CHEMICALS OVERVIEW

The United States is actively engaged in chemicals management, both at the domestic and international levels as the safe and effective management of chemicals helps ensure protection of the environment and public health. Several major regulatory and voluntary initiatives are underway domestically, including our active efforts to evaluate and register new chemicals and pesticides. The United States is also a strong supporter of UNEP’s Strategic Approach to International Chemicals Management (SAICM), an international framework to promote the goal that by 2020 chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment. We look forward to working through the CSD to further enhance the role and efforts of SAICM and to share information on U.S. programs and practices.

1. DOMESTICALLY-FOCUSED AGENCIES AND PROGRAMS

**EPA Office of Prevention, Pesticides, and Toxic Substances** protects public health and the environment from potential risks of pesticides and toxic chemicals. The EPA's **Office of Pollution Prevention and Toxics (OPPT)** manages programs to evaluate new and existing chemicals and their risks, takes appropriate action, finds ways to prevent or reduce pollution, and implements stewardship programs to encourage companies to reduce and prevent pollution. The EPA **Office of Pesticide Programs (OPP)** registers pesticides for use in the US and establishes maximum residue levels for pesticides on food, coordinates issues ranging from worker protection to prevention of misuse of pesticides, and participates in partnerships, such as the **Pesticide Environmental Stewardship Program**.

The following description of United States programs is organized by the five objectives of the **Strategic Approach to International Chemicals Management** (SAICM): risk reduction, knowledge and information, governance, capacity-building and technical cooperation, and illegal international traffic.

1.a. Risk reduction:

**Managing and Reducing Risks to Industrial Chemicals**

**Reviewing New Industrial Chemicals.** Through the **New Chemicals Program**, EPA manages the potential risk from chemicals new to the marketplace by setting conditions, up to and including a ban on production or import, on the manufacture, processing, use and disposal of a new chemical before it enters into commerce or on a “significant new use” of an existing or new chemical. Certain genetically modified microorganisms are also considered “new chemical” under TSCA. Anyone who plans to manufacture or import a new chemical substance for a non exempt commercial purpose is required to provide EPA with notice before initiating the activity. Notice is also required before beginning any activity that EPA has designated as a “significant new use”. These notices must contain information on the specific chemical identity, use,
anticipated production volume, exposure and release information, and existing available test data.

**Nanoscale Materials.** EPA has received and reviewed numerous new chemical notices under TSCA for nanoscale materials including carbon nanotubes and fullerenes. Based on case-specific information, EPA has taken steps to control or limit exposures to these nanoscale materials, including: limiting the uses that have potential downstream exposures; requiring the use of personal protective equipment, such as impervious gloves and approved respirators National Institutes of Occupational Safety and Health of the Centers (NIOSH) for Disease Control and Prevention (CDC); and limiting environmental releases.

EPA has also required testing to generate health and environmental effects data in a number of cases, and has regulated the manufacture and use of certain new chemical nanoscale materials through administrative orders or Significant New Use Rules under TSCA. EPA has also allowed the manufacture of specific new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were very tightly controlled to protect against unreasonable risks (using, for example, the protective equipment and environmental release limitations discussed above). EPA has initiated rulemaking to require data submission for nanomaterials in current commerce in the US, and testing for several nanomaterials with significant data gaps.

**Managing Existing Chemicals**

EPA has announced a comprehensive approach to enhancing the current existing chemicals management program. The enhanced program includes the following activities:

- Initiating regulatory risk management actions on lead, mercury, formaldehyde, polychlorinated biphenyls (PCBs), glymes and nanoscale materials.
- Developing action plans designed to target EPA risk management efforts on chemicals of concern. These action plans will be based on EPA’s review of available hazard, exposure, and use information, and will outline the risks that each chemical may present and specific steps that EPA will take to address those concerns. The initial set of action plans were published on EPA’s website for the following chemicals: brominated flame retardants (PBDEs, including penta, octa, and decabromidiphenyl ethers) in products; perfluorinated chemicals; certain phthalates; and short-chain chlorinated paraffins. EPA posted these action plans in December 2009 and will complete and post additional chemical action plans at four-month intervals.
- Requiring information needed to understand chemical risks by: requiring that companies submit information to fill the remaining gaps in basic health and safety data on high production volume (HPV) chemicals; making the reporting of chemical use information more transparent, more current,
more useful, and more useable by the public; and requiring additional reporting and testing of nanoscale chemical substances.
  
  - Increasing public access to information about chemicals
  - Engaging stakeholders in prioritizing chemicals for future risk management through public notices and public meetings.

- **PFOA Stewardship Program.** Eight major companies committed voluntarily to reduce facility emissions and product content of perfluorooctanoic acid (PFOA) and related chemicals on a global basis by 95% no later than 2010, and to work toward eliminating emissions and product content of these chemicals by 2015. The voluntary stewardship program has also been complemented by regulatory actions that address significant new uses of perfluoroalkyl sulfonate (PFAS) and perfluorooctyl sulfonate (PFOS) chemicals.

- **Mercury.** Issued on July 2006, the **EPA Mercury Roadmap** describes progress in addressing mercury issues domestically and internationally, and outlines major ongoing and planned actions. The Roadmap focuses on six areas:
  
  - Addressing mercury releases to the environment
  - Addressing mercury uses in products and industrial processes
  - Managing commodity-grade mercury supplies
  - Communicating risks to the public
  - Addressing international mercury sources
  - Conducting mercury research and monitoring.

  EPA intends to initiate rulemaking to phase out or ban the use of mercury in certain products, such as certain switches, relays, measuring devices and other products.

  The **Mercury-Containing Products and Alternatives Database** compiles information on the manufacturers, sectors of use, product descriptions and quantity of mercury-containing products, as well as alternatives to the mercury-containing products.

- **Reducing Children’s Lead Exposure.** Lead may cause a range of health effects, from behavioral problems and learning disabilities to seizures and death. Children under six years of age are most at risk. The primary sources of lead exposure for most children in the US are deteriorating lead-based paint, lead-contaminated dust, and lead-contaminated residential soil. In order to meet the 2010 United States’ government goal of eliminating childhood lead poisoning as a major public health concern, EPA is focusing funding resources on populations that have rates of lead poisoning above the national average and on populations where sufficient screening has not yet occurred to determine rates of lead poisoning. In addition, in March 2008 EPA finalized its Lead Renovation, Repair, and Painting rule requiring persons engaged in renovation, repair, and painting activities in pre-1978 housing and child-occupied facilities to be trained and certified and to use lead-safe
work practices for activities that disturb lead-based paint to reduce potential exposure to dangerous levels of lead. EPA has agreed to propose the strengthening of the lead paint work practice standards for renovation and remodeling to expand coverage, require clearance testing after certain renovation jobs, and address lead safe work practices for public and commercial buildings. In addition, EPA will initiate rulemaking assessing whether to ban or otherwise regulate the use of lead weights in tires.

• **Reducing Exposure to Asbestos.** Asbestos is the common name for a group of naturally occurring mineral fibers with high tensile strength, the ability to be woven, and resistance to heat and most chemicals. Asbestos have been used in a wide range of manufactured goods, including construction materials, and automobile clutches and brakes. If asbestos fibers are released into the air when asbestos is disturbed or in poor condition, it can result in inhalation into the lungs. Asbestos exposure has been associated with a number of serious health problems and diseases, including asbestosis, lung cancer, and mesothelioma.

**Managing and Reducing Risks to Pesticides**

**Reviewing New Pesticides.** EPA ensures that pesticides, when used according to label directions, can be used without posing unreasonable risks to the environment. This standard requires that EPA also conclude that human dietary exposures to pesticides are safe. Before selling or distributing a pesticide in the US a registration must be obtained from EPA. EPA requires more than 100 different scientific studies and tests from applicants. Where pesticides may be used on food or feed crops, EPA also sets tolerances for the amount of the pesticide that can remain in or on foods. EPA gives priority in its registration program to conventional chemical pesticides that meet reduced risk criteria: low-impact on human health, low toxicity to non-target organisms (birds, fish, and plants), low potential for groundwater contamination, lower use rates, low pest resistance potential, and compatibility with Integrated Pest Management. For antimicrobial pesticides that make public health claims and all other pesticides that make public health claims, EPA requires special tests to ensure their efficacy to control disease-causing microbes. EPA also regulates biopsticides, which are naturally occurring substances that control pests (biochemical pesticides), microorganisms that control pests (microbial pesticides), and pesticide substances produced by plants containing added genetic material (plant-incorporated protectants).

**Reassessment and Risk Management of Currently Registered Pesticides.** Under the Reregistration Program EPA reviews pesticides initially registered before November 1984 to ensure that they meet current scientific and regulatory standards. A website listing the status of each pesticide in the Reregistration Program includes decision documents, fact sheets and related documents. The Reregistration Program is nearing completion and EPA is now in the process of implementing the new Registration Review Program, which is designed to provide for the continual reevaluation of existing pesticides. Through Registration Review EPA reviews each registered pesticide every 15 years to make sure that as the ability to assess risks evolves
and as policies and practices change, all pesticide products in the marketplace can still be used safely.

EPA is reviewing the safety of all existing tolerances (maximum limits for pesticide residues in food) and tolerance exemptions to ensure that they meet the more stringent safety standards. In 2007, EPA completed 9,721 tolerance reassessment decisions. In addition, EPA reviews the labels of pesticide products to ensure that it includes appropriate information about the proper handling and use of the product. EPA also ensures that the directions for use and the use restrictions on the label reflect EPA’s conclusions of the supporting science and risk assessments for the pesticide. Also, EPA regulates storage and disposal of pesticides and their containers, and provides guidance to household consumers, farmers, registrants, retailers, and commercial applicators.

EPA places particular emphasis on children in making regulatory decisions about pesticides. Risk assessments include evaluations for children in various age groups, since children's eating and activity patterns change as they grow up.

**Pesticide Field Programs:**

- **Pesticide Environmental Stewardship Program** is a voluntary program that forms partnerships with pesticide users to reduce potential risks and implement pollution prevention strategies.

- **School Integrated Pest Management (IPM)** reduces pesticide risk and exposure to children by using common sense strategies to reduce sources of food, water and shelter for pests in school facilities.

- **Worker Protection Standards (WPS)** are designed to protect employees on farms, forests, nurseries, and greenhouses from occupational exposures to agricultural pesticides.

- **Certification and Training of Pesticide Applicators.** Employees are responsible for training workers and handlers in the safe use of pesticides, ensuring that their employees understand the basic concepts of pesticide safety.

- **National Strategies for Health Care Providers Pesticide Initiative** is aimed at improving the training of health care providers in the recognition, diagnosis, treatment, and prevention of pesticide poisonings among those who work with pesticides. The latest edition of EPA's handbook *Recognition and Management of Pesticide Poisonings* is available in English and Spanish.

**Working to Prevent Pollution**

Pollution prevention (P2) reduces or eliminates waste at the source by modifying production processes, promoting the use of non-toxic or less-toxic substances, implementing conservation techniques, and re-using materials rather than putting them into the waste stream. For related and more activities in this area and with respect to relevant chemicals-related sector and
supply-chain activities, see also the US submission to the chapters on Sustainable Production and Consumption (SPC) and Waste.

**Chemical Risk Reduction through Pollution Prevention**

- **Sustainable Futures** is a partnership among EPA, the chemical industry, and other stakeholders, which offers models for quickly and cost effectively screening chemicals for hazards and/or risks early in the development process. Participation in the program can allow companies to more quickly commercialize environmentally preferable new chemicals and identify safer alternatives for existing chemicals. Participants in the training sessions also included government scientists from Australia, Europe (Poland, Germany, Slovakia, and the Netherlands) and Japan, and scientists from several consulting firms.

- **Design for the Environment (DfE) Program** works in partnership with a broad range of stakeholders focusing on industries that combine the potential for chemical risk reduction and improvements in energy efficiency with a strong motivation to make lasting, positive changes. Of note is the Furniture Flame Retardancy Partnership, which fosters informed substitution by providing objective information about hazards associated with flame retardant chemicals, allowing furniture manufacturers to select safer substitutes for flame retardants.

- **Green Chemistry Program** promotes environmentally conscious design of chemical products and processes. It includes the annual Presidential Green Chemistry Challenge Awards, which recognizes the significant scientific, economic, human health, and environmental benefits that green chemistry technologies offer.

- **Green Engineering Program** is defined as the design, commercialization and use of processes and products that are feasible and economical while minimizing risks and the generation of pollution at the source. The goal of the program is to incorporate risk related concepts into chemical processes and products designed by academia and industry.

- **Chemical Management Services (CMS)** is a business model in which a customer purchases chemical services rather than just chemicals; and the service provider is compensated based on the quality and quantity of services provided to reduce chemical lifecycle costs, risks, and environmental impacts, not on the volume of chemical sold. Therefore the service provider and their customer achieve bottom line benefits through reduced chemical use, cost, and waste.
Sector-Focused Pollution Prevention Programs

- **Sector Strategies Program** develops comprehensive strategies to improve environmental protection, energy efficiency, and resource management in major US manufacturing and business sectors. The *2008 Sector Performance Report* presents current data on the chemical manufacturing sector.

- **Green Building** is the practice of creating healthier and more resource efficient models of construction, renovation, operation, maintenance, and demolition of buildings. The many elements of green building include: energy, water, materials, waste and indoor environment. [EPA is also making its own buildings greener](https://www.epa.gov/greenbuilding).

- **Environmentally Sound Electronics Design and Lifecycle Management:**
  - **Electronic Product Environmental Assessment Tool (EPEAT)** helps purchasers buy environmentally preferable electronics by providing a list of registered products, participating manufacturers and guidance. EPEAT registered products meet an environmental performance standard for electronic products – IEEE 1680-2006. EPEAT products (computer desktops, laptops, and monitors) contain less toxic and hazardous substances, are easier to recycle, and are more energy efficient than conventional products serving the same purpose.
  - **Federal Electronics Challenge (FEC)** empowers the government agencies to manage their electronics in an environmentally sound manner during all three life-cycle phases - acquisition and procurement, operation and maintenance, and end-of-life management.
  - **Cathode Ray Tube (CRT) Rule:** In July 2006, the US streamlined the hazardous waste management requirements for CRTs and CRT glass destined for recycling to eliminate confusion about proper way to recycle or dispose this material, encouraging increased reuse and recycling of CRTs.
  - **Plug-In to eCycling Program** is a partnership between EPA and consumer electronics manufacturers, retailers, and service providers that offers opportunities to donate or recycle used electronics. The [Guidelines for Materials Management](https://www.epa.gov/epaoswer-recycling-guidelines) ensures environmentally safe recycling of old electronics, and aims to promote and maintain adequate markets for the reuse and recycling of electronic equipment.

Community-Focused Programs

- **Community Action for a Renewed Environment (CARE)** is a competitive grant program that allows a community to create a partnership to implements solutions to reduce releases of toxic pollutants and minimize people’s exposure in their local environment.

### 1.b. Knowledge and Information:

**Information Collection and Access**
• The **High Production Volume (HPV) Challenge Program** “challenges” companies to make health and environmental effects data publicly available on chemicals produced or imported in the US in quantities of **1 million pounds or more per year**. Under the program, companies have sponsored more than 2,250 HPV chemicals, including 860 chemicals sponsored through international efforts. This represents 93% of the total volume of chemicals in commerce in the US. The **High Production Volume Information System (HPVIS)** is a database that provides access to information on HPV chemicals. Currently, HPVIS contains information on 1,102 chemical substances, either as a single chemical or as a member of a chemical category.

• **Chemical Substance Inventory Update Reporting (IUR).** Since 1986, companies that manufacture or import chemicals may be required to periodically report information, such as the identity of the chemical, the amounts manufactured or processed, and certain details about their manufacture. This information is used to identify potential use and exposure scenarios. The 2006 data collected consisted of updated information for approximately 7,500 chemicals. For the first time, this information included: manufacturing information for inorganic chemicals; enhanced manufacturing information for organic chemicals (e.g., the physical form of the chemical and the number of potentially exposed workers); and additional screening-level exposure-related processing and use information for organic chemicals produced at 300,000 pounds or greater at a single site.

• **Nanoscale Materials Stewardship Program (NMSP)** was launched in January 2008 to help provide a firmer scientific foundation for regulatory decisions by encouraging submission and development of information, including risk management practices, for nanoscale materials. The NMSP contains a basic and an in-depth program. EPA released its interim report on the NMSP in January 2009, solicited comments on the interim report and expects to issue a final report and program evaluation in early 2010.

• **ACToR (Aggregated Computational Toxicology Resource)** is a collection of more than 200 sources of publicly available data that are searchable by chemical name and by chemical structure. Data includes chemical structure, physico-chemical values, in vitro assay data and in vivo toxicology data. Chemicals include, but are not limited to, high and medium production volume industrial chemicals, pesticides (active and inert ingredients), and potential ground and drinking water contaminants. ACToR also contains the data being produced by the **ToxCast™** chemical screening prioritization program. The majority of chemicals in ACToR have chemical structures, which will facilitate studies of structure-function relationships.

• **Envirofacts** is a single point of access to EPA environmental data with information about environmental activities that may affect air, water, and land anywhere in the US.

• **Toxics Release Inventory (TRI) is the US pollutant release and transfer registry or PRTR.** US EPA’s TRI database is publicly available and contains information on toxic
chemical releases and other waste management activities reported annually by certain covered industry groups as well as federal facilities. The Program is also working to ensure that the TRI data and information are useful and meaningful to the public and a variety of stakeholders both inside and outside the Agency.

- **EPA Air Toxics Web Site** provides information on the air toxic management program, including rules and implementation, air toxics assessment, urban and regional programs, education and outreach.

- **Clearinghouse for Inventory and Emissions Factors** includes information on EPA’s emission inventories, emission factors, emissions modeling, and the emissions monitoring knowledge database.

- **The Toxicology and Environmental Health Information Program (TEHIP)** evolved from the Toxicology Information Program (TIP) that was established in 1967 at the National Library of Medicine (NLM) in response to recommendations made in the 1966 report "Handling of Toxicological Information," prepared by the President's Science Advisory Committee. The TIP objectives were to: (1) create automated toxicology data banks, and (2) provide toxicology information and data services. In the mid-1990's, the mission of TIP was expanded to include environmental health. TEHIP, by creating, organizing, and disseminating toxicology and environmental health information, now serves as a premier information portal for resources in these subject areas.

  TEHIP maintains a comprehensive toxicology and environmental health website that includes access to resources produced by TEHIP and by other government agencies and organizations. This website includes links to databases, bibliographies, tutorials, and other scientific and consumer-oriented resources. TEHIP also is responsible for the Toxicology Data Network (TOXNET®), an integrated system of toxicology and environmental health databases that are available free of charge on the web.

- **Materials and Waste Exchanges** are markets for buying and selling reusable and recyclable commodities, diverting materials out of landfills. Some exchanges are coordinated by state and local governments; others are wholly private, for-profit businesses. In general, waste exchanges tend to handle hazardous materials and industrial process waste, while materials exchanges handle non-hazardous items.

### Tools and Methods for Analyzing Chemical Properties and Exposure

- Launched in 2007, **ToxCast™** develops a cost-effective approach for prioritizing the toxicity testing of large numbers of chemicals in a short period of time. Using data from state-of-the-art high throughput screening (HTS) bioassays developed in the pharmaceutical industry, ToxCast™ is building computational models to forecast the potential human toxicity of chemicals. These hazard predictions will provide EPA with science-based
information to prioritize chemicals for more detailed toxicological evaluations, and lead to more efficient use of animal testing.

- **Structure Activity Relationships (SAR)** is a technique routinely used by EPA to estimate physical, chemical and toxicological properties of chemicals being reviewed based on the relationship between the structure of a molecule and its ability to affect a biological system.
  - The **EPI (Estimation Program Interface) Suite™** is a suite of physical/chemical property and environmental fate estimation models.
  - **ECOSAR (Ecological Structure Activity Relationships)** is used to predict the toxicity of industrial chemicals to aquatic organisms such as fish, invertebrates, and algae. The program estimates a chemical’s acute (short-term) toxicity and, when available, chronic (long-term) toxicity.

- **Distributed Structure-Searchable Toxicity (DSSTox) Database Network** provides a public website for searching standardized chemical structure files associated with toxicity data. The structure browser delivers a simple, easy-to-use structure-searching which allows for improved structure-activity and predictive toxicology capabilities.

- **Risk-Screening Environmental Indicators (RSEI)** is a screening tool that analyzes risk factors to put **Toxics Release Inventory (TRI)** release data into a chronic health context. RSEI is often used by government regulators, communities, journalists, industry and others to examine trends, identify important emissions situations for follow-up, support community-based projects and initially screen potential impacts of emissions.

- The tools found on EPA’s **Fate, Exposure, and Risk Analysis** website are useful for evaluating the health risks and environmental effects of toxic air pollutants. Information is provided on EPA’s Total Risk Integrated Methodology model, multimedia fate and transport modeling, human exposure modeling, and risk assessment methodologies.

- **Support Center for Regulatory Atmospheric Modeling** contains information on models and other techniques used to assess air quality and emission control strategies and to support regulatory decisions.

- EPA conducts **economic analyses** as part of its decision making process, such as strategic planning or priority setting, development of voluntary actions and regulations, and the measurement of results. Economic analyses include market studies, financial feasibility studies, and industry sector studies. More detailed economic analyses or **regulatory impact analyses** (RIAs) incorporate risk findings with valuation to assess benefits of regulatory actions being considered and compare these benefits to estimated costs.

- **Priority-Setting Scoring Tools** are designed to quickly prioritize concerns and are especially useful when trying to evaluate large numbers of chemicals. These tools include:
- **PBT Profiler** predicts a chemical's potential to persist in the environment, bio-concentrate in animals, and be toxic, based on a chemical's structure. The PBT Profiler can also tell the user if the chemical belongs to a category that is known to present human health concerns as described in [EPA's Chemicals Category Report](https://www.epa.gov/chemicals/chemicals-category-report). The PBT Profiler was developed by EPA through a collaborative effort with the chemical industry and Environmental Defense to identify pollution prevention opportunities for chemicals without experimental data.

- **Use Clusters Scoring System (UCSS)** screens clusters of chemicals that are used to perform a particular task; and provides an initial ranking of chemicals using human and environmental hazard and exposure data.

**Pesticides Knowledge & Information**

- **Online Registration Kit** contains pertinent forms and information needed to register a pesticide product with EPA.

- The **Pesticide Product Label System** is a collection of images of pesticide labels which have been approved by EPA.

- **Pesticides publications.** EPA posts an alphabetical listing of the status of each pesticide in the registration and reregistration review processes. Also, EPA posts a collection of fact sheets on health and safety, regulatory action, and specific pesticides. In addition, EPA provides printed information on pesticides through the [National Service Center for Environmental Publications](https://www.epa.gov/pesticides/pesticide-information).

- The **National Agriculture Center** provides information on how to comply with US pesticides laws.

- The **National Pesticide Information Center** provides objective, science-based information about pesticides to enable people to make informed decisions about pesticides and their use.

- Pesticide product registrants are required to submit adverse effects information about their products to the EPA.

- **Pesticide-Related Harmonized Test Guidelines.** US EPA recommends the pesticide registrant provide data from tests conducted according to [Harmonized Test Guidelines](https://www.epa.gov/pesticides/pesticide-testing-and-analysis), to minimize variations among the testing procedures that must be performed. EPA publishes many pesticide analytical methods and procedures, including residue analytical methods for food, feed, and animal commodities; **Standard Operating Procedures for antimicrobial testing methods**; and environment chemistry methods for soil and water are used to determine the fate of pesticides in the environment.

**Risk Assessment Tools**
- **Risk Assessments** and **Integrated Risk Information System (IRIS)**. EPA provides information on risk assessments, including tools, guidance and guidelines. IRIS is a compilation of electronic reports on specific substances found in the environment and their potential to cause human health effects.

- **Screening Level Risk Assessment Tools** are often used in the absence of appropriate monitoring data or to compliment exposure related data. These tools have the following characteristics: require minimal data entry, quickly screen exposure concerns, and create conservative estimates of exposure. Screening Level Tools include:

  - **Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER)** estimates occupational inhalation and dermal exposure to a chemical, as well as releases to air, water and land, during industrial and commercial manufacturing, processing, and use of the chemical.
  
  - **Exposure, Fate Assessment Screening Tool (E-FAST)** estimates the concentrations of chemicals released to air, surface water, landfills, and from consumer products.
  
  - **Pesticide Inert Risk Assessment Tool (PIRAT)** estimates exposure and risk to pesticide inert ingredients that are used in a residential setting. This includes assessing both indoor and outdoor residential uses of pesticides. PIRAT will assess acute and chronic risks and will be able to assess adults and children separately.

- **High Tiered Risk Assessment Tools** can be tailored to the specific exposures and the specific environment in which exposures occur. These tools are used in detailed risk assessments and, when used appropriately, these can provide comprehensive exposure estimates with a greater level of accuracy. Higher tier tools have the following characteristics: provide detailed exposure assessment, require detailed data sources, and need to be used by knowledgeable scientists.

  - **Multi-Chamber Concentration and Exposure Model, (MCCEM) version 1.2** estimates average and peak indoor air concentrations of chemicals released from products or materials in houses, apartments, townhouses, or other residences; and inhalation exposures to these chemicals, calculated as single day doses, chronic average daily doses, or lifetime average daily doses.
  
  - **Wall Paint 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.
  
  - **Swimmer Exposure Assessment Model (SWIMODEL)** estimates the human exposure doses to the pesticides and toxic pollutants in swimming pools for competitive and noncompetitive (recreational-type) swimmers.

- **Pesticides Exposure Databases and Models** define the intensity, frequency, and duration of a chemical's exposure within a given context, based on the use or release of the chemical
and the activity patterns of those (human or ecological systems) exposed. Exposure databases provide data regarding chemical use, physiological or ecological data and descriptors typically required in exposure modeling (Pittinger 2003).

- **Residential Exposure Standard Operating Procedures (SOPs)** are designed to provide standard default methods for developing residential exposure assessments for both handler and post application exposures when chemical - and/or site-specific field data are limited.

- **Endocrine Disruptor Screening Program.** EPA is validating methods or assays to identify and characterize the endocrine activity of pesticides, commercial chemicals, and environmental contaminants, specifically in relation to estrogen, androgen, and thyroid hormones. The validation framework includes reduction of animal use, refine procedures involving animals to make them less stressful, and replace animals where scientifically appropriate.

### Pollution Prevention Technical Assistance & Information Sharing

- **Pollution Prevention Resource Exchange (P2Rx)** is a consortium of eight regional centers that offer a range of services for business, government and technical assistance providers including information for specific industry sectors, training, library resources, referrals and research. The centers collect, synthesize, and update technical information; and provide contact information for experts and other sources. The Pollution Prevention Information Clearinghouse (PPIC) is a free information service of the U.S. EPA dedicated to reducing and eliminating industrial pollutants through technology transfer, source reduction, education and public awareness.

- **Compliance Assistance Centers** help businesses, local governments, and federal facilities to understand and comply with environmental requirements and save money through pollution prevention. The centers offer easy access to plain-language materials and other resources through: web sites targeted to industry sectors, virtual plant tours, telephone assistance, “ask the expert,” email discussion groups, State Resource Locators that offer a wide range of topics on environmental compliance information. The centers are sponsored by EPA in partnership with industry, academic institutions, environmental groups, and other government agencies.

- **EPA Office of Pollution Prevention and Toxics Tribal Program** works in partnership with tribal governments to safeguard and protect the environment from toxic hazards and to promote pollution prevention in Indian country. The OPPTS Tribal newsletter features a wide variety of environmental information, perspectives, and issues that affect American Indian Tribes.

### 1.c. Governance:
Selection of Relevant United States Laws

- The Toxic Substances Control Act (TSCA) provides authorities to require the development and submission of data relating to the health and environmental effects of commercial and industrial chemicals, and to regulate such chemicals when they present an unreasonable risk to human health and the environment. Under TSCA, EPA has established reporting, record-keeping, testing, and control-related requirements for new and existing chemicals.

- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulates the sale, distribution and use of pesticides in the US. FIFRA authorizes EPA to review and register pesticides for specified uses, and to suspend or cancel the registration of a pesticide if subsequent information shows that continued use would pose unreasonable risks.

- The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes EPA to set maximum residue levels, or tolerances, for pesticides used in or on foods or animal feed.

- The Food Quality Protection Act of 1996 (FQPA) amended FIFRA and FFDCA setting tougher safety standards for new and old pesticides, and to make uniform requirements regarding processed and unprocessed foods.

- The Resource Conservation and Recovery Act (RCRA) gives EPA the authority to control hazardous waste from the “cradle-to-grave:” generation, transportation, treatment, storage, and disposal of hazardous waste. RCRA also provides a framework for the management of non-hazardous solid wastes. RCRA address environmental problems that could result from underground tanks storing petroleum and other hazardous substances.

- The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or Superfund provides a Federal "Superfund" to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other emergency releases of pollutants into the environment. Through CERCLA, EPA was given power to seek out those parties responsible for any release and assure their cooperation in the cleanup.

- The Emergency Planning & Community Right-to-Know Act (EPCRA), also known as Title III of the Superfund Amendments and Reauthorization Act (SARA), is designed to help local communities protect public health, safety, and the environment from chemical hazards.

- The Pollution Prevention Act (PPA) established pollution prevention as the national policy for controlling pollution at its source. EPA works to reduce pollution before it occurs by supporting innovative changes in the production and use of raw materials.

- The National Environmental Policy Act (NEPA) policy is to assure that all branches of government give proper consideration to the environment prior to undertaking any major federal action that significantly affects the environment.
• The **Clean Air Act** is the law that defines EPA's responsibilities for protecting and improving the nation's air quality and the stratospheric ozone layer. The last major change in the law, the Clean Air Act Amendments of 1990, was enacted by Congress in 1990. Legislation passed since then has made several minor changes.

• The objective of the **Federal Water Pollution Control Act**, commonly referred to as the **Clean Water Act (CWA)**, is to restore and maintain the chemical, physical, and biological integrity of the nation's waters by preventing point and nonpoint pollution sources, providing assistance to publicly owned treatment works for the improvement of wastewater treatment, and maintaining the integrity of wetlands.

• The **Safe Drinking Water Act (SDWA)** is the main federal law that ensures the quality of Americans' drinking water. Under SDWA, EPA sets standards for drinking water quality and oversees the states, localities, and water suppliers who implement those standards.

**Public Involvement Tools and Resources.** Public involvement encompasses the full range of activities used to engage the public in the decision-making processes. Public involvement is a progression that starts with outreach to build awareness and interest. It evolves to information exchange, through collaboration and recommendation to agreement and decision-making.

**1.d. Capacity-Building and Technical Cooperation:**

United States government activities on capacity-building and technical cooperation are described under section III.2. Internationally-Focused Agencies and Programs.

**1.e. Illegal International Traffic:**

**Importing and Exporting Industrial Chemicals.** The US government can refuse entry into the US of a shipment of any chemical substance or mixture that fails to comply with the requirements under the Toxic Substances Control Act (TSCA). TSCA also requires a person who exports or intends to export a chemical substance or mixture that is subject to certain TSCA regulatory actions to notify EPA of the export. For most enforcement cases under TSCA, the Agency pursues an administrative civil penalty action in order to expeditiously receive a monetary penalty and remedy the violation.

**Importing and Exporting Pesticide Products.** With limited exceptions, pesticides which are sold or distributed in the US must first be registered with EPA. All registered pesticides sold or distributed within the US for export to other countries must bear the product label approved by EPA. Pesticides that are not registered for use in the US may be manufactured in the US and exported subject to certain conditions. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that exporters of unregistered pesticides first obtain a statement signed by the foreign purchaser indicating the purchaser's awareness of the unregistered status of such pesticide in the US. The requirement is shipment-specific for a particular exporter, product and purchaser. To ensure that government officials in the receiving country are informed of the
shipment, EPA transmits a copy of the statement to the Designated National Authority (DNA) under the UN program on Prior Informed Consent. This process is useful in tracking unused or abandoned pesticides in developing countries, particularly DDT in Africa.

2. INTERNATIONALLY-FOCUSED AGENCIES AND PROGRAMS

The use and release of certain chemicals can be of serious concern if they have significant impacts on human health or the environment. Some chemicals and pollutants can cross national and international boundaries and move long distances through air and water. Because of this, negotiation and implementation of international agreements and collaborative activities are essential to ensuring environmental protection in the United States as well as our partners throughout the world—particularly the developing nations who have weak protocols and tracking mechanisms.

2.a. Risk reduction:

The United States participates in the Strategic Approach to International Chemicals Management (SAICM), a voluntary initiative to help countries and participants manage chemicals foster the sound management of chemicals. SAICM works toward the goal that by 2020 chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment. The United States has provided support to the overall implementation of SAICM, including the first regional meeting of the Group of Latin American and the Caribbean, as well as financial and technical support to projects under the Quick Start Program. The US has also contributed to international cooperation on several emerging policy issues within SAICM.

The United States engages international partners, multilaterally and bilaterally, to address key mercury issues including data collection and inventory development, source characterization, and best practices for emissions and use reduction. As called for by UNEP Governing Council Decision 23/9 IV of February 2005, the US has been a catalyst in the development of the UNEP Global Mercury Partnerships designed to achieve reductions in use and emissions of mercury globally. The United States strongly supports the negotiation under the UN Environment Program of a new, legally binding instrument to reduce mercury releases into the environment.

Ozone-Depleting Substances (ODSs). In 1985 the Vienna Convention established a mechanism for international co-operation in research into the ozone layer and the effects of ozone depleting substances. That year also marked the first discovery of the Antarctic ozone hole. On the basis of the Vienna Convention, in 1987 the Montreal Protocol on Substances that Deplete the Ozone Layer was finalized and calls for the 191 Parties to phase out the use of man-made ozone depleting substances.

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal controls the international trade in hazardous wastes through a "notice and consent" regime for the export of hazardous waste to importing countries. The United States signed the
Basel Convention in 1990 and in 1992 the United States Senate provided its advice and consent; however, before the United States can ratify the Convention, there is the need for additional legislation to implement its requirements.

The **Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Hazardous Chemicals and Pesticides** provides governments with the advance information they need to assess the risk of importing certain chemicals and pesticides. The United States signed the PIC Convention in 1998, but has not yet become a Party.

The **Stockholm Convention on Persistent Organic Pollutants** aims to protect human health and the environment from chemicals that are toxic, have the potential to accumulate in unhealthy quantities in humans and animals, are stable and thus resistant to natural breakdown, and can be transported over long distances. The Convention creates a science-based procedure to add new chemicals beyond the initial twelve covered by the convention. The Convention entered into force on May 2004. The US signed the Stockholm Convention it in 2001, but it has not yet become a Party.

The United States also participates in the **Partnership for Clean Fuels and Vehicles**, which has successfully eliminated lead from gasoline in most countries and is working to reduce sulfur and other emissions, and the **Partnership for Clean Indoor Air** which reduces health risks from indoor burning of coal and other fuels which emit air toxics as well as criteria pollutants.

The **Convention on Long-Range Transboundary Air Pollution (LRTAP)**, signed in Geneva in 1979 to address transboundary acid deposition in Europe. In the intervening years, Protocols have been added to cover a broad range of pollutants. The Parties to the convention include countries from western and Eastern Europe, Canada and the US. Of the eight protocols to the Convention, the US primarily focuses on:

- The 1998 Protocol on Heavy Metals, the US is a Party to the protocol
- The 1998 Protocol on Persistent Organic Pollutants (POPs) entered into force on October 2003 to reduce use and release of 16 POPs, the US is not a Party to the protocol
- The 1999 Protocol to Abate Acidification, Eutrophication and Ground-level Ozone, the US is a Party to the protocol

The **Great Lakes Binational Toxics Strategy (GLBTS)**. Since 1997, Environment Canada (EC) and EPA, along with stakeholders from industry, academia, state/provincial and local governments, Tribes, First Nations, and environmental and community groups have worked together toward the goal of virtually eliminating persistent toxic substances, such as mercury, PCBs and dioxin from discharging into the Great Lakes environment. The GLBTS also tracks trends of these substances in gull eggs and fish as well as open water, air and sediment. New challenges are presented by emerging substances of concern, such as flame retardants. Voluntary projects of the GLBTS include the burn barrel outreach campaign and the wood stove exchange campaign.
US Canada Air Quality Agreement is a 15 year old bilateral agreement addressing transboundary air pollution originally focused on the problem of acid rain.

The Arctic Contaminants Action Program (ACAP) is a working group of the Arctic Council, and encourages national actions by Arctic governments to reduce emissions of pollutants. It includes initiatives to manage local sources of contamination, such as the Indigenous Peoples Community Action Initiative implemented by the Russian association of Indigenous Peoples of the North.

2.b. Knowledge and Information:

Globally Harmonized System (GHS) for the Classification and Labeling of Chemicals provides comprehensive standardized system for internationally-recognizable chemical hazard communication.

EPA worked with UNEP to develop the Chemical Information Exchange Network (CIEN), which improves access to chemicals management information by developing an in-country network of government officials and stakeholders, providing Internet connectivity where needed, and providing training on accessing chemicals management information and developing country-specific web resources.

USAID has developed Comparative Risk Assessments (CRA) to help ascertain which chemical pollutant is projected to cause the most mortality and morbidity and thence offer a roadmap for a developing country or region to address potential chemical abuses. CRA was conducted in Bangkok; Cairo; Lima, Peru; Caspian Sea; and others. These proved useful in targeting Aid monies to the right cleanup and coordinating other donors as well. In Egypt USAID targeted on removal of lead from the atmosphere including removing lead from gasoline and cleaning a lead smelter in Cairo.

Materials and Waste Exchanges. USAID’s Ecoasia program has the objective of reducing chemical pollutants and promoting best practices. It aims to build upon existing standards and efforts in the region to harmonize test procedures and specifications for CFLs and improve the quality of CFLs being produced and sold in Asian countries. This includes a project to Test and benchmark the quality of CFLs in the region; develop harmonized minimum test procedure for CFLs; develop common “tiers” for rating CFL performance and quality; and support schemes for compliance and enforcement of the testing and standards programs.

Other ECO-Asia activities that affect chemicals include:

USAID ECO-Asia Reports

Innovative Approaches to Financing Energy Efficiency in Asia (August 2009)

Biofuels in Asia: An Analysis of Sustainability Options (March 2009)

Policy Brief: Biofuels in Asia: An Analysis of Sustainability Options (March 2009)
More information about USAID/RDMA’s regional clean energy activities is available at http://usaid.eco-asia.org/programs/cdcp/index.html. USAID is also currently addressing the Agent Orange cleanup in Vietnam at Danang Base.

**Organization for Economic Cooperation and Development (OECD) Information tools:**

- **OECD High Production Volume (HPV) Chemicals Program** is a voluntary program in which each participating country’s government works with industry to obtain screening-level toxicity data and other basic information on HPV chemicals. Each country prepares assessments of these data for presentation at biannual meetings. Under this program, EPA has committed to review approximately 500 chemicals between 2005 and 2010.

- The US supports the development of the **OECD eChemPortal**, which provides public access to information on properties and effects of chemicals prepared by international, national and regional chemical review programs. The eChemPortal currently provides searching capabilities by chemical substances and, in phase two, will provide searching by chemical properties. The eChemPortal provides access to databases from the US, European Chemical Substances systems, Japan, Finland, Australia and New Zealand.

- The **OECD Clearing House on New Chemicals** has been working on the development of a software tool to assist in the generation of forms needed for notification of new chemical substances in OECD member and non-member countries. This tool is intended to consist of a database that will sit behind a company firewall, to capture the information needed for preparation of dossiers. The Clearing House is also further developing the “parallel” review process (whereby a company would submit the same notification package to two or more countries and the countries would agree to a common hazard assessment for the substance), new chemicals working definitions, exemptions and reduced notification approaches by OECD countries.

- The **OECD Test Guidelines Program** develops protocols for studies to assess physicochemical properties, environmental fate, ecotoxicity, and health effects endpoints. A foundation of the OECD chemicals program is the Mutual Acceptance of Data (MAD)
agreement among OECD countries to accept for review studies generated in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice regardless of where the study was performed.

- The primary objective of the **OECD Principles of Good Laboratory Practice (GLP)** is to ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations in the framework of harmonizing testing procedures for the Mutual Acceptance of Data (MAD).

- **OECD Working Party on Manufactured Nanomaterials (WPMN)** is engaged in a variety of projects to further the understanding of the properties and potential risks of nanomaterials, such as development of a Database on Environmental Health and Safety (EHS) Research, test guidelines, cooperation on voluntary and regulatory programs, and cooperation on risk assessments. The WPMN has identified a representative list of manufactured nanoscale materials for environmental health and safety testing, and has also published a list of testing endpoints. In addition, the WPMN has launched a Sponsorship Program for Testing Manufactured Nanomaterials, for which the OECD will act as a clearinghouse and will prepare a guidance manual. EPA is sponsoring fullerenes, single walled carbon nanotubes, multiwalled carbon nanotubes, silver and cerium oxide, and is co-sponsoring titanium dioxide, zinc oxide and dendrimers. The US chaired the WPMN from 2006-2009.

**Pollutant Release and Transfer Registries (PRTRs):**

- **OECD PRTRs.** OECD produces documents describing the experiences of countries that have developed PRTRs; current and emerging uses of PRTR data; how PRTRs differ; and the identification, selection, and adaptation of release estimation techniques that industry can use to calculate PRTRs. The OECD coordinates PRTR activities to enable member countries to improve information about implementation of PRTRs.

- **North American Commission for Environmental Cooperation (CEC)** annually publishes the *Taking Stock: North American Pollutant Releases and Transfers* report, which is a consolidation of certain PRTR data from the Canadian National Pollutant Release Inventory, the US Toxics Release Inventory, and Mexico’s Registro de Emisiones y Transferencia de Contaminantes. Only those data common to all three PRTR systems are used. There are only about nine industrial sectors and 60 chemicals that are commonly reported to each of these PRTRs.

- The US works with **UNITAR** and **Central American Commission for Environment and Development (CCAD)** to facilitate development of PRTRs in two countries in Central America, and the development of a PRTR in Chile, through funding related to US trade agreements with those countries.

2.c. Governance:
EPA works with a number of countries to improve environmental governance through training and capacity building. In the context of bilateral programs, EPA conducts training, development and implementation of environmental laws, environmental inspections, environmental impact assessment, enforcement and compliance, and resolving environmental disputes. In addition, EPA has provided tailored expertise to various countries on structuring environmental agencies and strengthening public participation in environmental decision-making. EPA is also active in the International Network for Environmental Compliance and Enforcement (INECE) and the IUCN Commission on Environmental Law.

2.d. Capacity-Building and Technical Cooperation:

• The United States, Canada and Mexico developed a strategy for **regional implementation of SAICM in North America** under the **Sound Management of Chemicals (SMOC)** initiative of the Commission for Environmental Cooperation (CEC). In June 2008, the Ministers approved a renewed North American agenda for chemicals management, involving the following:
  - Establish a foundation for chemicals management to increase comparability of chemical management approaches, with an initial focus on supporting Mexico’s development of an inventory of industrial chemicals.
  - Develop and implement a sustainable regional approach for environmental and human biomonitoring and assessment, with an early emphasis on supporting Mexico to implement its Environmental Monitoring and Assessment Program (Programa de Monitoreo y Evaluación Ambiental—PRONAME).
  - Reduce or eliminate the risk from chemicals of mutual concern: mercury; dioxins and furans, and hexachlorobenzene; and lindane and other isomers of hexachlorocyclohexane.
  - Improve environmental performance of sectors.

• Under the **Central America and Dominican Republic Free Trade Agreement (CAFTA-DR)**, the US is working with CCAD and governments in the region on:
  - Regional SAICM implementation – building upon national priorities
  - Developing mercury inventories and eliminating mercury in the health care sector
  - Improving chemical security and management
  - Working with stakeholders to adapt the US program on pesticide safety in the region.

These are examples of US efforts to mainstream chemicals management into development assistance cooperation.
• **Promoting Shared Scientific and Technical Expertise on Pesticides.** EPA interacts with other countries and international organizations to share scientific and technical expertise on pesticides, lessen the resource burden on governments and the regulatory community, and maintain high standards for the protection of human health and the environment. Some of these activities include: collaboration with China (including interacting on an informal basis with USAID particularly with regards to disposal of DDT); Agent orange; Dieldrin disposal (sometimes employing local cement kilns to meet EPA Emission standards for Dioxin); International Food Safety Standards (CODEX); FAO/WHO Joint Meeting on Pesticide Residues; North American Free Trade Agreement Technical Working Group on Pesticides; OECD Working Group on Pesticides; and International Program on Chemical Safety.

• This US sponsored with UNEP the **Workshop on Managing Perfluorinated Chemicals and Transitioning to Safer Alternatives** held in Geneva, Switzerland, to explore opportunities for managing PFCs and making a transition from PFOS, PFOA, PFOS and PFOA precursors, and related higher homologue chemicals to safer alternatives.

• The United States also sponsored the **Workshop on Continuing PCB Management in the Latin American and Caribbean Countries** in Panama City, which built upon the previous regional activities and provided an opportunity for all stakeholders involved to share their experience and identify opportunities to advance towards the goal of eventually eliminating PCBs from the region.

• The US is co-sponsoring a series of regional workshops on nanomaterial health and safety issues, as recommended at SAICM Second International Conference on Chemicals Management (ICCM-2), which are planned to be held jointly under the auspices of UNITAR, the SAICM Secretariat and the OECD.

• USAID has a long history of developing local capacity and **Clean Production Centers** (CPCs) throughout the world, which re-design local industrial processes to reduce materials, energy, and materials and pave the way for replication of these technologies in economies of the developing world. CPCs are created as a response to the enormous shift in the manufacturing base from the G7 countries to the developing world. USAID has interacted and built centers in many geographical regions including Asia, Eurasia, Latin America and Caribbean, the Near East, Africa, and Eastern Europe. Through CPCs, the developing world now pays more attention to reduction of chemical abuse to the environment on purely economic motivations, and the payoffs have been large. Plants improve processes related to leather tanneries, smelting, lead/copper mining, dairy, food processing, steel manufacturing, fishmeal, pulp and paper, brewery, fruit and vegetables, and hotels and hospitality, among many others.

• **Waste Exchange Pollution Prevention Project:** USAID developed an internet based waste exchange network in Bolivía at the Association of Industries--based upon a model supplied by Chile (CORFU). Bolivian officials were trained in Chile and the model was developed and
is operational. A small fee is charged for each transaction—from the waste creator excess material to the waste consumer and vice versa. Other countries have expressed an interest in replicating this model. Eventually the operating cost is covered by the “deals” and chemicals are reduced.

2.e. Combating Illegal International Traffic:

- The US supports UNEP’s Green Customs Initiative, which builds the capacity of customs officials to combat illegal trade in ozone-depleting substances and other hazardous chemicals.

- EPA developed, adapted and delivered a Survey Training Course for Customs Officers and Inspectors on trade in hazardous wastes (Basel Convention), ozone-depleting substances (Montreal Protocol), chemicals covered by the Rotterdam and Stockholm Conventions, and endangered species (CITES). The effort was carried out in close cooperation with international and regional organizations with the aim to influence or establish the necessary policy, legal, enforcement, and managerial authorities to interdict non-compliant shipments.

- The United States is working with CCAD and countries party to the Central America and Dominican Republic Free Trade Agreement (CAFTA-DR) to adopt inter-agency or ministerial agreements with environment, health, agriculture and customs authorities to improve chemical enforcement. To date, El Salvador and Honduras have adopted such agreements.