011 et seq.), funded from 1985 until 1993, authorized loans and grants to help financially needy public and private schools correct serious asbestos hazards. The Asbestos Hazard Emergency Response Act (AHERA) (TSCA Title II) of 1986, directs EPA to issue TSCA regulations to establish requirements regarding asbestos abatement in schools. The Asbestos School Hazard Abatement and Reauthorization Act of 1990 (ASHARA) (20 USC 4011) reauthorized and made some minor changes in AHERA, and also reauthorized ASHAA (also see Appendix B, section B-2.2).

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 2002, the Asbestos Strategies project was commissioned by the EPA to the Global Environment and Technology Foundation (GETF). The project had two objectives: (1) to offer recommendations and options on effective asbestos oversight, outreach and education approaches; and (2) to provide an opportunity for key stakeholders to share their knowledge on barriers, incentives, lessons learned, best practices, and viable technology applications as they relate to asbestos use and management.

Throughout 2002, the GETF held more than 50 interviews with experts. The GETF also presided over a cross-sector focus group in October, 2002 with 53 stakeholders representing federal and state government agencies, industry, organized labor, technical experts, and key private sector organizations. The result was a series of short-term and long term

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

recommendations to EPA. The top five short term recommendations were to: update existing Asbestos-in-Buildings Guidance, encourage voluntary compliance with existing regulations, consider a federal legislative ban on asbestos, clarify the asbestos definition to address asbestos contamination in vermiculite (see below) and other minerals, and develop a national mesothelioma registry. The top five long-term recommendations were to: update Asbestos Model Training Curricula, enforce existing asbestos regulations, reduce unintended asbestos in products, reduce asbestos-containing products in commerce, and partner with state agencies in support of asbestos training.

Asbestos contamination in vermiculite has also more recently become a national concern. Preliminary studies indicated that vermiculite itself generally poses very low hazards to the general public and consumers, although a more serious risk may be present for those who work with vermiculite and have more frequent and longer duration exposures.

In May of 2003, EPA issued the results of a "Pilot Study To Estimate Asbestos Exposure from Vermiculite Attic Insulation (VAI)," which found that disturbed VAI can create a potential risk to consumers. EPA also launched a consumer awareness campaign in May, along with the Agency for Toxic Substances and Disease Registry (ATSDR). The campaign included the publication of a consumer guidance brochure on VAI, which states that consumers should not disturb VAI due to its potential to contain asbestos fibers. EPA and ATSDR also recommend that homeowners only remove VAI if the material would otherwise be significantly disturbed during a renovation activity, and that any needed removal be performed only by an asbestos abatement professional. EPA is initiating further studies on vermiculite attic insulation, as well as other asbestos-related issues. EPA will also continue to address asbestos-related issues through an Asbestos Action Plan and research agenda currently under development.

2.4 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).

In 1994, the EPA embarked upon the Dioxin Exposure Initiative (DEI), a research program to further evaluate the exposure of Americans to dioxin and related compounds. DEI is jointly funded and managed by the EPA Office of Research and Development and OPPT. The DEI is a

multi-year effort placing particular emphasis on gaining as much information as possible that could be incorporated into the final dioxin reassessment and used to support EPA development and implementation of an Agency-wide dioxin risk management strategy. The fundamental goal of the initiative is to quantitatively link dioxin sources to potential general population exposure. An additional goal of the initiative is to estimate, where possible, past trends in dioxin exposure and to establish a current baseline for monitoring future trends.

2.5 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. Recently, OPPT began developing a new Mercury Action Plan using a multi-media approach to strategically coordinate EPA's mercury risk reduction and pollution prevention efforts across EPA offices.

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 are reductions in mercury uses, releases, and exposure.

3.0 THE POLLUTION PREVENTION ACT AND VOLUNTARY POLLUTION PREVENTION PROGRAMS

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). 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.

3.1 THE 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 integrated 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) 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.

3.2 VOLUNTARY POLLUTION PREVENTION 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 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): 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**: 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)**: a federal government-wide program managed by OPPT that requires and assists Executive agencies in the purchasing of environmentally preferable products and services.
- **Green Chemistry**: an initiative under OPPT's DfE Program that focuses on P2 through the environmentally conscious design of chemical products and processes.
- **Green Engineering**: 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)**: 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.
- **Hospitals for a Healthy Environment (H2E)**: a voluntary partnership between EPA, the American Hospital Association (AHA), and its members, to implement P2 practices in hospitals, focusing on mercury waste elimination and hospital waste reduction.
- **Sustainable Futures**: 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.

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

3.3 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), 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, 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.

4.0 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.

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 voluntary HPV Challenge Program 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.

The HPV Challenge 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.

Industry has responded to this challenge by sponsoring over 2,100 HPV chemicals in the HPV Challenge Program. In 1999 and 2000, 418 U.S. chemical companies volunteered to provide EPA and the public with data on 2,159 HPV chemicals over a five-year period.[12] Since the spring of 2000, industry has been submitting either actual data, or plans to generate and submit such data. Full data sets take approximately 2 years to complete, so chemicals that were started in the first full year of the program are just now being completed.

EPA has issued a proposed test rule under TSCA §4 to obtain needed hazard information on some portion of the HPV chemicals that have not been sponsored. The first such rulemaking was proposed in December 2000, covering 37 HPV chemicals (65 FR 81658). The final rule is

[12] As of 11/21/03, the number of chemicals and companies that have committed to the HPV Challenge Program are: 2,231 (sponsored chemicals), 331 (number of companies), and 96 (number of consortia – companies working together to meet the Challenge).

planned for promulgation in early 2004. Additional HPV test rules addressing other unsponsored chemicals are also under consideration.

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 Program is the public presentation of hazard data for the SIDS endpoints described above. After a company or consortium (group of companies working together) agrees to "sponsor" a chemical or group of chemicals (i.e., a chemical category), an HPV Challenge Submission is made. The HPV Challenge Submission consists of a cover letter, a Test Plan, and 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, and if it is considered adequate, the claim that no new testing is necessary. 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. For example, Robust Summaries guidance templates exist for each of the SIDS endpoints (http://www.epa.gov/chemrtk/robsumgd.htm). Similar documents exist for categories, structure-activity relationships, and evaluation of data adequacy. In the last one, guidance is given for 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 done using current OECD or equivalent test guidelines.

Once a submission is received by the EPA, it is posted on the EPA website (http://www.epa.gov/chemrtk/volchall.htm) for a 120-day comment period. This allows interested parties, the 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, 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.

Over 85% of the chemicals sponsored to date in the HPV Challenge Program are being handled as part of a category. This means that the sponsor has proposed that a group of chemicals can be considered together in addressing the SIDS endpoints. In other words, the sponsor asserts 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. Unlike 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.

Additional information regarding the HPV Challenge program is provided in Appendix B, section B-4.

4.1 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). 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* 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: a summary of the toxicology information, a summary of the exposure information, a risk characterization, and a 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 the VCCEP test battery 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 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. 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 panel's opinions and makes it available to the sponsor and the public.

OPPT reviews the sponsor's assessment and develops a response to the sponsor specifically on the data needs assessment. The response focuses primarily on whether any additional information is needed to adequately characterize the potential risks to children. EPA's response is sent to the sponsor and made available to the public.

Additional information regarding the Voluntary Children's Chemical Evaluation Program is provided in Appendix B, section B-4.5

5.0 GLOBAL CHEMICAL ISSUES

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 must also coordinate with foreign governments on an ad-hoc basis as issues and opportunities arise. For example, in the context of the TransAtlantic Business Dialogue effort, the chemical industry of the European Union (EU) and the U.S. have approached regulatory authorities on both sides of the Atlantic to raise issues of inconsistent regulations. As another example, the U.S. and Canada have agreed to enable Canadian risk assessors to utilize U.S. risk assessment work for their examination of new substances.

Key organizations and agreements that OPPT coordinates with and/or otherwise participates in include:

- **Organization for Economic Cooperation and Development (OECD): SIDS, GHS, MAN, Test Guidelines Program, and MAD.** The OECD is an international organization consisting of 30 industrialized countries in Europe, North America, Asia, and the Pacific. OPPT participates in OECD's programs 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, 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 experimental studies to assess physicochemical properties, environmental fate, ecotoxicity, and health toxicity endpoints. A foundation of this program is the Mutual Acceptance of Data (MAD) agreement among OECD countries to accept OECD Test Guideline-run studies for review regardless of where the study is performed.

- **United Nations Environmental Program (UNEP): POPs, PIC, and SAICM.** UNEP was established in 1972 under the United Nations system, and includes a chemicals unit tasked with helping governments take needed global 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. In coordination with the Intergovernmental Forum on Chemical Safety (IFCS), UNEP is currently involved in further development of a Strategic Approach to

International Chemicals Management (SAICM). In February, 2003, UNEP initiated a global mercury program which will help less developed countries to better characterize and address their mercury pollution problems.

- **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.

- **Intergovernmental Forum on Chemical Safety (IFCS).** Established in 1994, the IFCS is an intergovernmental arrangement whereby representatives of governments meet, together with non-governmental organizations, to integrate and consolidate national and international efforts to assess and manage chemicals. The IFCS provides policy guidance, identifies priorities, develops strategies and, where appropriate, makes recommendations to governments, international organizations, intergovernmental bodies and non-governmental organizations.

- **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 Group, OPPT has assisted in the development of North American Regional Action Plans for several substances of international concern, including PCBs, mercury and dioxin.

- **Great Lakes Binational Toxics Strategy (Canada/U.S.)**. The purpose of the binational strategy (the Strategy) is to set forth a collaborative process by which Environment Canada (EC) and the EPA, in consultation with other federal departments and agencies, Great Lakes states, the Province of Ontario, Tribes, and First Nations, will work in cooperation with their public and private partners toward the goal of virtual elimination of persistent toxic substances resulting from human activity, particularly those which bioaccumulate, from the Great Lakes Basin, so as to protect and ensure the health and integrity of the Great Lakes ecosystem. This Strategy has been developed under the auspices of the Binational Executive Committee (BEC), which is charged with coordinating the implementation of the binational aspects of the *Revised Great Lakes Water Quality Agreement of 1978, as amended by Protocol signed November 18, 1987*. This agreement is monitored by the International Joint Commission United States and Canada.

Additional information regarding global chemical issues is provided in Appendix B, section B-5.

6.0 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.

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). 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).

OPPT has also developed models to estimate hazard to humans and the environment. For example, OncoLogic® 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 judgement (see Appendix B, section B-6.9). ECOSAR (Ecological Structure Activity Relationships) 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 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) and the Wall Paints Exposure Assessment Model (WPEM). 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).

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 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.

7.0 OUTREACH AND COORDINATION

7.1 OUTREACH TO THE PUBLIC AND OTHER STAKEHOLDERS

OPPT's outreach efforts are extensive and varied. They may be characterized in terms of both the chosen medium or mechanism as well as the target audience. Mechanisms that OPPT currently employs to reach out to stakeholders include public dockets, publications (both printed and electronic), interactive websites, clearinghouses of information, hotlines, media notices and events, workshops, and 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 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), provides both general and technical information on TSCA regulations and policies to a broad range of stakeholders.

- The National Lead Information Center Information, which provides information on lead hazards to the public, is funded by EPA, HUD, and CDC.

- The Pollution Prevention Information Clearinghouse 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) (see Appendix B, section B-3.2.1), a voluntary partnership focused on industry outreach. DfE consists of programs that works 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.

7.2 COORDINATION WITH OTHER FEDERAL AGENCIES AND CONGRESSIONAL ACTIVITIES

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 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.

7.3 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.

7.3.1. 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 primary state organizations OPPT deals with routinely are ECOS and the National Pollution Prevention Roundtable (NPPR).

An example of OPPT's commitment to working with states is the Forum on State and Tribal Toxics Action (FOSTTA), initiated in 1991 (see Appendix B, section B-7.2.1). FOSTTA serves 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. Currently there are three projects: Chemical Information and Management Project (CIMP), Pollution Prevention (P2) Project, and Tribal Affairs Project (TAP). FOSTTA provides a mechanisms for policy-level discussions on toxic chemicals and pollution prevention issues and serves as a forum for the exchange of

program and enforcement information among States, Tribes, OPPT, and EPA's Office of Enforcement and Compliance Assistance (OECA).

With regards to national chemicals of concern, EPA Headquarters and the Regions support the work in the States in several ways, including grants, model programs, national meetings 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). 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) - funded with state and federal funds, these centers provide technical assistance to businesses, particularly small businesses; and P2 Resource Exchange Centers (P2Rx) - 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.

7.3.2. 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 programs in Indian Country. To foster effective use of resources, OPPT, working with the Office of Pesticide Programs (OPP), is developing a Tribal Strategic Plan, in consultation with the Tribes to provide a road map for implementing its programs in Indian country over the next five years. This plan is being developed with input from the Tribes through five focus groups held around the country. Over 100 Tribal representatives attended the focus group meetings and provided their perspective on high priority areas for action.

OPPT's commitment to working with the Tribes is evidenced in FOSTTA, which in 2000 expanded the work with Tribes by creating a specific Tribal Affairs Project (TAP). As noted above, FOSTTA serves 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 TAP focuses on chemical and prevention issues that are most relevant to the Tribes, including lead control and abatement, subsistence food and hazard communications, and outreach. Through the input derived from this group, OPPT has developed a better understanding of the Tribes' unique

issues. FOSTTA is managed through a cooperative agreement with ECOS, in conjunction with the National Tribal Environmental Council (NTEC).

Activities of the OPPT Tribal program include development of a Tribal Strategy, publication of a tribal newsletter (http://www.epa.gov/opptintr/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 issued numerous grants to Tribes under various of the Offices' programs including lead, PBTs and pollution prevention.

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, and a Tribal Traditional Lifeways/Subsistence Technical Workshop, which convened 30-40 Tribal experts, leaders, elders, scientists and environmental directors.

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 Native American environmental professionals capacity. Another example is the effort in conjunction with the NPPR to develop a tribal sector hub in the Pollution Prevention Resource Exchange to support Tribal pollution prevention collaboration and technical assistance.

Additional information regarding OPPT's coordination with Tribes is provided in Appendix B, section B-7-2.