DRAFT

REGULATORY PROGRAMS
Great Lakes Regional Collaboration
PBT Strategy Team White Paper on Regulatory Programs

EPA's website lists 33 select environmental laws enacted by Congress through which EPA carries out its efforts, ranging in date from the 1938 Federal Food, Drug, and Cosmetic Act to the 1990 National Environmental Education Act. Cleanup enforcement authority is derived from several statutes: the Comprehensive, Environmental Response, Compensation and Liability Act (CERCLA or Superfund); the Resource Conservation and Recovery Act (RCRA), including the Underground Storage Tank (UST) Program; and the Oil Pollution Act (OPA) under the Clean Water Act. Each of these statutes deal with sites where there's been a migration or a release, or a threat of release, of hazardous substances into the environment. Most of the Areas of Concern identified in the Great Lakes Water Quality Agreement are associated with at least one cleanup enforcement site, supporting assessment (pollutant concentration and extent) of the contamination.

Clean Air Act

Major programs of the Clean Air Act include authorization and overview of state implementation plans; performance standards for stationary sources; enforcement and permitting; ozone protection; prevention of significant deterioration of air quality; visibility protection; emission standards for mobile sources; and air quality monitoring and modeling. The 1977 Clean Air Act required EPA to set ambient air quality standards (NAAQS); EPA had to first identify the pollutants. Primary NAAQS for NO_2, CO, VOCs, PM-10, SO_2, and lead were set by EPA between 1977 and 1990, and the acid rain program was initiated. Attainment and non-attainment areas are identified for these NAAQS.

The 1990 Clean Air Act amendments identified 189 hazardous air pollutants (HAPs) and required EPA to regulate categories of HAP sources through a maximum achievable control technology (MACT) or specific technology. These regulations are national emission standards for hazardous air pollutants (NESHAPs). The sources are categorized as follows. "Major sources" are stationary sources emitting or having the potential to emit 10 tons per year of any HAP or 25 tons of any combination of HAPs. "Area sources" are non-major stationary sources of HAPs. "Stationary source" means any buildings, structures, equipment, installations or substance emitting stationary activities (i) which belong to the same industrial group, (ii) which are located on one or more contiguous properties, (iii) which are under the control of the same person (or persons under common control), and (iv) from which an accidental release may occur. "New source" means a stationary source constructed or reconstructed after a rule establishing an applicable HAP emission standard is proposed. The initial list of 189 HAPs (see Section 112(b)) includes many PBT substances and groups of chemicals. For example, particulate organic matter (POM) includes organic compounds with more than one benzene ring and which have a boiling point greater than or equal to 100°C. Challenges in regulating the categories include developing an accurate list of sources.

The EPA Administrator may add pollutants to the HAP list by rule *after* reviewing the pollutant's presence, route of exposure, threat of adverse human health effects (including but not limited to, *substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which may cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects through ambient concentrations, bioaccumulation, deposition, or otherwise* (excluding substances subject to Section 112(r)).

Section 112(m) of the 1990 Clean Air Act is specific to the Great Lakes and Coastal Waters. The Administrator of EPA and the Under Secretary of Commerce for Oceans and Atmosphere (NOAA) are required to identify and assess the extent of atmospheric deposition of HAPs to the Great Lakes. Furthermore, the Administrator of EPA is required to oversee the Great Lakes Monitoring Network in accordance with Annex 15 of the Great Lakes Water Quality Agreement. Section 112(m) also requires the Administrator to report to Congress on these monitoring programs biennially.

For a more detailed description of the Clean Air Act programs, please see *The Plain English Guide to the Clean Air Act* (EPA-400-K-93-001, April 1993), found at http://www.epa.gov/oar/oaqps/peg_caa/pegcaain.html. Also, see several *Great Waters Report(s) to Congress* at http://www.epa.gov/air/oaqps/gr8water/index.html.

Clean Water Act

Growing public awareness and concern for controlling water pollution led to enactment of the Federal Water Pollution Control Act Amendments of 1972. As amended in 1977, this law became commonly known as the Clean Water Act. The Act established a basic structure for regulating discharges of pollutants into the waters of the United States, the national pollution discharge elimination system (NPDES). It gave EPA the authority to implement pollution control programs such as setting wastewater standards for industry. The Clean Water Act also continued requirements to set water quality standards for all contaminants in surface waters. The Act also funded the construction of sewage treatment plants under the construction grants program and recognized the need for planning to address the critical problems posed by nonpoint source pollution. Revisions in 1981 streamlined the municipal construction grants process, improving the capabilities of treatment plants built under the program. Over the years, many other laws have changed parts of the Clean Water Act. Title I of the Great Lakes Critical Programs Act of 1990, for example, codified parts of the Great Lakes Water Quality Agreement of 1978, signed by the U.S. and Canada, where the two nations agreed to reduce certain toxic pollutants in the Great Lakes. That law required EPA to establish water quality criteria for the Great Lakes addressing 29 toxic pollutants with maximum levels that are safe for humans, wildlife, and aquatic life. (See 40 CFR Part 132.) It also required EPA to help the States implement the criteria on a specific schedule. "Hazardous substances" are defined at 40 CFR 116.4.

EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were the "Green Book" (FWPCA, 1968) and the "Red Book" (USEPA, 1976), and "Gold Book" (USEPA, 1986). These early efforts were premised on the use of literature reviews and the collective scientific judgment of Agency and advisory panels. However, when faced with the need to develop criteria for human health as well as

aquatic life, the Agency determined that new procedures were necessary. Continued reliance solely on existing scientific literature was deemed inadequate because essential information was not available for many pollutants. EPA scientists developed formal methodologies for establishing scientifically defensible criteria. These were subjected to review by the Agency's Science Advisory Board of outside experts and the public. This effort culminated on November 28, 1980, when the Agency published criteria development guidelines for aquatic life and for human health, along with criteria for 64 toxic pollutants. However, the individual criteria documents, as updated, are the official guidance documents. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute criteria) and criteria continuous concentrations (chronic criteria) that the Agency recommends to protect aquatic life resources. EPA continues to update and add criteria for additional chemicals.

States and Tribes typically adopt both numeric and narrative criteria. Numeric criteria are important where the cause of toxicity is known or for protection against pollutants with potential human health effects. Narrative criteria are also important -- narrative "free from toxicity" criteria typically serve as the basis for limiting the toxicity of waste discharges to aquatic species (based on whole effluent toxicity testing).

Section 303(c)(2)(B) of the Clean Water Act requires States and authorized Tribes to adopt numeric criteria for § 307(a) priority toxic pollutants for which the Agency has published § 304(a) criteria, if the discharge or presence of the pollutant can reasonably be expected to interfere with designated uses. The § 307(a) list contains 65 compounds and families of compounds, which the Agency has interpreted to include 126 priority toxic pollutants.

In addition to narrative and numeric (chemical-specific) criteria, other types of water quality criteria include: *biological criteria,* a description of the desired aquatic community, for example, based on the numbers and kinds of organisms expected to be present in a water body; *nutrient criteria,* a means to protect against nutrient over-enrichment and cultural eutrophication; and, *sediment criteria,* a description of conditions that will avoid adverse effects of contaminated and uncontaminated sediments.

For Sediment Quality Guidelines, see http://www.epa.gov/waterscience/cs/guidelines.htm#noaa.

For a more thorough, brief introduction (66 slides) to the Clean Water Act, please visit the Watershed Academy's Web-based training module called, "Introduction to the Clean Water Act" found at **http://www.epa.gov/watertrain/cwa/** . For the current water quality criteria table, go to **http://www.epa.gov/waterscience/standards/wqcriteria.html**.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
CERCLA, commonly known as Superfund, was enacted by Congress on December 11, 1980. This law created a tax on the chemical and petroleum industries and provided broad Federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment. Over five years, $1.6 billion was collected and the tax went to a trust fund for cleaning up abandoned or uncontrolled hazardous waste sites. CERCLA: established prohibitions and requirements concerning closed and abandoned

hazardous waste sites; provided for liability of persons responsible for releases of hazardous waste at these sites; and established a trust fund to provide for cleanup when no responsible party could be identified.

The law authorizes two kinds of response actions: Short-term removals, where actions may be taken to address releases or threatened releases requiring prompt response; and, Long-term remedial response actions, that permanently and significantly reduce the dangers associated with releases or threats of releases of hazardous substances that are serious, but not immediately life threatening. These actions can be conducted only at sites listed on EPA's National Priorities List (NPL).

CERCLA was amended by the Superfund Amendments and Reauthorization Act (SARA) on October 17, 1986. SARA:

- stressed the importance of permanent remedies and innovative treatment technologies in cleaning up hazardous waste sites;
- required Superfund actions to consider the standards and requirements found in other State and Federal environmental laws and regulations;
- increased State involvement;
- increased the focus on human health problems;
- encouraged greater citizen participation; and,
- increased the size of the trust fund to $8.5 billion.

The CERCLA tax has not been reauthorized by Congress, and the trust fund is only adequate to continue remedial actions at a reduced rate. (correct?)

Under CERCLA, "hazardous substance" is any material EPA has designated for special consideration under the Clean Air Act, the Clean Water Act, the Toxic Substances Control Act, or the Resource Conservation and Recovery Act (RCRA). EPA also may designate additional substances as being hazardous under CERCLA.

Programs Related to Superfund: Abandoned Mine Lands, Brownfields Economic Redevelopment Initiative, Construction Completion, Dynamic Field Activities, Emergency Response Program, Environmental Justice in Waste Programs, Environmental Response Team, Lead Workgroups, National Advisory Council on Environmental Policy and Technology (NACEPT) Superfund Subcommittee, National Risk-Based Priority Panel, Natural Resource Damages: EPA and Natural Resource Trustee Roles and Responsibilities, Post Construction Completion, Reauthorization, Risk Assessment, Site Assessment, Superfund Analytical Services/Contract Laboratory Program (CLP), Superfund Redevelopment Initiative, Superfund Reforms (all linked at http://www.epa.gov/superfund/programs/index.htm#epa).

Emergency Planning and Community Right-to-Know Act

Also known as Title III of SARA, EPCRA was enacted by Congress as the national legislation on community safety. This law was designated to help local communities protect public health, safety, and the environment from chemical hazards. EPCRA establishes requirements for Federal, State and local governments, Indian Tribes, and industry regarding emergency planning and “Community Right-to-Know” reporting on hazardous and toxic chemicals. The Community Right-to-Know (Toxic Release Inventory) provisions help increase the public’s knowledge and

access to information on chemicals at individual facilities, their uses, and releases into the environment. States and communities, working with facilities, can use the information to improve chemical safety and protect public health and the environment.

The Extremely Hazardous Substance (EHS) profiles contain information about each of the 356 EHS currently listed as part of Section 302 of EPCRA. Each chemical profile includes physical/chemical properties, health hazards, fire and explosion hazards, reactivity data, precautions for safe handling and use, and protective equipment for emergency situations. The profiles were originally developed in 1985 for the 402 chemicals then called "acutely toxic chemicals" under the Chemical Emergency Preparedness Program. Subsequent additions and deletions resulted in 366 chemicals listed in February 1988 as extremely hazardous substances. Other chemicals may be added or deleted in the future.

Endangered Species Act

The Endangered Species Act provides a program for the conservation of threatened and endangered plants and animals and the habitats in which they are found. The U.S. Fish and Wildlife Service of the Department of the Interior maintains the list of 632 endangered species (326 are plants) and 190 threatened species (78 are plants). Species include birds, insects, fish, reptiles, mammals, crustaceans, flowers, grasses, and trees. (Controversially, the ESA does not identify algae or protozoans that serve as the base of the aquatic food web for protection.) Anyone can petition FWS to include a species on this list. The law prohibits any action, administrative or real, that results in a "taking" of a listed species, or adversely affects habitat. Likewise, import, export, interstate, and foreign commerce of listed species are all prohibited. EPA's decision to register a pesticide is based in part on the risk of adverse effects on endangered species as well as environmental fate (how a pesticide will affect habitat). Under FIFRA, EPA can issue emergency suspensions of certain pesticides to cancel or restrict their use if an endangered species will be adversely affected. Under a new program, EPA, FWS, and USDA are distributing hundreds of county bulletins that include habitat maps, pesticide use elimitations, and other actions required to protect listed species.

Five Laws Affecting EPA's Pesticide Programs (August 1998)

There are over 20,000 pesticide products registered for use in the United States. Several laws govern the Federal regulatory program for these pesticide products. Under Federal law, the Environmental Protection Agency is largely responsible for regulating the sale and use of pesticides, and the allowable levels of such pesticides in or on food. EPA's authority, and the limits to that authority, are contained in two core statutes, (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA). In 1996, both statutes were amended by the Food Quality Protection Act (FQPA). In addition, many other Environmental and procedural statutes provide shape and direction to the Agency's pesticide program. This overview covers several of the most common statutes affecting EPA's pesticide program.

1. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) FIFRA provides the overall framework for the federal pesticide program. Under FIFRA, EPA is responsible for registering, or licensing pesticide products for use in the United States. Pesticide registration decisions are based on a detailed assessment of the potential effects of a product on human health and the environment, when used according to label directions. These approved labels have the force of law, and any use which is not in accordance with the label directions and precautions may be

subject to civil and/or criminal penalties. FIFRA also requires that EPA reevaluate older pesticides to ensure that they meet more recent safety standards. FIFRA requires EPA and states to establish programs to protect workers, and provide training and certification for applicators as well.

2. Federal Food, Drug, and Cosmetic Act (FFDCA) The Federal Food, Drug, and Cosmetic Act (FFDCA) governs the establishment of pesticide tolerances for food and feed products. A tolerance is the maximum level of pesticide residues allowed in or on human food and animal feed. EPA and the Food and Drug Administration (FDA) are responsible for administering the Act.

3. Food Quality Protection Act (FQPA) This law, passed in 1996, amends both FIFRA and FFDCA, setting a tougher standard for pesticides used on food. FQPA established a single, health based standard to be used when assessing the risks of pesticide residues in food or feed. The new safety standard is measured considering the aggregate risk from dietary exposure and other non-occupational sources of exposure, such as drinking water and residential lawn uses. In addition, when setting new, or reassessing existing, tolerances under the new standard. EPA must now focus explicitly on exposures and risks to infants and children. Decisions must consider whether tolerances are safe for children assuming, when appropriate, an additional safety factor to account for uncertainty in data.

Other FQPA Requirements include:

- Under FQPA, EPA may only establish a tolerance if there is "a reasonable certainty" that no harm will result from all combined sources of exposure to pesticides (aggregate exposures). FQPA also considers the combined effects of human exposure to different pesticides that may act in similar ways on the body (cumulative exposure).
- By 2006, EPA must review all old pesticides to make sure that the residues allowed on food meet the new safety standard.
- FQPA also requires that pesticides be tested for endocrine disruption potential. Endocrine disruptors may be linked to a variety of sexual, developmental, behavioral, and reproductive problems.
- EPA must distribute a brochure to supermarkets discussing pesticides on foods in order to better inform the public.

4. Federal Advisory Committee Act FACA establish policies and procedures for seeking external stakeholder input on Federal Agency activities. This law ensures that such consultation is open to the public and transparent. OPP FACA committees have included:

- Tolerance Reassessment Advisory Committee
- Food Safety Advisory Committee
- Endocrine Disruptors Screening and Testing Advisory Committee
- Pesticide Program Dialogue Committee
- FIFRA Scientific Advisory Panel (SAP) and Scientific Advisory Board
- State FIFRA Issues Research and Evaluation Group (SFIREG)

5. Safe Drinking Water Act (SDWA) The Safe Drinking Water Act was established to protect the quality of drinking water in the United States from both underground and above ground

sources. In 1996, Congress amended the law to require the development of a screening and testing program for chemicals and pesticides for possible endocrine disrupting effects. EPA must develop and present a screening program to Congress and begin implementation by August 1999 to determine whether certain substances may have endocrine effects. This same requirement was contained in FQPA.

A pesticide is any substance or mixture of substances intended for:

- preventing,
- destroying,
- repelling, or
- mitigating any pest.

The term pesticide applies to insecticides, herbicides, fungicides, and various other substances used to control pests. Many household products are pesticides. Under United States law, a pesticide is also any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

Pests are living organisms located where they are not wanted or that cause damage to crops or humans or other animals. Examples include: insects, mice and other animals, unwanted plants (weeds), fungi, microorganisms such as bacteria and viruses, and prions which cause bovine spongioform encephalitis.

By their very nature, most pesticides create some risk of harm. Pesticides can cause harm to humans, animals, or the environment because they are designed to kill or otherwise adversely affect living organisms. At the same time, pesticides are useful to society. Pesticides can kill potential disease-causing organisms and control insects, weeds, and other pests. Biologically-based pesticides, such as pheromones and microbial pesticides, are becoming increasingly popular and often are safer than traditional chemical pesticides.

The U.S. definition of pesticides is quite broad, but it does have some exclusions:

- Drugs used to control diseases of humans or animals (such as livestock and pets) are not considered pesticides; such drugs are regulated by the Food and Drug Administration.
- Fertilizers, nutrients, and other substances used to promote plant survival and health are not considered plant growth regulators and thus are not pesticides.
- Biological control agents, except for certain microorganisms, are exempted from regulation by EPA. (Biological control agents include beneficial predators such as birds or ladybugs that eat insect pests.)
- Products which contain certain low-risk ingredients, such as garlic and mint oil, have been exempted from Federal registration requirements, although State regulatory requirements may still apply.

Regulatory action fact sheets discuss how EPA regulates certain chemicals or types of pesticides and other regulatory actions at http://www.epa.gov/pesticides/factsheets/reg_fs.htm.

Food Quality Protection Act

See FIFRA and the 'Setting Tolerances for Pesticide Residues in Food' fact sheet

In addition, Section 405(p) of the 1996 Food Quality Protection Act (FQPA) requires that EPA develop (within 2 years) and implement (within 3 years) an estrogenic effects screening program for all pesticides using validated test methods. The FQPA also gives EPA the authority to require testing of other chemicals "that may have an effect that is cumulative to an effect of a pesticide."

The FQPA states that data can be obtained via Section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Section 4 of TSCA, or an "order" if it can be shown that neither FIFRA nor TSCA can be applied. Similarily the newly amended Safe Drinking Water Act (SDWA) gives EPA authority to require testing of substances found in drinking water and to which there may be substantial exposure.

National Environmental Policy Act (NEPA) 1969, as amended

Through NEPA, Congress imposed the requirement on Federal Agencies to perform environmental impact statements or a finding of no *significant* impact for major federal actions. *Actions* include projects and programs entirely or partly run by federal agencies; new or revised agency rules, regulations, plans, policies, or procedures; and legislative proposals. Federal agencies are directed to use all practicable legal means to restore and enhance the quality of the *human environment* and avoid or minimize any possible adverse *effects* of their actions on the quality of the *human environment*. *Effects* include both direct effects (caused by the action, simultaneous with the action, and at the location of the action) and indirect (caused by the action, later in time, farther removed in distance). *Indirect effects* include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems. *Human environment* includes the natural and physical environment and the interrelationship of people with that environment. *Significant* as used in NEPA requires consideration of context (society as a whole, the affected region, the affected interests, and the locality), intensity (severity of good and bad impacts, degree to which public health and safety is affected, unique characteristics of the geographic area, degree of controversy, uncertainty in the degree of human effects, whether the action is precedent-setting, relationship to other possibly insignificant actions with significant cumulative effects, adverse impact to Historic Places or significant resources, effect on endangered or threatened species, or critical habitat), and whether the action threatens a violation of law imposed to protect the environment.

Oil Pollution Act

The Oil Pollution Act (OPA) of 1990 streamlined and strengthened EPA's ability to prevent and respond to catastrophic oil spills. A trust fund managed by the Coast Guard and financed by a tax on oil is available to clean up spills when the responsible party is incapable or unwilling to do so. OPA requires oil storage facilities and vessels to submit to the Federal government plans detailing how they will respond to large discharges. EPA has published regulations for aboveground storage facilities; the Coast Guard has done so for oil tankers. OPA also requires the development of Area Contingency Plans to prepare and plan for oil spill response on a regional scale.

Pollution Prevention Act (nonregulatory; grant authority)

The Pollution Prevention Act focused industry, government, and public attention on reducing the amount of pollution through cost-effective changes in production, operation, and raw materials use. Opportunities for source reduction are often not realized because of existing regulations, and the industrial resources required for compliance, focus on treatment, and disposal. Source reduction is fundamentally different and more desirable than waste management or pollution control.

Safe Drinking Water Act

The Safe Drinking Water Act was established to protect the quality of drinking water in the U.S. This law focuses on all waters actually or potentially designed for drinking use, whether from above ground or underground sources. The Act authorized EPA to establish safe standards of purity and required all owners or operators of public water systems to comply with primary (health-related) standards (e.g., maximum contaminant levels in treated water). State governments, which assume this power from EPA, also encourage attainment of secondary standards (nuisance-related).

Solid Waste Disposal Act , as amended (Resource Conservation and Recovery Act or RCRA)
RCRA gave EPA the authority to control hazardous waste generation, transportation, treatment, storage, and disposal of hazardous waste. Waste is hazardous when it is ignitable, corrosive, or reactive (explosive). Also, if waste contains concentrations of 40 toxic chemicals above regulatory thresholds, it is considered hazardous. There are 500 specific hazardous wastes that have been defined by EPA. RCRA also set forth a framework for the management of non-hazardous wastes. The 1986 amendments to RCRA enabled EPA to address environmental problems that could result from underground tanks storing petroleum and other hazardous substances. RCRA focuses only on active and future facilities and does not address abandoned or historical sites. One of RCRA's goals is to clean up waste which may have spilled, leaked, or been improperly disposed and which poses a threat to human health or the environment. The Federal Hazardous and Solid Waste Amendments (HSWA) are the 1984 amendments to RCRA that required phasing out land disposal of hazardous waste.

Through national voluntary and educational programs, EPA works to assure the safe management of nonhazardous household, industrial, and mining wastes. We promote and encourage the use of combined methods to manage solid waste. These methods are: source reduction or waste prevention, which means any practice that reduces the amount or toxicity of waste generated; recycling, which conserves disposal capacity and preserves natural resources by preventing potentially useful materials from being thrown away; and landfilling and waste combustion.

Toxic Substances Control Act (U.S. EPA; U.S. Customs, Department of State; ATSDR, U.S. DHHS)
The Toxic Substances Control Act (TSCA) of 1976 was enacted by Congress to give EPA the ability to track the 75,000 industrial chemicals currently produced or imported into the United States. EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human-health hazard. EPA can ban the manufacture and import of those chemicals that pose an unreasonable risk. Also, EPA has mechanisms in place ('Pre-Manufacture Notice' and 'Significant New Use' Rules) to track the thousands of new chemicals that industry develops each year with either unknown or dangerous characteristics. EPA then can control these chemicals as necessary to protect human health and the environment. TSCA supplements other Federal statutes.

Under TSCA, EPA has broad authority to issue regulations designed to gather health/safety and exposure information on, require testing of, and control exposure to chemical substances and mixtures. Drugs, cosmetics, foods, food additives, pesticides, and nuclear materials are exempt from TSCA. EPA's TSCA Inventory currently contains over 70,000 existing chemicals. The TSCA Inventory is a compilation of the names of all existing chemical substances along with

their respective Chemical Abstract Service (CAS) Registry numbers, production/importation volume ranges, and specific sites of production/importation. Chemicals produced in annual volumes above 1 million pounds are considered High Production Volume or "HPV" chemicals. This subset of 3,000-4,000 HPV chemicals is the main focus of OPPT's Existing Chemicals Data Collection and Data Development (Testing) activities. Data on chemicals that are collected or developed are made accessible to the public and are intended to provide input for efforts to evaluate potential risk from exposures to these chemicals.

Master Testing List - Executive Summary

Section 2 of the Toxic Substances Control Act (TSCA) states, "It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and development of such data be the responsibility of those who manufacture and those who process such chemicals and mixtures."

Under Section 4, EPA can by rule require testing after finding that (1) a chemical may present a hazard to human health or the environment, and/or the chemical is produced in substantial quantities that could result in significant or substantial human or environmental exposure, (2) the available data to evaluate the chemical are inadequate, and (3) testing is needed to develop the needed data. In order to determine the hazard, EPA considers:

- Substantial production/importation (1 million pounds), and;
- Substantial release (1 million pounds or 10% of production/importation), or;
- Substantial human exposure (1,000 workers or 10,000 consumers or 100,000 general population), or;
- Significant human exposure (Determined on a case-by-case basis).

The Chemical Testing Program in EPA's Office of Pollution Prevention and Toxics (OPPT) also works with members of the U.S. chemical industry to develop needed data via TSCA Section 4 Enforceable Consent Agreements (ECAs) and Voluntary Testing Agreements (VTAs). ECAs and VTAs are usually less resource intensive than formal TSCA rule-making and allow EPA to consider agreed-upon pollution prevention and other types of product stewardship initiatives by the chemical industry as a possible substitute for or adjunct to certain types of needed testing. OPPT has been using a "Master Testing List" (MTL) since 1990 to establish its TSCA Existing Chemical Testing Program agenda. The MTL presents a consolidated listing of OPPT's Existing Chemical Testing Program priorities as well as those brought forward to OPPT by other EPA program offices, other Federal agencies, the TSCA Interagency Testing Committee, and international organizations such as the Organization for Economic Cooperation and Development (OECD). The main purposes of the MTL are to (1) identify chemical testing needs of the Federal Government (including EPA) and relevant international organizations (e.g., OECD), (2) focus limited EPA resources on the highest priority chemical testing needs, (3) publicize the testing priorities for industrial chemicals, (4) obtain broad public input on OPPT's TSCA Chemical Testing Program and its priorities, and (5) encourage voluntary initiatives by the U.S. chemical industry to fill the priority data needs that are identified on the MTL.

The identification of testing needs on the MTL provides an opportunity for responsible companies to initiate voluntary activities to develop the needed data for their own MTL-listed chemicals. In those instances in which companies decline to take this opportunity, EPA is put in a position of having to initiate formal, resource intensive, regulatory actions such as promulgating TSCA Section 4 Test Rules. Issuance of such rules can be viewed as "forcing" chemical companies to adhere to their own professed standards of product stewardship and corporate responsibility.

The MTL contains over 500 individual existing chemicals and more than 10 existing chemical categories and presents EPA's TSCA Chemical Testing Program priorities for 1996-1998. Testing actions are currently being developed on more than 200 chemicals listed on the MTL while testing is currently underway on almost 300 chemicals identified on the MTL. In addition, more than 100 chemicals are being removed from the MTL at this time, over 70 of those because their testing programs have been completed.
It is also important to note that the Chemical Testing Program and the MTL are integral components of the TSCA Existing and New Chemicals Programs. These programs are responsible for assessing and managing health and environmental risks that may be posed by existing and new chemicals covered by TSCA. The "universe" of existing chemicals on the TSCA Chemical Substances Inventory that may present the greatest potential health and/or environmental concerns have been and continue to be identified and refined through various existing chemical screening activities within OPPT.

EPA must make statutory TSCA Section 4 "data inadequacy" and "testing is necessary" findings.
TSCA Section 4 testing must be conducted via EPA-approved test methods/guidelines.
The relationship with industry can be somewhat adversarial.
TSCA Section 12(b) export notice requirements are triggered by TSCA Section 4 test rules.