

**January 2007**

**APPENDICES TO**

**OVERVIEW:**

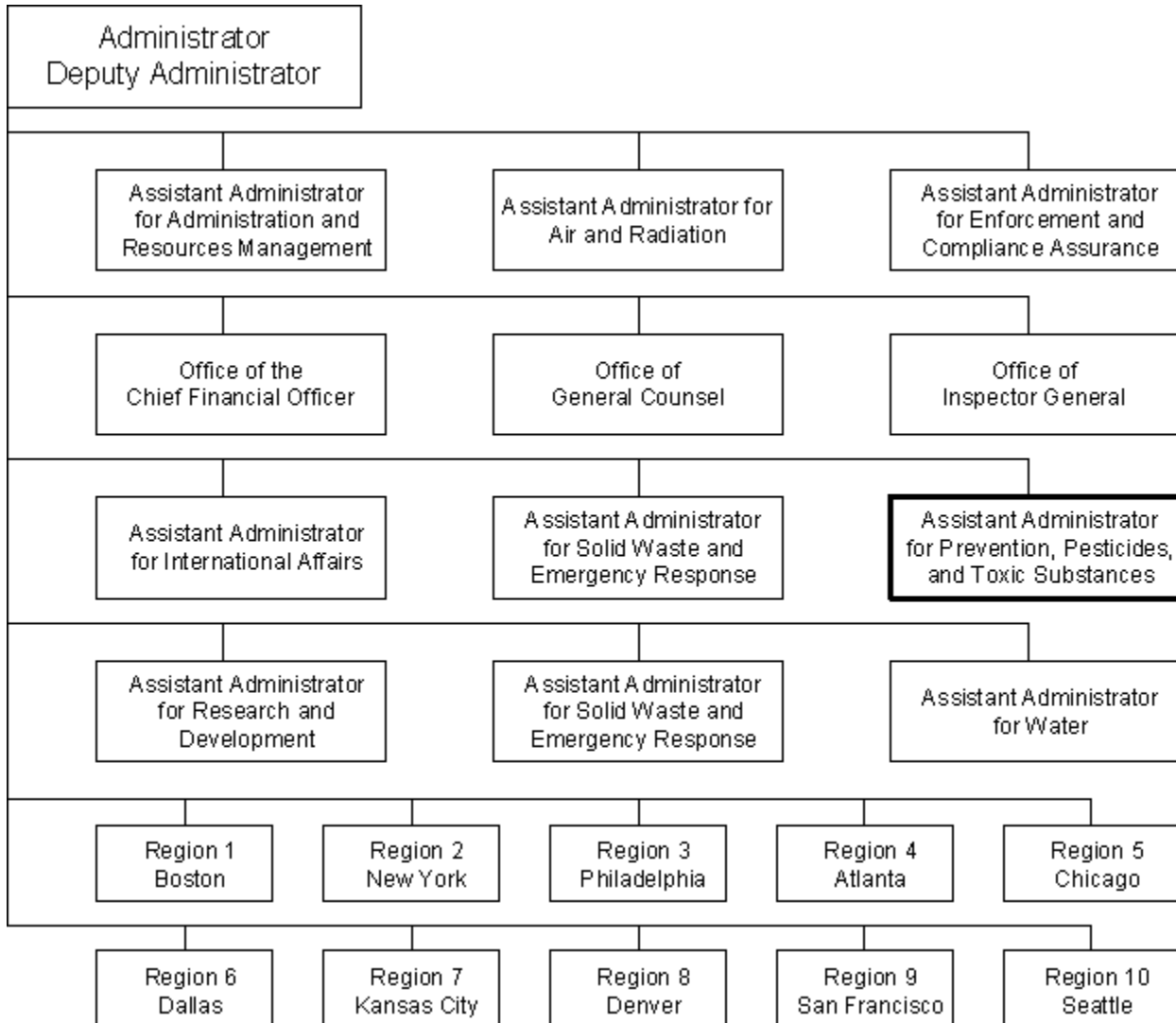
**OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS**

## Appendices

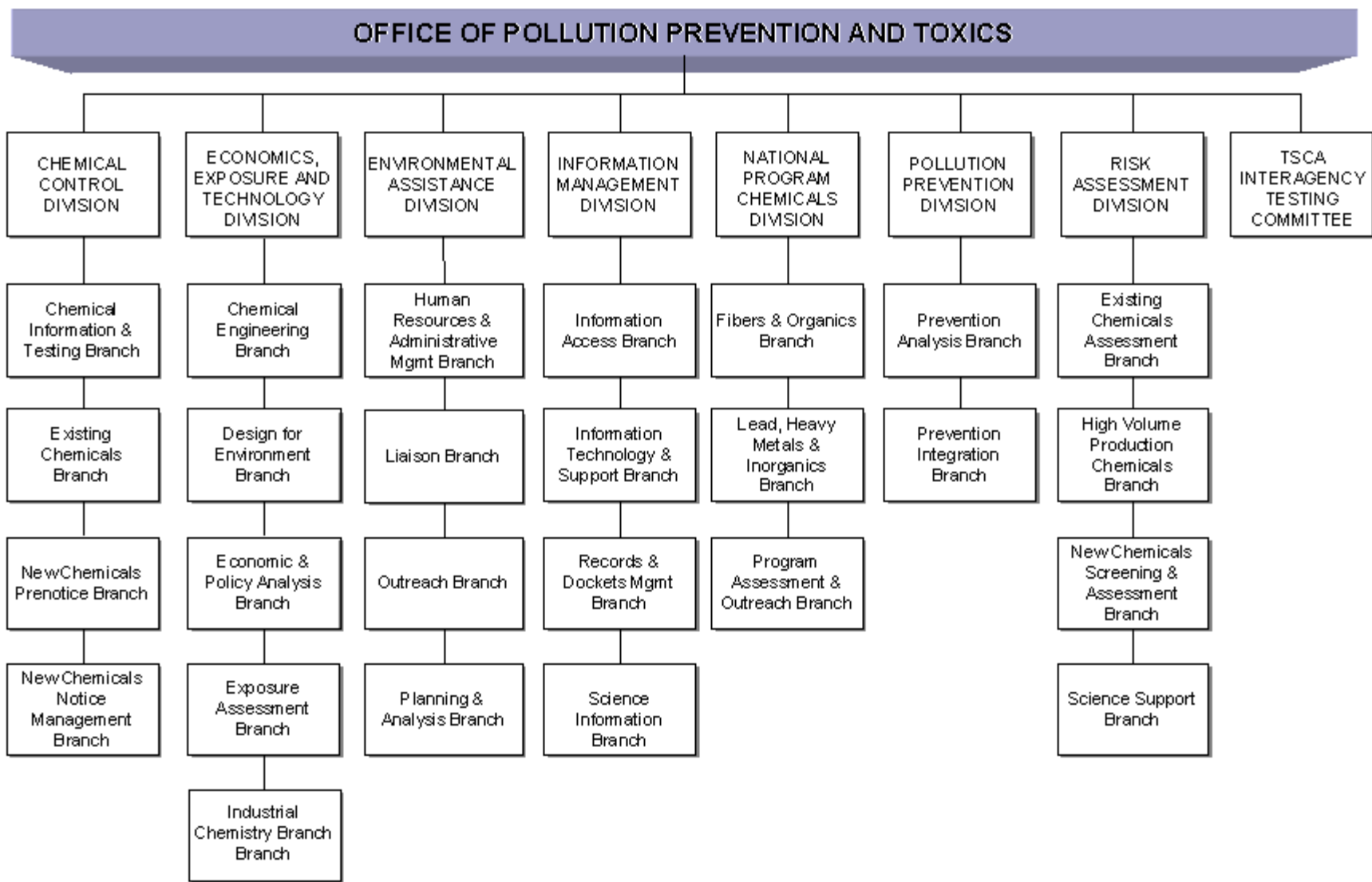
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**Appendix A:**  
**Organizational Charts for EPA and OPPT**

## Appendix A: Organizational Charts for EPA and OPPT



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



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**Appendix B:**  
**Supplementary Information on OPPT Programs**

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## Appendix B: Supplementary Information on OPPT Programs

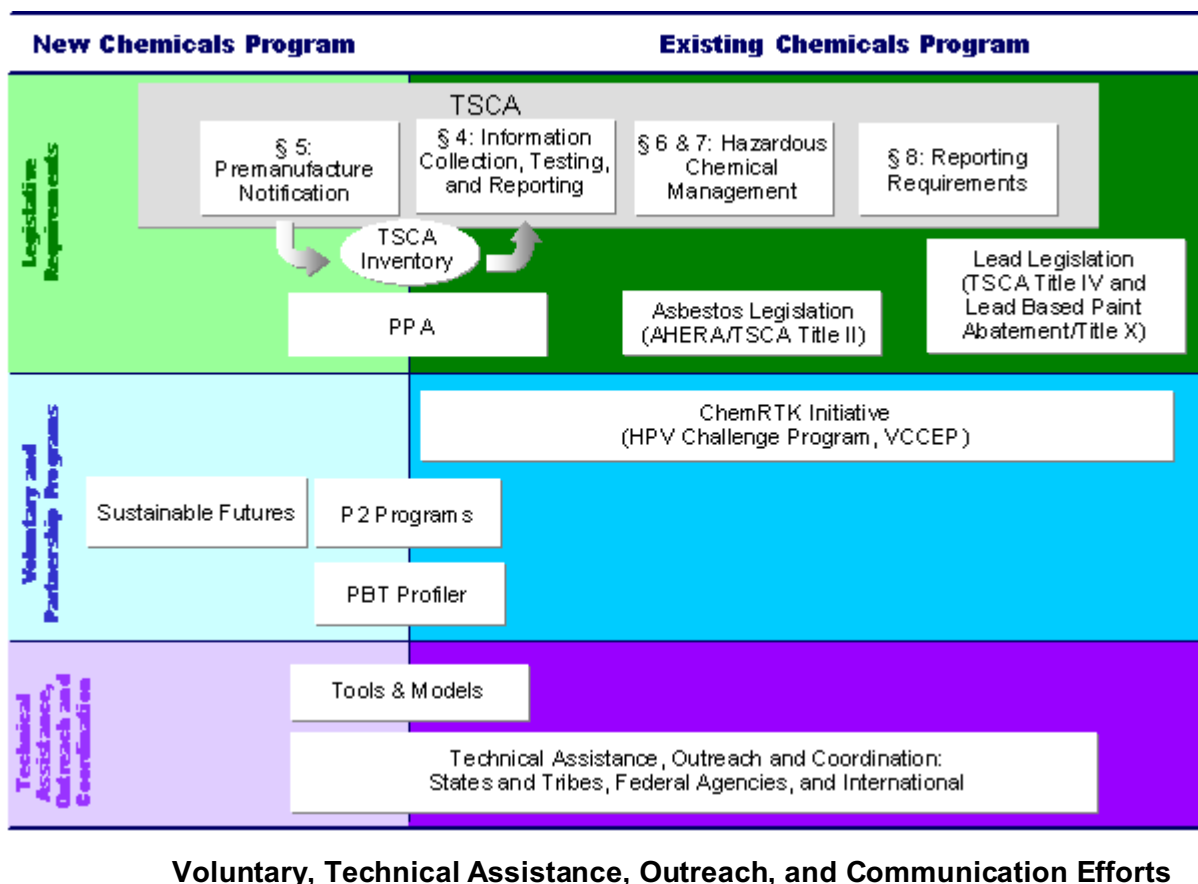


A table of links to EPA source information on a given topic, is included in Appendix D, “Source Information and Additional Web Resources.”

## B-INTRODUCTION

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

**Figure B-1. Overview of OPPT’s Framework for Chemical Management: Legislative,**



## **B-1 THE TOXIC SUBSTANCES CONTROL ACT (TSCA)**

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

### **B-1.1 THE TSCA CHEMICAL SUBSTANCE INVENTORY**

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

- Many public libraries and company libraries have copies of the TSCA Inventory. In addition, the Inventory is available at federal depository libraries. To find the closest federal depository library, call your local library or look in the Directory of U.S. Government Depository Libraries.
- Assistance in determining whether a chemical substance is on the TSCA Inventory is available on a fee basis from at least two organizations: the Chemical Abstracts Service (CAS) and Dialog. To request assistance, phone CAS at (800) 848-6538 or Dialog at (800) 334-2564. Other companies may offer similar services in the future; contact the TSCA Hotline at [tsc-hotline@epa.gov](mailto:tsc-hotline@epa.gov) or at (voice) 202-554-1404, (fax) 202-554-5603 for an up-to-date list.
- A copy of the TSCA Inventory can be purchased from the National Technical Information Service (NTIS):  

NTIS: (703) 487-4650 TSCA Inventory: searchable CD-ROM database, includes also SARA Title III; or through the NTIS Web site
- Cornell University has posted an extract of the Public Inventory at <http://msds.pdc.cornell.edu/tscsrch.asp>. Though the University's posting is not an official government version of the Inventory, it can be useful.

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

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

## **B-1.2**      **NEW CHEMICALS PROGRAM (TSCA §5)**

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

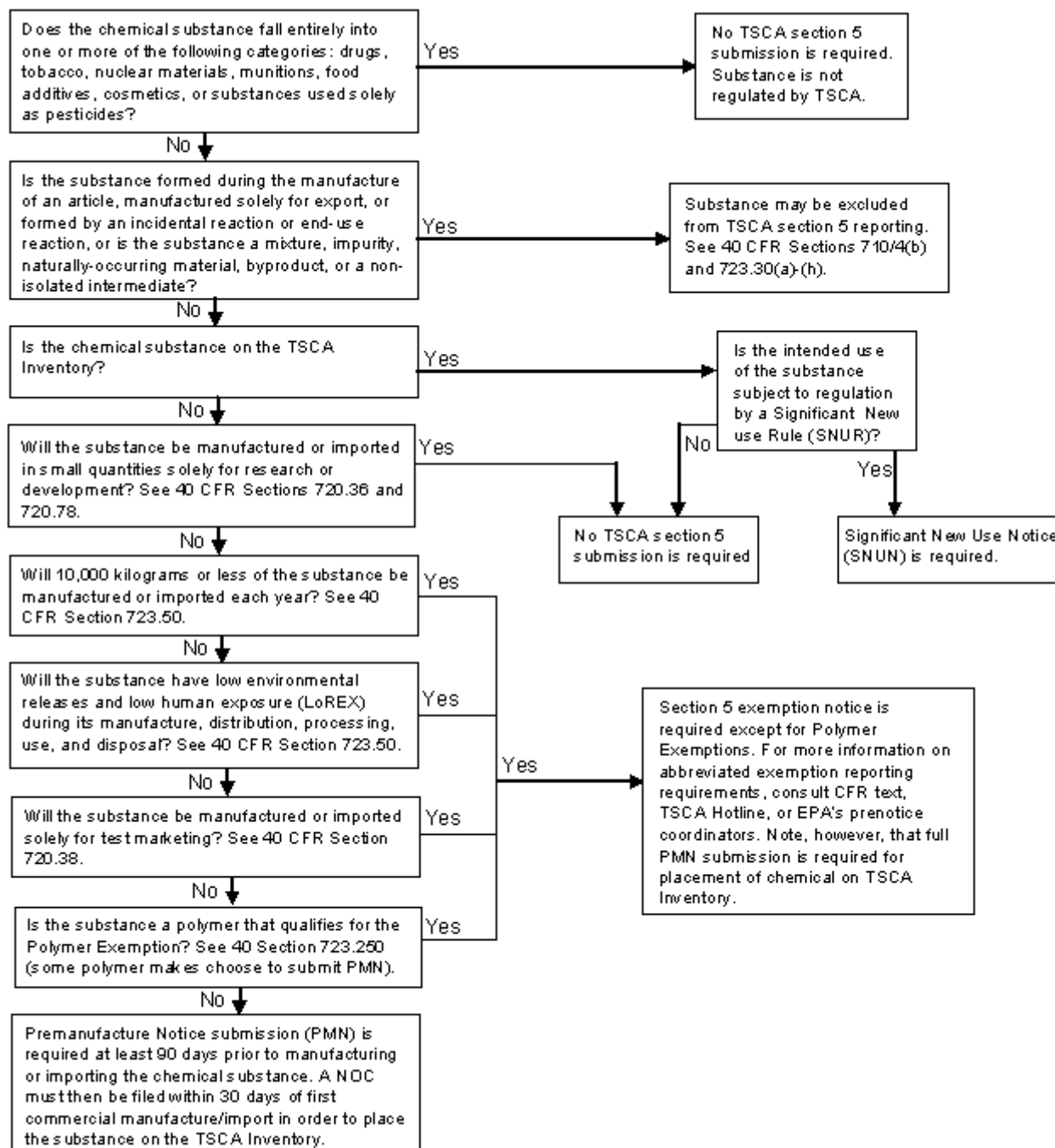
### **B-1.2.1**      ***Premanufacture Notification***

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

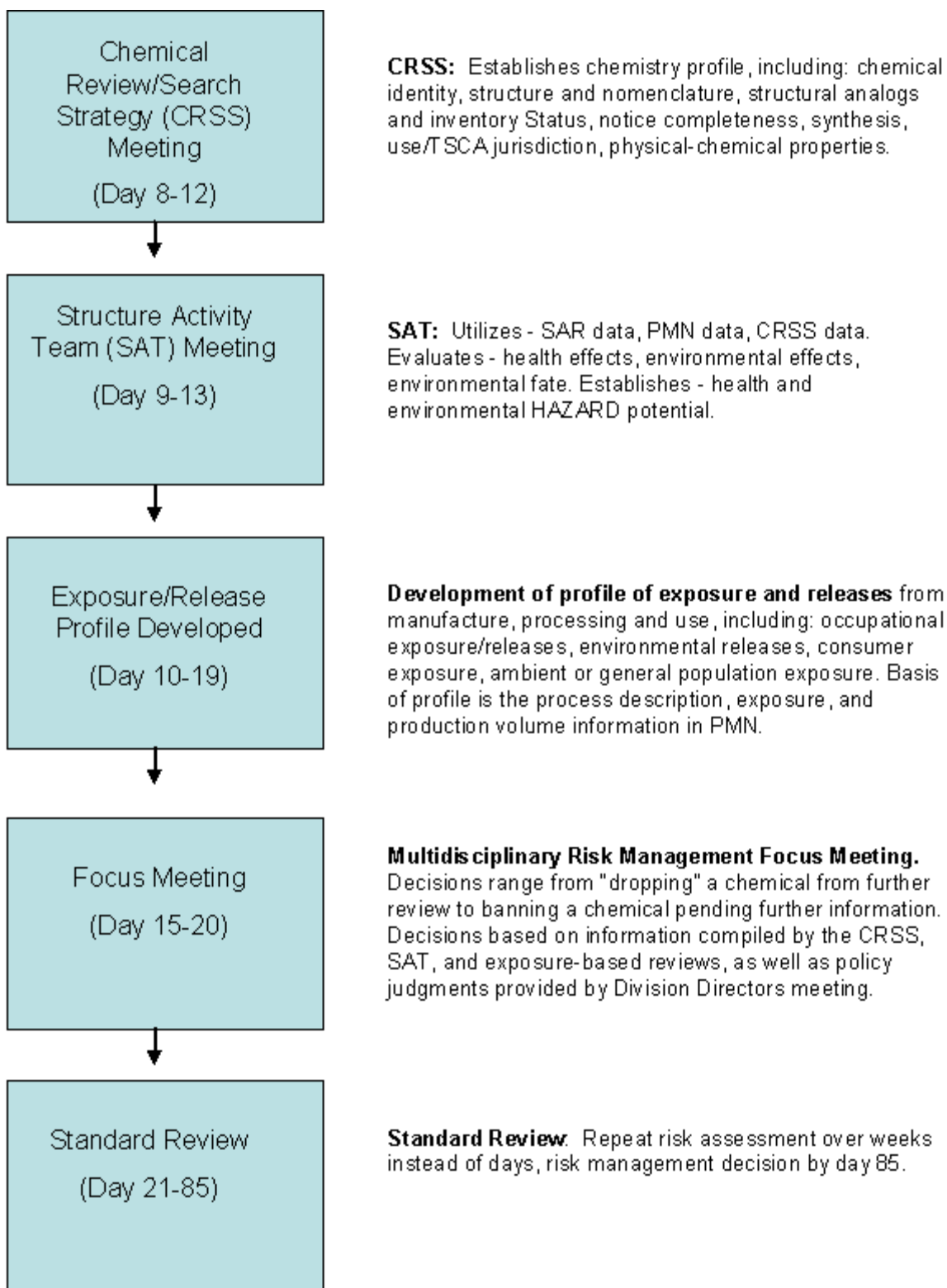
EPA provides industry with five possible exemptions under the new chemicals program. Each of these exemptions has specific reporting requirements which are unique to the exemption class. The five possible exemptions are:

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

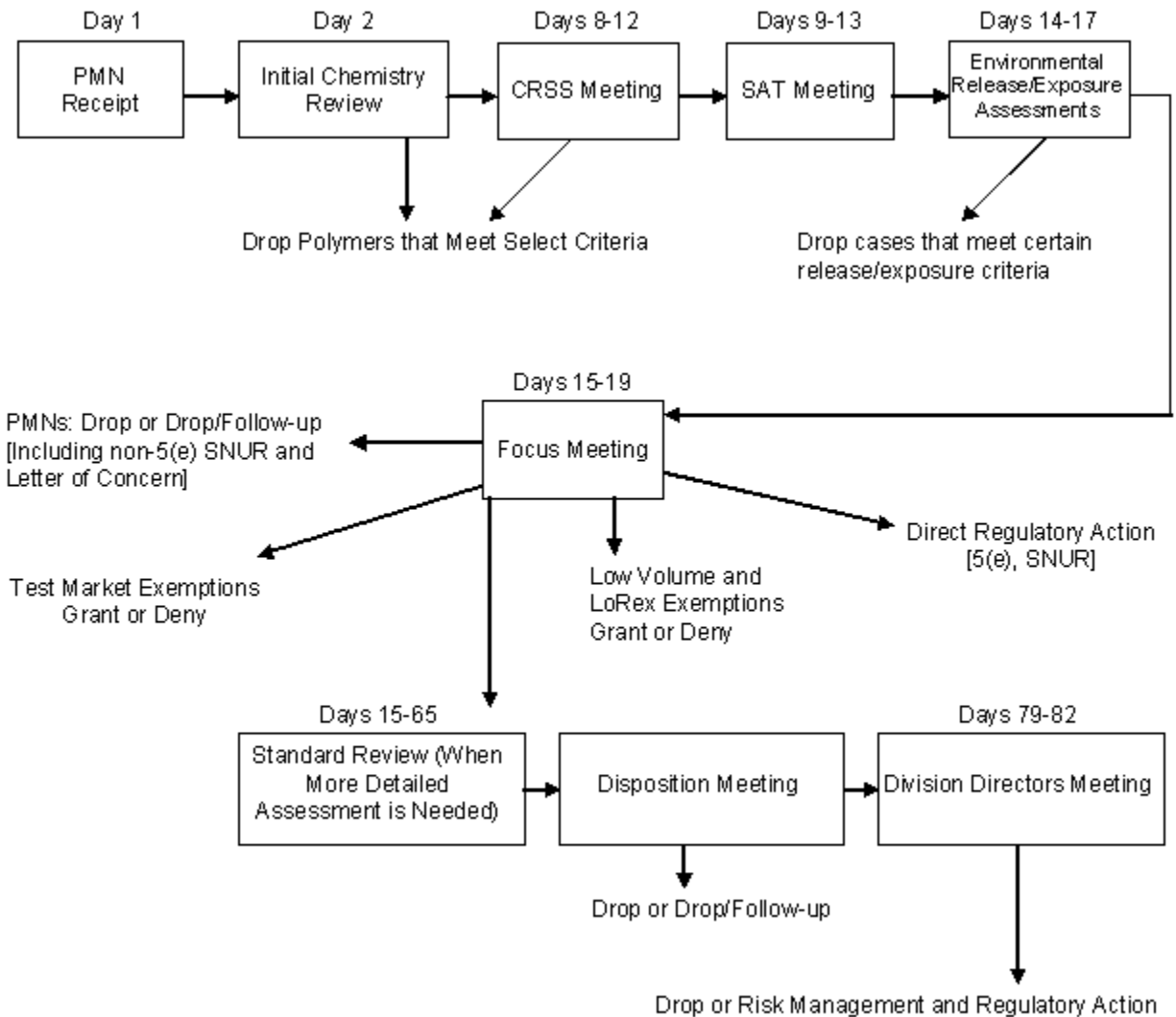
An overview of the PMN process is provided in Figures B-2, B-3, and B-4 below.



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



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



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

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

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

One of the most important recommendations from the OECD workshop was that an attempt be made to evaluate the predictive power of the (Q)SAR method, used by the EPA, in comparison to the results obtained by the EU in its minimum pre-marketing data set (MPD). It was also recommended that this evaluation be achieved by applying the (Q)SAR methods to chemicals for

which screening level test data were already available and then comparing the properties predicted by SAR with the properties observed from experimental testing. This recommendation was the starting point for the collaborative project between the EU and EPA. The project was limited to evaluation of the predictive power of the (Q)SAR techniques used by EPA in the context of new chemicals, and was not designed to be an evaluation of (Q)SAR techniques in general.

Looking at the overall results of the study, EPA noted that the physical/chemical properties generally appear to be the most difficult to predict accurately, but are among the most inexpensive to measure. On the other hand, prediction of health hazards appears reasonably good, although there is an issue with the prediction of systemic toxicity, which the EPA systems tend to under-predict. Targeted testing may offer a cost effective alternative to use of a standard test battery. EPA's ecotoxicity predictions appear to be reasonably accurate in assessing acute toxicity for fish and daphnia.

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

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

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

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

- The microorganism is intended for commercial use
- The microorganism is not on the TSCA Inventory
- The microorganism is "intergeneric" : it is the result of the deliberate introduction of genetic material from one organism into a microorganism from a different genus than that of the donor/source organism. For example, a *Pseudomonas* bacterium into which *Escherichia coli* DNA has been deliberately introduced would be considered intergeneric

- The microorganism is not subject to review by other Federal Agencies (e.g., FDA reviews pharmaceuticals, etc.). Microorganisms subject to TSCA review include those used in applications such as bioremediation, fuel production, biomass conversion, nitrogen fixation, biosensors, and closed system fermentation for the production of enzymes and specialty chemicals.

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

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

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

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

#### ***B-1.3.1 TSCA Interagency Testing Committee***

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

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



Data Reporting (HaSDR) rule to obtain unpublished studies on ecological effects, environmental fate and health effects (see section B-1.3.4 for additional information on TSCA §8(d)).

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

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

### **B-1.3.2      *Master Testing List***

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

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

On April 12, 1990, the Fifth Circuit Court of Appeals remanded to EPA the TSCA §4 test rule for the chemical cumene, based on a challenge to this rule by the Chemical Manufacturers Association (CMA), *Chemical Manufacturers Association v. Environmental Protection Agency* 899 F.2d 344 (5<sup>th</sup> Cir. 1990). The Fifth Circuit Court of Appeals required EPA to articulate criteria for the findings EPA made in the cumene test rule (53 FR 28195, July 27, 1988). That is

to say, the Court required the Agency to “articulate the standards or criteria on the basis of which it found the quantities of cumene entering the environment from the facilities in question to be ‘substantial’.” EPA decided to use this opportunity to articulate criteria for all findings under §4(a)(1)(B)(I) of TSCA.

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

**The “B” Policy.** Section 4(a)(1)(B)(I) requires the Administrator to find that a chemical substance or mixture is or will be produced in substantial quantities, and “(I) it enters or may reasonably be anticipated to enter the environment in substantial quantities, or (II) there is or may be significant or substantial human exposure to such substance or mixture,” to impose testing requirements. However, TSCA does not define the criteria or standards to be used, or the meanings of the words “significant” or “substantial.” Additionally, the legislative history of TSCA provides no elucidation of these terms.

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

### **Findings.**

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

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

- ***Substantial or Significant Human Exposure.*** It is EPA's belief that TSCA §4(a)(1)(B) was intended to address situations where large numbers of people may be exposed to a chemical substance and where little or no hazard data exists to indicate whether or not that chemical substance may present an unreasonable risk. EPA based its thresholds for workers on experience gained through case-by-case analysis of existing chemicals:
  - General population:
    - substantial: 100,000 people
    - significant: <100,000 people exposed more directly or on a routine or episodic basis
  - Consumers:
    - substantial: 10,000 people
    - significant: <10,000 people exposed more directly or on a routine or episodic basis
  - Workers:
    - substantial: 1,000 workers
    - significant: <1,000 workers exposed more directly or on a routine or episodic basis.

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

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

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

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

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

Exemptions for such reporting are as follows:

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

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

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

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

Examples of significant adverse reactions include:

- Long-lasting or irreversible damage to human health;
- Partial or complete impairment of bodily functions;
- Impairment of normal activity by all/most persons exposed at one time/each time an individual is exposed;
- Gradual or sudden changes to animal or plant life in a given geographic area;

- Abnormal numbers of deaths/changes in behavior or distribution of organisms;
- Long lasting or irreversible contamination of the physical environment.

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

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

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

- The original allegation as received;
- An abstract of the allegation;
- The results of any self-initiated investigation regarding the allegation; and
- Copies of any further required information regarding the allegations (e.g., copies of any reports required to be made to the U.S. Occupational Safety and Health Administration).

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

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

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

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

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

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

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

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

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

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

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

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

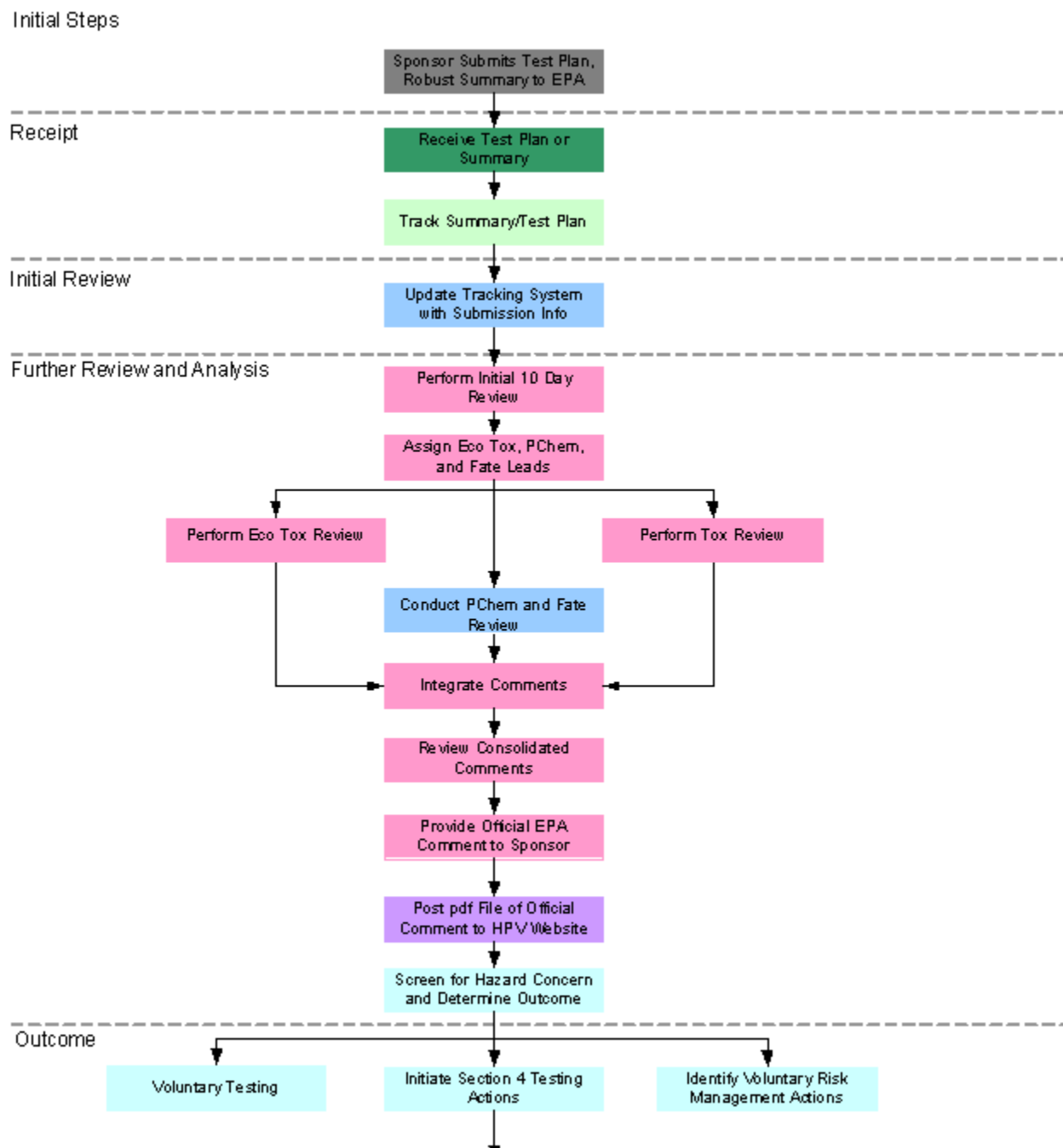
EPA has received §8(e) submissions alerting the Agency that chemical substances already known to be capable of causing serious health and/or environmental effects were detected in significant amounts in environmental media (e.g., soil, surface waters, groundwater, air (including workplace air)) or in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

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

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

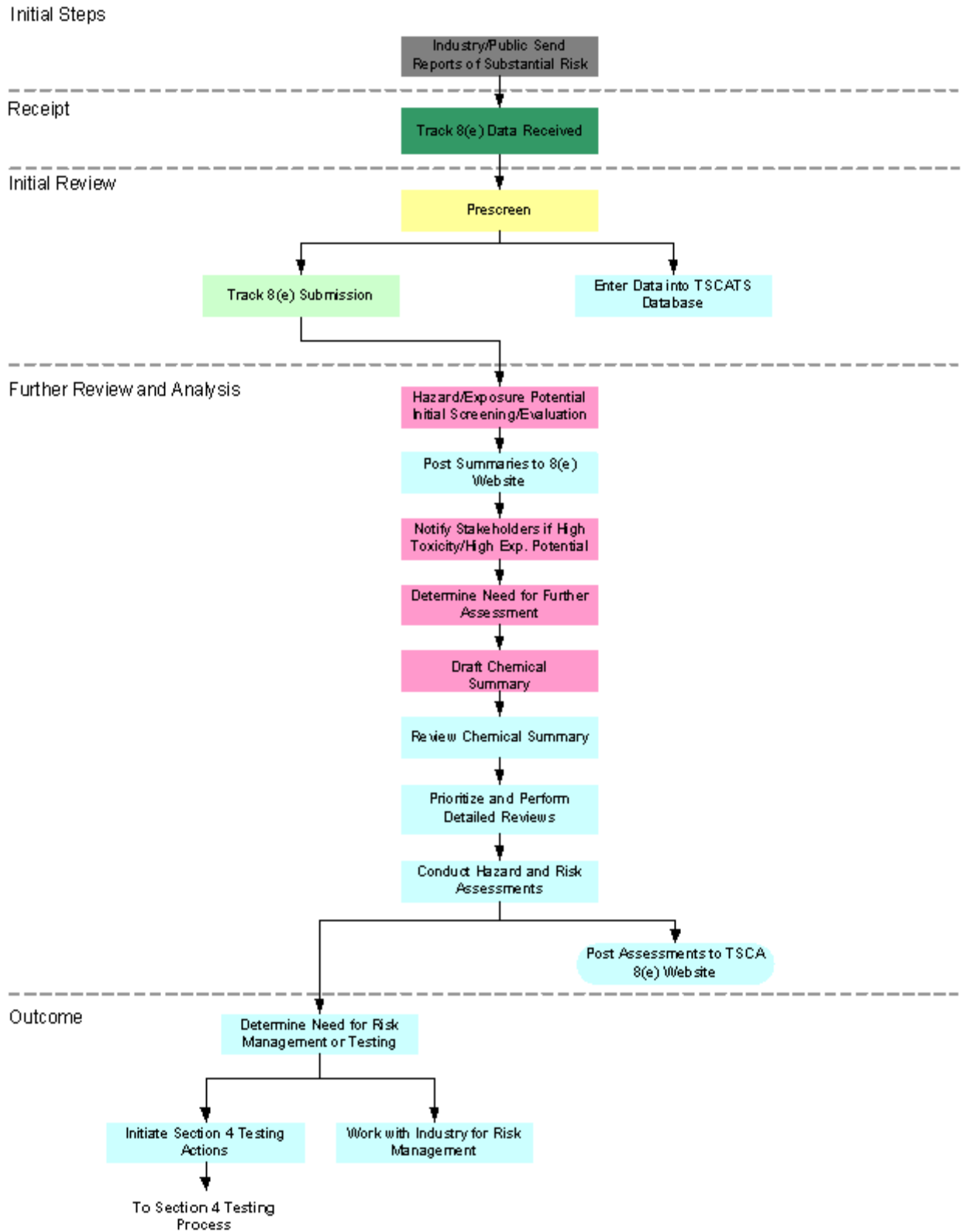
**Initial Steps.** The process is illustrated with a description of assessment activities that begin with the submission of materials from companies participating in a voluntary program (Figure B-5) or following TSCA §8(e) reporting requirements (Figure B-6), or identification of chemicals of interest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

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



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





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

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

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

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

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

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

**Outcomes.** Possible review outcomes when a concern is verified:

- The chemical may need additional testing to fully determine hazard or risk. This can result in voluntary testing actions by industry or the development and issuance of a TSCA §4 Chemical Testing Rule.
- EPA may initiate regulatory consideration or, alternatively, may work with industry/the various stakeholders to identify and implement risk management strategies for the chemical (for example, refer to the discussion of PFOS/PFOA in Section 1.4.3 of the Overview in the main part of this document).

#### ***B-1.4***      ***OTHER TSCA PROVISIONS***

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

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

- The submission of data is required under §4 or 5(b);

- An order has been issued under §5;
- A rule has been proposed or promulgated under §5 or 6; or
- Action is pending, or relief has been granted under §5 or 7.

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

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

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

#### **B-1.4.2 Import Certifications (TSCA §13)**

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

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

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

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

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

## **B-2 NATIONAL PROGRAM CHEMICALS**

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

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

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

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

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

**Pre-Renovation Lead Information Rule (PLIR) (TSCA §406(b)).** If conducted improperly, renovations in housing with lead-based paint can create serious health hazards to workers and occupants by releasing large amounts of lead dust and debris. Thus, TSCA §406(b) (15 U.S.C. § 2686(b)) requires renovators, prior to beginning renovations in pre-1978 homes, to distribute a

Lead Hazard Informational Pamphlet (see Section B-2.1.4) to educate their customers on lead hazards and how they can be minimized. EPA published a final rule, “Requirements for Hazard Education Before Renovation of Target Housing” in June 1998 (63 FR 29908, June 1, 1998).

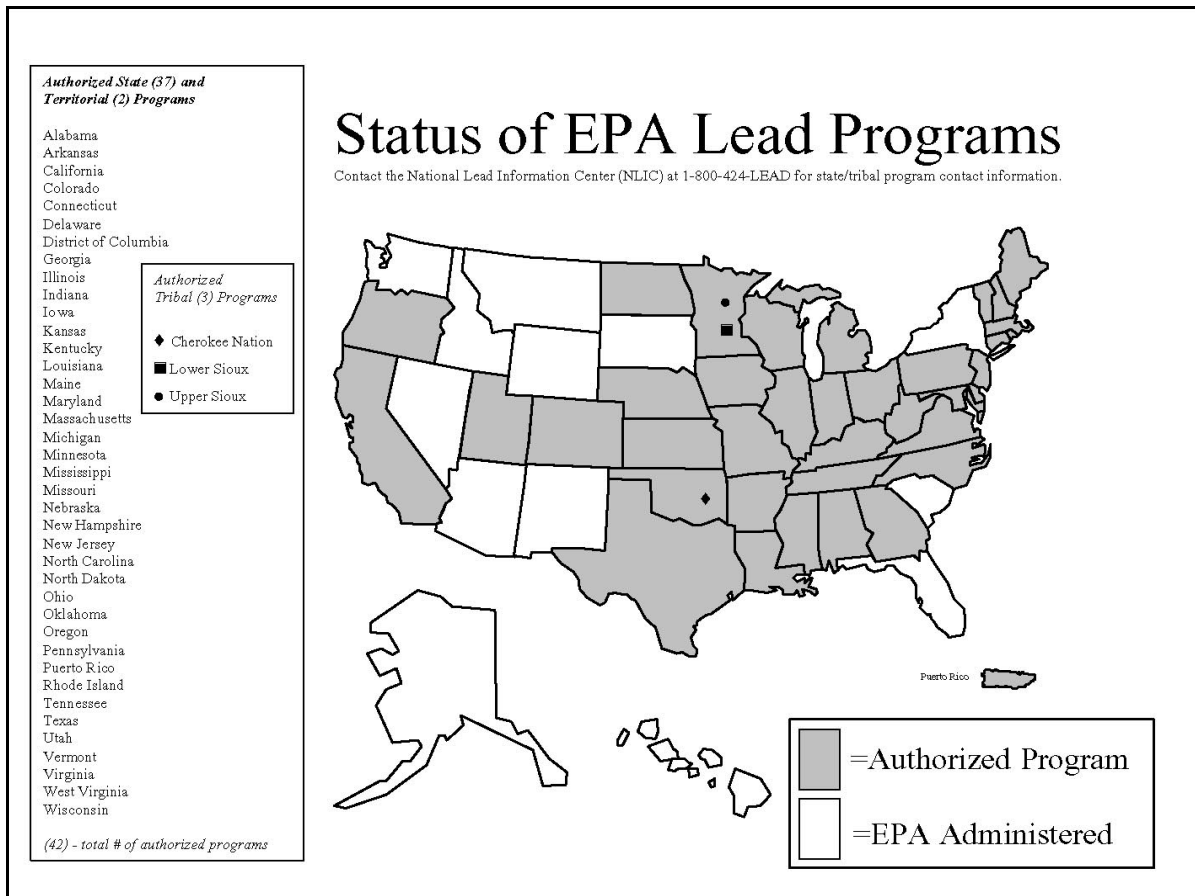
### ***B-2.1.3 Training and Certification for Lead-Based Paint Activities (TSCA §§402 and 404)***

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

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

### ***B-2.1.4 Lead Outreach and Education***

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



**Figure B-7. Status of EPA Lead Programs.**

### **B-2.1.5 Supporting Research**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Periodic Surveillance.** After the AMP has been implemented, the LEA must conduct periodic surveillance in each building that it leases, owns, or otherwise uses as a school building at least once every six months. The purpose of surveillance is to look at all known or suspect asbestos-containing building materials (ACBM) and note any changes in the material. Periodic



surveillance does not need to be conducted by a licensed consultant. It is often conducted by custodial or maintenance personnel.

**Custodial & Maintenance Training and Short-Term Worker.** All maintenance and custodial staff who may work in a building that contains asbestos-containing building materials (ACBM) must receive at least two hours of asbestos awareness training whether or not they are required to work with ACBM. Other requirements include:

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

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

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

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

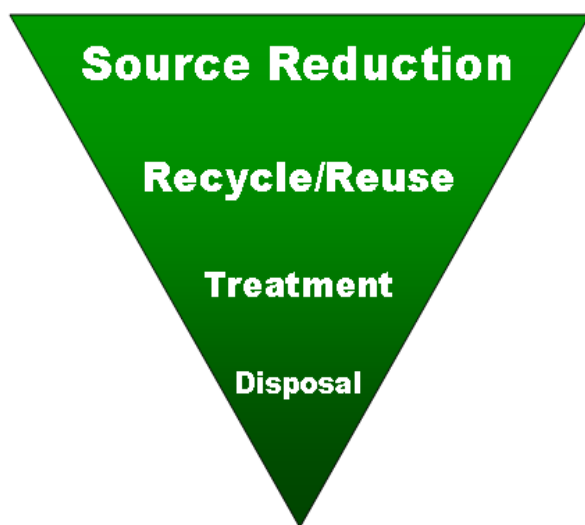
## ***B-3***            ***POLLUTION PREVENTION***

### ***B-3.1***           ***POLLUTION PREVENTION ACT (PPA)***

The major provisions of the PPA include:

- Defining pollution prevention as source reduction and establishing the pollution prevention hierarchy (see Figure B-8);

- Providing matching funds for state and local P2 programs through the Pollution Prevention Incentives for States (PPIS) grant program to promote P2 techniques by businesses (42 U.S.C. §13104);
- Establishing a P2 strategy outlining the Agency’s intent to promote source reduction and collect data on source reduction and recycling (42 U.S.C. §13106); and
- Operating a source reduction clearinghouse, the Pollution Prevention Information Clearinghouse, dedicated to reducing or eliminating industrial pollutants through technology transfer, education, and public awareness (42 U.S.C. §13105).



**Figure B-8. Pollution Prevention Environmental Management Hierarchy**

**B-3.1.1 Grant Programs**

OPPT sponsors three grant programs that specifically promote P2 activities.

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

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

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

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

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

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

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

### ***B-3.1.2 Pollution Prevention Information Clearinghouse (PPIC)***

As mandated by the PPA (42 U.S.C. §13105), EPA established the Pollution Prevention Information Clearinghouse (PPIC) to serve as a free, nonregulatory service dedicated to reducing or eliminating industrial pollutants through technology transfer, education, and public awareness. This is accomplished through EPA's P2 website, PPIC's P2 Information Products (EPA documents, pamphlets, and fact sheets, which can be ordered through the Clearinghouse) and

PPIC's Reference and Referral Service (the Clearinghouse can answer questions about P2 or refer appropriate contacts). The PPIC public interface is accessible online at <http://www.epa.gov/oppt/ppic/>

## ***B-3.2 HIGHLIGHTS OF VOLUNTARY POLLUTION PREVENTION PROGRAMS***

### ***B-3.2.1 Design for the Environment (DfE) Program***

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

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

DfE provides decision-makers with information, tools, and incentives to make informed decisions that integrate risk, performance, and cost concerns. The DfE process systematically promotes continuous environmental improvement by first identifying the array of technologies, products, and processes that can be used to perform a particular function within an industry and related P2 opportunities. The next step is evaluating and comparing the relative risks, performance, and costs of the alternatives. The final step is disseminating this information to the entire industry community and encouraging use of this information by providing mechanisms and incentives to institutionalize the alternatives.

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

### ***B-3.2.2 Environmentally Preferable Purchasing***

EPA's Environmentally Preferable Purchasing (EPP) is a federal-wide program that encourages and assists Executive agencies in the purchasing of environmentally preferable products and services. Specifically, the program seeks to help Executive agencies prevent waste and pollution by considering environmental impacts along with price and performance and other traditional factors when deciding what to buy. The Federal government is the single largest consumer in the

U.S., spending over \$200 billion annually on a wide variety of products and services. The government's purchase and use of products and services leave a large environmental footprint. Through its purchasing decisions, the Federal government can minimize environmental impacts while giving a boost to manufacturers that produce environmentally preferable products and services.

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

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

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

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

### **B-3.2.3 Green Chemistry**

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

substances during the design, manufacture, and use of chemical products and processes. The Program is composed of four major areas:

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

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

#### ***B-3.2.4 Green Engineering Program***

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

The goals of the Green Engineering Program are:

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

The focus of the Green Engineering Program in the past few years has been on the academic community. The aim is to develop future chemical engineers with Green Engineering knowledge. To accomplish its goals, the Green Engineering Program first developed a standardized textbook and modules that can be used by universities for Green Engineering courses and provide starting references for practicing engineers. The textbook, titled “Green Engineering: Environmentally Conscious Design of Chemical Processes and Products,” was

completed and published via Prentice Hall in September 2001. This textbook is being used and/or incorporated into a number of chemical engineering departments domestically and abroad. In addition, engineers from other engineering disciplines (e.g., civil and environmental engineering) have expressed interest in incorporating Green Engineering principles into their curricula.

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

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

### ***B-3.2.5 Green Suppliers Network***

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

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

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

Key Green Suppliers Features:

- **Technical Reviews.** A team composed of lean manufacturing experts from the local National Institute of Standards and Technology Manufacturing Extension Partnership (NIST MEP) and state environmental experts perform industry-

specific, one-on-one reviews at manufacturing facilities. Green Suppliers Network reviews provide custom solutions to fit a company's needs.

- **Lean and Clean.** Using *Lean and Clean* manufacturing practices, Green Suppliers Reviews combine environmental considerations and lean manufacturing techniques to enhance process efficiencies, which can lead to substantial environmental and economic benefits.
- **Supply Chain Relationships.** Green Suppliers also provides a forum for all members of the supply chain to work together to identify options for change.
- **Metrics.** MEP centers will aggregate and quantify economic and environmental benefits identified during Green Suppliers reviews.
- **Continuous Improvement.** Green Suppliers establishes a delivery mechanism to engage manufacturers and their suppliers in continuous environmental/economic improvement.
- **Implementation.** Green Suppliers can form partnerships with state, local and other federal agencies to bring the best technical, financial and research assistance to participating companies

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

### **B-3.2.6 Sustainable Futures**

In December 2002, EPA announced the launch of Sustainable Futures, a new voluntary pilot project under the TSCA New Chemicals Program (67 FR 76282, December 11, 2002). Sustainable Futures is a pilot project designed to encourage the application of P2 principles during the development of new chemicals submitted as PMNs under TSCA §5. The goal of this pilot project is to encourage P2 and the development of inherently low-hazard chemicals. Furthermore, OPPT seeks to gain additional data and experience regarding the P2, risk reduction, and source reduction benefits of the use of hazard, exposure, and risk screening methodologies in new product development efforts. Companies participating in Sustainable Futures will be encouraged to use pollution prevention-based screening techniques to reduce the toxicity of new chemicals. One approach is the EPA's Pollution Prevention Framework, which is implemented by means of a set of computer models that predict risk-related properties of chemicals using structure activity relationships (SARs) and standard (default) scenarios. These models have been developed by EPA's Office of Pollution and Toxics (OPPT) to screen new chemicals by capturing the expertise of multiple EPA scientists, grantees, and support contractors working for 20+ years screening chemicals in the absence of data. The Pollution Prevention Framework Project presents these models to industry with the hope that the models will be useful in identifying potential problem chemicals and processes early in the research and development



(R&D) process. EPA will consider providing regulatory flexibility in the form of certain expedited review to participants in the pilot project.

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

## **B-4 HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM**

### **B-4.1 CATEGORIES**

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

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

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

For example, under the OECD HPV SIDS Program, some instances have been identified where, using chemical category approaches, less than a full set of SIDS data for every chemical in the category has been judged sufficient for screening purposes. This alternative helps to reduce burden on industry, as well as minimize animal testing concerns. Guidance on the development

and implementation of categories in the HPV Challenge Program is provided on the website at <http://www.epa.gov/hpv/pubs/general/categuid.htm>.

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

#### ***B-4.2            DATA ADEQUACY***

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

The guidance for assessing adequacy of existing data describes how to determine whether existing data are sufficient to meet the SIDS program requirements, and is provided on the website at <http://www.epa.gov/pubs/general/datadfin.htm>.

In its guidance document, EPA proposes that submitters consider a two-tiered system to evaluate existing data. In Tier I, criteria are used to assess the overall scientific integrity of the information. Any data or information that do not meet the Tier I criteria would be rejected from further consideration in the HPV Challenge Program. In Tier II, a more rigorous evaluation of existing data that has passed Tier I occurs (existing data generated via OECD or equivalent guidelines can enter directly into Tier II evaluation). However, some Tier I studies that do not advance to Tier II may still be useful in a weight-of-evidence analysis. Whether used or not, it is prudent to make publicly available all of the studies that have been reviewed, possibly in the form of a bibliography.

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

purposes”, whereas in the document “Determining the Adequacy of Existing Data” EPA uses the term to mean usefulness for hazard identification purposes.

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

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

### **B-4.3            NON-SIDS DATA**

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

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

- Physicochemical properties: include information on flash point, flammability and explosivity. Other types that are usually not presented but are of interest include the Henry’s Law Constant (a measure of a substance’s tendency to stay in water or volatilize into air) and  $K_d$  (partition coefficient between soil/sediment and water).
- Environmental fate: bioconcentration (which is often presented in an HPV submission) and waste water treatability information (which is not usually submitted but is useful to determine whether a substance would degrade or be altered by conventional wastewater treatment technologies)
- Ecological effects: SIDS for ecological effects focuses on acute effects on aquatic vertebrates, invertebrates, and plants and on chronic aquatic toxicity if certain criteria are met (substances with estimated  $\log K_{ow} > 4.2$  are not likely to be acutely toxic but may be toxic under prolonged exposure periods). Occasionally, non-SIDS information on effects on either microorganisms or terrestrial organisms (plants, birds, mammals) is presented.
- Human health effects (laboratory animal studies): there are many types of animal studies performed (as well as *in vitro* studies) to assess potential effects on organisms, including humans. Some examples include: skin/eye irritation, skin/respiratory sensitization, carcinogenicity, specific toxicities (e.g. neurological, immunological, and endocrine effects), and metabolism data.

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

Examples of “non-SIDS” use/exposure information include:

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

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

#### ***B-4.4***      **INTERNATIONAL HPV**

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

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

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

- focus on HPV chemicals;
- are based on the OECD SIDS test battery;
- include the steps of information gathering, test plan development, and conducting SIDS testing as needed to provide a complete set of screening level hazard data;
- allow the use of category approaches to group chemicals and the use of Structure Activity Relationship (SAR) analysis as an alternative to testing where scientifically appropriate.

#### ***B-4.5***      **VCCEP PROCESS**

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

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

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

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

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

**3. Submission of Tier 1 data.** Sponsors (or consortium) would subsequently submit to EPA a Tier 1 Hazard Assessment, a Tier I Exposure Assessment, and a Tier 1 Risk Assessment. A Data Needs Assessment would also be submitted to EPA and would describe additional hazard testing and/or exposure data needed to fully evaluate the risks of a chemical to children and, where relevant, prospective parents.

**4. Peer Consultation regarding Tier 2 data needs.** At EPA's request, a third party would periodically convene a Peer Consultation to evaluate the Tier 1 information with emphasis on the Data Needs Assessment. The Peer Consultation would evaluate whether Tier 1 data needs were

met by the sponsor's submission and whether the Tier 1 submission fully characterized the chemical's potential risk to children and whether there are remaining Tier 2 data needs. A possible conclusion of the Peer Consultation is that no more work is needed. Results and comments from the Peer Consultation Process will be compiled by the third party and submitted to EPA.

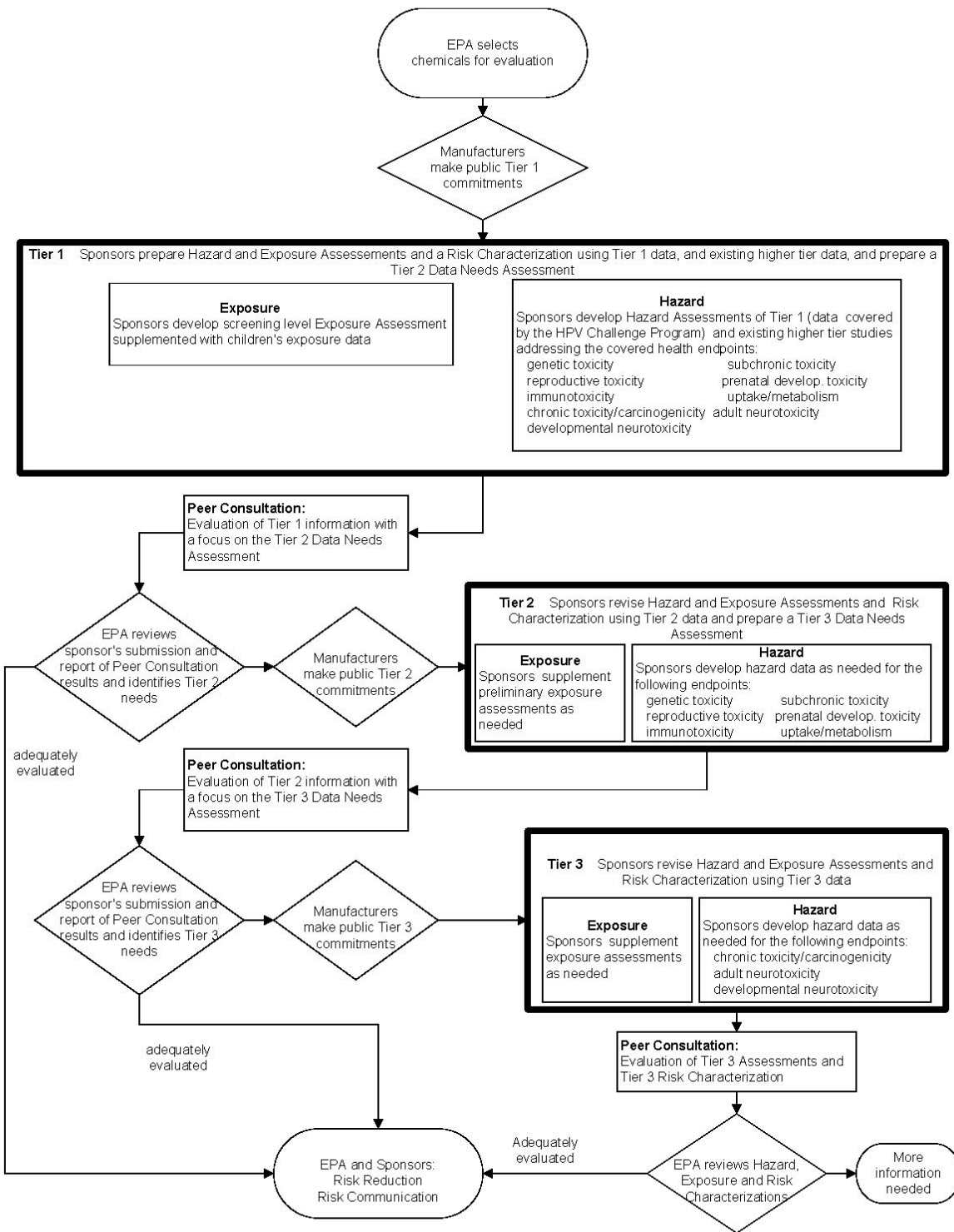
**5. EPA review of Peer Consultation results.** EPA would review the sponsor's submission and the third party report and announce the Tier 2 Data Needs Decision. The sponsor will be informed by mail and the public by the VCCEP web site. If EPA's approach differs substantially from that indicated by the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

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

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

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

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



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



## **B-5 GLOBAL ISSUES AND INTERNATIONAL COORDINATION**

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

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

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

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

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

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

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

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

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

In 2001, the OECD published the *Environmental Outlook for the Chemicals Industry* (OECD, 2001a). The OECD report predicts that the chemical industry will continue to expand over the next 20 years, with faster growth rates in non-OECD countries, while chemical companies in OECD countries will shift production to life science and specialty chemicals, and more companies will merge to form larger and fewer multinationals. The OECD recognizes that over

the last three decades many essential elements of good chemical safety policy have been developed and used both by countries and through international co-operation. At the same time, the OECD expects three main approaches to evolve to address the future development of the industry and some of the shortcomings of current policies:

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

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

#### **B-5.2 CHEMICAL REGULATIONS IN OTHER COUNTRIES**

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

There are also various approaches to existing chemical programs across the globe. The U.S. collects information on existing chemicals under TSCA §§4 and 8. The Inventory Update Rule, under TSCA §8, enables the Agency to collect data on production volume, plant site and site-limited status if the substance is produced at levels of 10,000 pounds or more per site. Currently, the U.S. is focusing on collecting test data on a subset of 3,000 high production volume (HPV)

chemicals, which are produced and/or imported in annual volumes of 1 million pounds or more across all U.S. companies. The EU has a requirement that manufacturers of existing substances provide data to the EC once they reach certain production volumes. Information requirements include production volume, classification, information on reasonable foreseeable uses, and physico-chemical data. Within the Canadian existing chemicals process, there is a Characterization and Screening of the Domestic Substances List (DSL) process, in which all substances on the DSL that have not been subject to notification and assessment as new substances need to be characterized and screened based on potential toxicity, bioaccumulation and persistence, and exposure potential.

## **B-6 TOOLS AND MODELS**

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

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

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

### **B-6.1 403 EMPIRICAL MODEL**

The §403 Empirical Model was developed by OPPT specifically to support the risk analysis for the Title X §403 rulemaking that sets health-based standards for levels of lead in a residential environment. The purpose of the model is to serve as a basis for predicting a national distribution of children's blood-lead concentrations as a function of environmental lead-levels

observed in the HUD National Survey. The model was used on the §403 risk analysis to help assess different options for health-based standards by estimating the reduction in average blood-lead concentrations and the reduction in the number of children with elevated blood-lead concentrations that would be associated with selection of a given set of health-based standards.

#### ***B-6.2***        ***AMEM***

The Arthur D. Little Migration Exposure Model (AMEM) was developed to estimate the migration of chemicals from polymeric materials used in home environments where these chemicals could become sources of indoor air pollution or potable water contamination. AMEM is primarily used for screening purposes and requires physical/chemical use information input that is then used to estimate releases from polymers (based on diffusion coefficients for six types of polymers). An exposure assessment model can then be used to estimate exposure.

#### ***B-6.3***        ***CHEMSTEER***

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

#### ***B-6.4***        ***E-FAST***

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

#### ***B-6.5***        ***ECOSAR***

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

### **B-6.6**      **EFDB**

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

- to allow rapid access to all available fate data on a given chemical without having to resort to expensive, time consuming, and inefficient primary literature searches;
- to identify critical gaps in the available information to facilitate planning of research needs; and
- to provide a data source for constructing structure-activity correlations for degradability and transport of chemicals in the environment.

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

### **B-6.7**      **EPI SUITE**

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

### **B-6.8**      **MCCEM**

The Multi-Chamber Concentration and Exposure Model (MCCEM) estimates average and peak indoor air concentrations of chemicals released from products or materials in houses, apartments, townhouses, or other residences. The data libraries contained in MCCEM are limited to residential settings. However, the model can be used to assess other indoor environments (e.g.

schools, offices) if the user can supply the necessary inputs. MCCEM estimates inhalation exposures to these chemicals, calculated as single day doses, chronic average daily doses, or lifetime average daily doses. (All dose estimates are potential doses; they do not account for actual absorption into the body.)

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

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

#### ***B-6.9***      ***ONCOLOGIC***

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

#### ***B-6.10***      ***PBT PROFILER***

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

To use the PBT Profiler online, the user enters a chemical using the CAS number. The PBT Profiler is linked to a database containing the CAS numbers and the associated chemical structures for over 100,000 discrete chemical substances. If the CAS number is in the database, the structure is retrieved and entered into the model. The PBT Profiler then predicts the PBT characteristics and provides a PBT Profile in an easy to understand format. A drawing program is also available so that the user can draw and enter the structure or the structure can be entered as a line notation using the Simplified Molecular Input Line Entry System. In addition, the PBT

Profiler compares the results of a profile with the PBT criteria established for PMNs submitted under TSCA §5 and the final rule for reporting chemicals to TRI (EPCRA §313).

#### ***B-6.11***      **RSEI**

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

#### ***B-6.12***      **UCSS**

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

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

#### ***B-6.13***      **WPEM**

The Wall Paints Exposure Assessment Model (WPEM) estimates the potential exposure of consumers and workers to the chemicals emitted from wall paint which is applied using a roller or a brush. WPEM is a user-friendly, flexible software product that uses mathematical models



developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. This is then combined with detailed use, workload, and occupancy data (e.g., amount of time spent in the painted room, etc.) to estimate exposure. WPEM provides exposure estimates such as Lifetime and Average Daily Doses, Lifetime and Average Daily Concentrations, and peak concentrations.

## ***B-7            OUTREACH AND COORDINATION***

### ***B-7.1        TECHNICAL ASSISTANCE EFFORTS***

#### ***B-7.1.1     State Technical Assistance Programs***

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

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

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

#### ***B-7.1.2     Business Technical Assistance Programs***

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

**Business Technical Assistance Programs (Business TAPs).** Business TAPs provide businesses with cutting edge environmental management assistance and help identify and

implement measures that reduce or eliminate pollution at its source. Business TAPs offer a variety of services, most of which are free, nonregulatory, and confidential. These services include:

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

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

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

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

## **B-7.2 COORDINATION WITH STATES AND TRIBES**

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

FOSTTA is a mechanism by which State and Tribal officials jointly, and in cooperation with OPPT, address toxics-related issues. FOSTTA is a partnership between OPPT and state and tribal leaders to increase understanding and improve collaboration on toxics and P2 issues among States, Tribes, and EPA. Created in 1991, FOSTTA is currently operated under a cooperative agreement with the Environmental Council of the States (ECOS) and the National Tribal Environmental Council (NTEC). In the past, FOSTTA committees or "projects" addressed

chemical management, the Agency's TRI, lead, P2, community-based activities, and tribal affairs (USEPA, 2002a). At this time, FOSTTA is composed of the Chemical Information and Management Project, Pollution Prevention Project, and the Tribal Affairs Project.

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

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

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

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

## ***B-8 AGENCY-WIDE INITIATIVES***

### ***B-8.1 RELEVANT GPRA GOALS***

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

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

- Clean air;

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

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

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

Each of these goals apply to all of EPA's programs and projects, and therefore encompass OPPT programs and projects. For example, pollution prevention principles are woven through all five goals in order to effectively reduce impacts on the air, water, land, and people. The last two 2003 GPRA goals have elements that focus specifically on OPPT's activities.

## ***B-8.2*** ***HOMELAND SECURITY***

In October 2002, EPA announced its Homeland Security Strategic Plan (USEPA Press Release, 2002). Based on EPA's core mission of protecting public health and safeguarding the environment, the plan identified an initial set of activities for the Agency to assist in protecting and responding to future terrorist attacks. EPA is currently revising this strategic plan to reflect both lessons learned over the past two years and the creation of the Department of Homeland Security.

OPPT will continue its work in the Acute Exposure Guidelines Levels Program. This program establishes short-term, peer reviewed, exposure levels for chemicals agents. These values are used extensively for emergency planning and response. OPPT is also working with other offices in the Agency to assess the Agency's overall role in chemical preparedness, response and site security.

### **B-8.3            INFORMATION QUALITY GUIDELINES**

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

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

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**Appendix C:**  
**Legislative and Regulatory Citations**



**Table C-1. Legislative and Regulatory Citations**

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

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

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

**Appendix D:**  
**Source Information and Additional Web Resources**

**Table D-1. Source Information and Additional Web Resources**

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

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

<b>Topic</b>	<b>Web Links for Source Information</b>
<b>HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM</b>	
Chemical Hazard Availability Study	<a href="http://www.epa.gov/oppt/chemtest/hazchem.htm">http://www.epa.gov/oppt/chemtest/hazchem.htm</a>
High Production Volume (HPV) Challenge Program	<a href="http://www.epa.gov/chemrtk/hpvol2.pdf">http://www.epa.gov/chemrtk/hpvol2.pdf</a> <a href="http://www.epa.gov/chemrtk/hpvfaqs.htm">http://www.epa.gov/chemrtk/hpvfaqs.htm</a>
Voluntary Children's Chemical Evaluation Program (VCCEP)	<a href="http://www.epa.gov/chemrtk/vccep/index.htm">http://www.epa.gov/chemrtk/vccep/index.htm</a>
<b>GLOBAL CHEMICAL ISSUES</b>	
Organization for Economic Cooperation and Development (OECD) and Screening Information Data Sets (SIDS)	<a href="http://www.epa.gov/oppt/sids/overview.htm">http://www.epa.gov/oppt/sids/overview.htm</a> <a href="http://www.chem.unep.ch/irptc/sids/sidspub.html">http://www.chem.unep.ch/irptc/sids/sidspub.html</a>
The International Organization for Standardization (ISO)	<a href="http://www.epa.gov/p2/programs/voluntary.htm">http://www.epa.gov/p2/programs/voluntary.htm</a>
UNEP/UNECE Persistent Organic Pollutants (POPs) Negotiations	<a href="http://www.chem.unep.ch/pops/">http://www.chem.unep.ch/pops/</a>
<b>TOOLS AND MODELS</b>	
OPPT Exposure Assessment Tools and Models	<a href="http://www.epa.gov/oppt/exposure/">http://www.epa.gov/oppt/exposure/</a>
PBT Profiler	<a href="http://www.epa.gov/oppt/pbtprofiler/">http://www.epa.gov/oppt/pbtprofiler/</a>
Information about ADL Migration Exposure Model (AMEM)	<a href="http://www.epa.gov/epahome/models.htm">http://www.epa.gov/epahome/models.htm</a>
Chemical Screening Tool For Exposures & Environmental Releases (ChemSTEER)	<a href="http://www.epa.gov/oppt/exposure/docs/chemsteer.htm">http://www.epa.gov/oppt/exposure/docs/chemsteer.htm</a>
Exposure, Fate Assessment Screening Tool (E-FAST)	<a href="http://www.epa.gov/oppt/exposure/docs/efast.htm">http://www.epa.gov/oppt/exposure/docs/efast.htm</a>
Ecological Structure Activity Relationships (ECOSAR)	<a href="http://www.epa.gov/oppt/newchemicals/21ecosar.htm">http://www.epa.gov/oppt/newchemicals/21ecosar.htm</a>
Estimation Program Interface (EPI) Suite	<a href="http://www.epa.gov/oppt/exposure/docs/episuite.htm">http://www.epa.gov/oppt/exposure/docs/episuite.htm</a>
Multi-Chamber Concentration and Exposure Model (MCCEM)	<a href="http://www.epa.gov/oppt/exposure/docs/mccem.htm">http://www.epa.gov/oppt/exposure/docs/mccem.htm</a>
Risk-Screening Environmental Indicators (RSEI)	<a href="http://www.epa.gov/oppt/rsei/">http://www.epa.gov/oppt/rsei/</a>
Use Clusters Scoring System (UCSS)	<a href="http://www.epa.gov/oppt/exposure/docs/ucss.htm">http://www.epa.gov/oppt/exposure/docs/ucss.htm</a>
Wall Paint Exposure Assessment Model (WPEM)	<a href="http://www.epa.gov/oppt/exposure/docs/wpem.htm">http://www.epa.gov/oppt/exposure/docs/wpem.htm</a>

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



**Appendix E:**  
**Copies of Legislation and Related Documents**