Appendix B: Overview and Analysis of the *Toxic Substances Control Act*, Its Implementation, and Voluntary Programs under EPA's Office of Pollution Prevention and Toxics

TSCA was passed in 1976 after years of debate over the scope of influence government (in this case EPA) should have over production decisions. Toward the end of the 1960s several notable incidents involving synthetic chemicals and heavy metals attracted the attention of the media and the American public. Government agencies were dealing with the "toxic of the month" problem and lacked a comprehensive way to address toxic chemical hazards other than limited regulations controlling emissions to air and water. During the spring of 1970, the newly established Council on Environmental Quality (CEQ), an Executive Branch office dedicated to coordinating national environmental policy, embarked on research into the problems of synthetic chemicals and metals and options for their control. The result of this research was a pioneering 1971 report, entitled *Toxic Substances.*[202]

The report noted particular concern about the large growth in production amount and sheer number and uses of synthetic substances in society. This concern was coupled with inadequate information on chronic chemical hazards, exposures, how chemicals reacted in the environment, and the levels of exposure at which effects might occur. CEQ noted that existing controls for industrial chemicals were inadequate and often ineffective, addressing only large-scale emissions to air and water but not consumer and disposal hazards. Existing controls only dealt with problems after the fact and did not deal with the "multiplicity of ways by which man can be exposed to these substances." Thus, the CEQ concluded that the evidence indicated the "high priority need for a program of testing and control of toxic substances," and that "we need no longer remain in a purely reactive posture with respect to toxic substances.[203]" While legislation existed to place responsibility for testing and safety on manufacturers of drugs and pesticides, no such legislation existed for the large number of industrial chemicals on the market.

Earlier regulation on clean water and air had addressed primarily wastes coming from production processes (an end of the pipe focus). These acts generally placed the burden on the Environmental Protection Agency (EPA) to establish standards and demonstrate risks before acting. However, TSCA exerted control over production and use decisions, affecting the types of chemicals that could be produced and limitations on their use, placing an upfront burden on manufacturers.

The most relevant sections of TSCA in the context of emerging contaminants include:

- Section 4: Testing of Chemical Substances and Mixtures
- Section 5: New Chemicals/Manufacturing and Processing Notices
- Section 6: Regulation of Hazardous Chemical Substances
- Section 8: Reporting and Retention of Information

---

[202] Council on Environmental Quality, *Toxic Substances*. (Washington, DC: U.S. Council on Environmental Quality, April 1971).
[203] Ibid.

- Section 9: Relationship to other laws
- Section 26: Action with Respect to Categories

These sections are discussed below:

Section 4

Section 4 of TSCA Compels EPA administrator to require testing of a chemical substance or mixture, new or existing if: (1) The subject chemical or mixture "may present an unreasonable risk (hazard/risk or "A" finding), **or** The chemical will be produced in substantial quantities and either may enter the environment in substantial quantities or lead to significant human exposure (exposure or "B" finding) **and (2)** Inadequate data exist for use in risk assessment **and (3)** Testing is necessary to develop the needed data. EPA has developed criteria for when substances meet the A or B hazard/risk or exposure finding.

Testing rules are generally written for individual chemicals though can be written for small groupings of similar substances. All testing rules must undergo detailed notice and comment procedures, including economic analysis. Chemical producers, importers and processors (including those who intend to produce, import or process) can be required to conduct health effects, environmental effects, environmental fate, and other types of needed studies (e.g., monitoring) under these rules. All studies conducted under a test rule must adhere to EPA approved test methods, including Good Laboratory Practice Standards (GLPS). Specific producers, importers and processors are required to immediately comply with test rules while others (processors and those that produce the substance as a by-product or non-isolated intermediate) would only be required to comply if specifically noted in the final test rule. The cost of performing the required testing is shared among manufacturers and/or processors of each test rule chemical.

Chemicals are referred for test rule development in the following types of instances:

Designation by the TSCA Interagency Testing Committee (ITC). A role of the ITC (made up of representatives from several federal agencies[204] is to identify chemicals subject to TSCA for which there are toxicity concerns and limited data on human or ecological effects, fate, etc. These chemicals can be formally added to a Priority Testing List (for testing to meet the needs of EPA or other agencies) and EPA must within one year issue a proposed test rule (or advanced notice of rulemaking) or notice stating the agency's rationale for not doing so.

Requests for testing action from other EPA offices. The OPPT receives requests for testing action development directly from other EPA Offices and other federal agencies but there is no statutory deadline or requirement to issue test rules for these requests.

[204] These include the Occupational Safety and Health Administration, EPA, National Institute for Occupational Safety and Health, the Department of Transportation, the Consumer Product Safety Commission and Department of Commerce.

Concerns raised by OPPT for existing or new substances. Through its implementation of TSCA's new and existing chemicals programs OPPT may identify chemicals for test rules but as above there is no statutory deadline for developing such rules.

These sources are integrated into a Master Testing List which consists of more than 500 substances and categories of substances (such as endocrine disruptors) for which there are federal government or international testing needs that could be filled by international, federal or voluntary or mandatory corporate actions.[205]

In addition to formal test rules EPA may also enter into Enforceable Consent Agreements (ECAs), which generally emanate from an invitation in a formal test rule notice where a consensus exists among the Agency and interested parties (including chemical manufacturers and representatives of the public) about the adequacy of the proposed testing program and other relevant features of the agreement. These agreements include the same types of testing as formal rules but allow more flexibility in the testing protocol (for example tiered testing) and interaction in developing the most relevant testing approach and are much more efficient legally and administratively.

Section 5

Section 5 of TSCA prohibits the manufacture, processing, or import of a "new chemical substance" or "significant new use" of an existing substance unless a pre-manufacture notification (PMN) is submitted to EPA at least 90 days before the commencement of manufacture or processing. The pre-manufacture stage is before actual marketing has occurred to ensure lifecycle attention to the chemical and its potential impacts. The PMN must contain mandatory and reasonably ascertainable information on the chemical identity, physical characteristics, processing, by products and use, and available toxicity data but there is generally no required testing for such substances. During this 90-day period, EPA reviews the chemical's human and environmental risks and exposures, examining the data submitted in addition to other information. As there are no particular testing requirements under Section 5, EPA relies heavily on predictive models, including structure activity relationships and expert judgment in reviewing new chemicals. EPA can then request more data, prohibit or limit manufacture, or halt the review process. Certain types of chemicals and chemical uses are exempted from the review process and EPA is authorized to make future exemptions.[206] EPA's new chemical review process is multilayered and extensive and has been reviewed in detail elsewhere.

After 90 days if the EPA has not initiated any action, the manufacturer or importer can issue a Notice of Commencement at which time manufacture or import can commence (this applies to all future manufacturers or importers unless EPA issues a Significant New Use Rule. The possible outcomes of a new chemicals review include:

[205] See www.epa.gov/oppt/chemtest/pubs/index1.pdf.

[206] These exemptions include: substances manufactured, processed, or distributed only for export; substances manufactured or processed only in small quantities for research and development, including product development; test marketing, if the substance "will not present any unreasonable risk of injury to health or the environment" as a result of the test marketing activity; non-isolated intermediates (temporary intermediates with no exposure); polymers meeting specific requirements; and Low Volume and Low Release and Exposure, subject to restrictions on use.

- no action by EPA;
- voluntary withdrawal by the manufacturer, often in response to concerns raised by EPA;
- Section 5e orders to prohibit or limit activities associated with the chemical if: there are insufficient data to evaluate effects and (1) it may present an unreasonable risk; or (2) it is or will be produced in substantial quantities or result in substantial exposure. Such orders can include: exposure mitigation, testing, labelling and hazard communication and record keeping. EPA frequently relies on Section 5e Consent orders as they are more efficient legally and administratively and allow more flexibility for the Agency and manufacturer/importer.
- Section 5f order limiting the substance if substance presents or will present an unreasonable risk.

EPA can also propose a Significant New Use Rule (SNUR) where there is an indication that production volumes will increase significantly or uses will change. To make a significant new use determination the Agency must consider the following factors (though a risk finding is not required): the projected manufacturing and processing volume, the anticipated extent to which the use changes the type or form of exposure, the magnitude and duration of exposure, and the manner and methods of manufacture, processing, distribution in commerce, and disposal

As a Section 5e order is only binding on original PMN submitter, a SNUR mimics the consent order and extends it to other companies that want to manufacture or import. SNURs can also be applied when there is concern for increased production (and need for additional testing/information as production volumes increase) or new uses of chemicals once they reach the market that may present an unreasonable risk (new uses of existing chemicals accounts for a significant portion of chemical use today). SNURs can also be applied for existing chemicals when production is discontinued (for example the Penta Brominated Diphenyl Ether or PFOS[207]) or particular uses are discontinued. Any company that wants to manufacture or import a chemical subject to a SNUR must submit a Significant New Use Notification to EPA 90 days prior to manufacture, with a review process similar to new chemicals.

Regulatory (And Voluntary Testing) Actions on PMNs through September 30, 2002 – Total PMNs – 36,000 With about ½ going on to TSCA Inventory

Regulatory Action	Number
§5(e) Consent Orders without SNURs	743
§5(e) Consent Orders with SNURs	500
Non-§5(e) SNURs	437
§5(f) Actions	4

[207] Following 3M's removal of PFOS from the market, in March 2002, EPA issued a SNUR on 13 known or discontinued PFOS chemicals, extending this to 75 additional chemicals and excluding from the definition of "significant new use" specifically defined controlled exposure uses in semiconductor manufacture, aviation hydraulics, and photography.

PMNs withdrawn often in face of action	1,552
Approximate Voluntary Testing Actions	300
TOTAL ACTIONS	3,536

Section 6

Section 6: Authorizes the EPA to issue regulations to address the risks of existing substances if "there is a reasonable basis to conclude that . . . a chemical substance or mixture . . . *presents or will present an unreasonable risk of injury to health or the environment* [emphasis added]. . . using the least burdensome requirements" that are necessary to address that risk. Such regulations can be issued immediately under Section 7 when a threat of harm is imminent. EPA actions under Section 6 can include the following (with burdens higher for stricter actions):

(a)(1) To prohibit (or limit) the manufacture, processing, or distribution in commerce of a substance/mixture;

(a)(2) To prohibit (or limit) the manufacture, processing, or distribution in commerce of substance/mixture for a particular use or for a particular use at a particular concentration;

(a)(3) To require a substance/mixture, or any article containing the substance/mixture, to be labelled or accompanied by warnings and instructions for use, distribution, or disposal;

(a)(4) To require manufacturers and processors of a substance/mixture to keep records of manufacturing/processing methods and conduct reasonable monitoring or testing necessary to assure regulatory compliance;

(a)(5) To prohibit or otherwise regulate commercial use of a substance/mixture;

(a)(6) To prohibit or otherwise regulate disposal of a substance/mixture, or any article containing the substance/mixture, by manufacturers, processors, or anyone who uses it, or disposes of it, for commercial purposes; or

(a)(7) To require manufacturers or processors to notify distributors, other persons in possession of the substance/mixture, and the general public of the risk of injury and replace or repurchase the substance/mixture.

EPA is required to evaluate a number of factors in making a Section 6 unreasonable risk finding, including health and environmental effects, exposure, the benefits of the substance/mixture, the availability of substitutes, and the economic effects of a rule. EPA can also undertake voluntary consent orders to achieve Section 6 actions, as was the case with Penta and Octa Brominated Diphenyl Ethers.

A listing of Section 6 actions taken by EPA is below[208]:

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

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

[208] U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics, "Overview: Office of Pollution Prevention and Toxics Programs," (December 24, 2003).

Section 8

Section 8 of TSCA involves recordkeeping and data generation. Section 8a gives broad authority for EPA to require, through rulemaking, that manufacturers and processors of chemicals (excluding small manufacturers) maintain records and report data to EPA including: chemical identity, use categories, health and environmental information, by products and people exposed. Such information is often used to inform ITC decisions or decisions to issue test or restriction rules under TSCA.

Such rules are also used to update the TSCA Inventory. In particular the Inventory Update Rule requires manufacturers or importers of non-polymeric chemicals over 25,000 lbs on the TSCA inventory at a single site every five years to report site specific current data on production, use (only domestic use and processing), certain data about manufacture, exposure, etc.[209] Additional information on domestic processing and use is required for chemicals manufactured in amounts of 300,000 pounds or more at a single site.[210] These data are used in EPA risk assessment and prioritization activities. The reporting requirements will be expanded to reporting of inorganic chemical substances with a site-specific production volume of 300,000 pounds or greater.

Section 8(e) of TSCA requires that firms notify EPA of new unpublished or published information that supports a conclusion of significant risk. It states that "any person who manufactures, processes or distributes in commerce a chemical substance or mixture in the U.S. and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall inform the EPA Administrator of such information, unless that person has actual knowledge that the Administrator has been adequately informed of such information."

Significant risk can include both exposure or hazard information on a particular chemical. Information that must be submitted include epidemiological or clinical studies, studies of occupational exposure, health effects studies, ecological effects studies, environmental fate studies, and both emergency and non-emergency reports of environmental contamination. Finally, under TSCA Section 8(d), EPA can issue rules to require that manufacturers or importers or processors submit lists of and unpublished or completed health studies. Finally, under Section 8(c) EPA can require companies to record, retain, and report allegations of

[209] The types of chemicals, the amounts manufactured or imported, certain details about their manufacture, and other data number of workers reasonably likely to be exposed to the chemical substance at the site of manufacture or import; the physical form(s) of the substance as it leaves the submitter's possession; the percentage of the total production volume associated with each physical form; and the maximum concentration of the chemical substance at the time it is reacted onsite to produce a different chemical substance or as it leaves the site where it is manufactured or imported.

[210] The type of processing or use operation; The NAICS codes that best describe the industrial activities associated with the processing or use; The industrial functions of the chemical substance during the processing or use operation; The percent production volume, number of sites, and number of workers associated with each processing or use/NAICS/industrial function combination; The commercial and consumer uses; The indication of the presence of the substance in consumer products intended for use by children; The percent of production volume associated with each commercial or consumer use; and The maximum concentration associated with each commercial or consumer use.

significant adverse reactions (for example by workers or consumers) without formal proof or causal evidence.

Section 9

Section 9 requires the EPA to formally refer regulation of an unreasonable risk to other agencies if that risk "may be prevented or reduced to a sufficient extent under a federal law not administered by the Administrator." These "referral agencies" include the Occupational Safety and Health Administration and the Consumer Product Safety Commission. If that agency determines that activity does not present a risk or initiates regulatory actions on their own within 90 days then EPA is prohibited from regulating that substance. This generally means that EPA actions on chemicals in consumer products are often referred to the Consumer Product Safety Commission and the laws it implements. EPA actions on chemicals that pose workplace risks are often referred to the Occupational Safety and Health Administration.

Section 26

Section 26 of TSCA allows EPA to extend any action taken with respect to a chemical substance or mixture to an entire category without undertaking rule-making. Categories are under TSCA defined as "a group of chemical substances the members of which are similar in molecular structure, in physical, chemical or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act." For new chemicals, more than 45 categories currently exist, with EPA providing guidance on the type of risk concerns and testing desired for each categories in its new chemicals review process.

Voluntary Programs under the auspices of TSCA and the EPA Office of Pollution Prevention and Toxics

Given the burdens associated with many of the TSCA requirements (discussed in the next section), the U.S. EPA Office of Pollution Prevention and Toxics has undertaken numerous voluntary chemical assessment and management initiatives. These fall into two broad categories – (1) programs on enhanced chemical testing, assessment, and characterization; and (2) programs on safer product design:

1. Programs on enhanced chemical testing, assessment, and characterization

In 1998, following studies on the lack of data on high production volume (HPV) chemicals, those used over one million pounds per year, EPA initiated its Chemical Right to Know Initiative. This program started with the High Production Volume Chemicals Challenge Program and the Voluntary Children's Chemical Evaluation Program. However, more recently as a result of obligations resulting from the U.S.-Canada-Mexico Security and Prosperity Partnership, the EPA has initiated the Chemicals Assessment and Management Program (CHAMP) to obtain data on mid-production volume chemicals.

Voluntary Children's Chemical Evaluation Program (VCCEP): In 1998, the EPA asked producers of some 23 chemicals that have been documented in human tissues to voluntarily evaluate their products with regards to their risks to children's health. In 1999, 35 companies and consortia agreed to test 20 of these chemicals. EPA later redrafted the project as a pilot program in response to stakeholder concerns of excessive animal testing. As part of the voluntary testing, manufacturers are asked to write a "Data Needs Assessment" to communicate to EPA what, if any, information should be collected during the next phase of the program (there are three tiers of testing in the project corresponding to increasingly detailed tests). Information is then evaluated by a Peer Consultation Group of experts in toxicology and in evaluating exposure. EPA then determines whether an additional round (a higher tier) of voluntary testing in necessary. EPA issued Data Needs Decisions for seven chemicals — n-dodecane, undecane, decane, benzene, m-xylene, o-xylene, and toluene — identifying whether additional hazard and/or exposure information were needed to adequately assess the potential risks to children and prospective parents. Sponsors of five chemicals have agreed to provide additional information to address uncertainties and one chemical (deca-BDE) was dropped as Tier 2 data were not provided. EPA is considering modifications to the program to enhance its effectiveness.

High Production Volume Challenge (HPV): In 1998, the EPA entered into a voluntary "challenge" with the American Chemistry Council and the environmental advocacy group Environmental Defense for industry to provide basic screening level data on some 2800 chemicals manufactured or imported in quantities over 1 million lbs per year. The HPV program allows companies the flexibility to test chemical categories based on the characteristics of a given substance as opposed to individual tests. To date, industry consortia have "adopted" about 2200 chemicals (which amounts to approximately 99% by tonnage of the HPV chemicals) and produced summaries of toxicity data. However, there are about 500 "orphan" chemicals (though it is unclear how many are still in manufacture) which have not been adopted by industry consortia and the program does not address chemicals that have achieved HPV status since 1998. EPA has only begun to issue rules for data on the remaining HPV chemicals. The EPA review process for HPV chemical submissions includes 3 steps: (1) Tier I – EPA used a computerized sorting process to prioritize the HPV chemicals into first, second, and third priority groups for further review; (2) EPA evaluates the quality and completeness of the data set contained in each HPV Challenge Program submission, identifies any data gaps, and characterizes the potential hazards of HPV chemicals. The key output of Tier II is a screening-level hazard characterization for each chemical or chemical category, and about 100 of these have been completed; (3) In March of 2008 EPA published a first collection of documents on chemical risk-based prioritization for HPV chemicals and approximately 150 have been completed so far. The documents are based on the Tier II hazard reports and use information gathered through the HPV program and the Inventory Update Rule and will inform future prioritization decisions. Where appropriate, EPA can then initiate further voluntary or regulatory options for chemicals indicating a need for elevated concern. Findings from these reviews can be found on the EPA HPV website - www.epa.gov/hpv.

Chemicals Assessment and Management Program (ChAMP): ChAMP encompasses a commitment made by President Bush, Canadian Prime Minister Stephen Harper and Mexican President Felip Calderon at the August 2007 Security Prosperity Partnership Summit that committed the three countries to work together to accelerate and strengthen the management of

chemicals in North America. Each country is sharing scientific information and approaches to chemical testing and risk management.

This commitment includes enhanced regulatory cooperation between the U.S. and Canada on high and moderate production volume chemicals, the establishment of a Mexican chemical inventory, coordinated Research & Development on new approaches to testing and assessment, and the development of mechanisms to share scientific information and best practices.

Under ChAMP (www.epa.gov/champ), by 2012, the U.S. will complete screening-level hazard and risk characterizations and initiate action, as needed, on 6,750 high and moderate production volume chemicals manufactured or imported in the U.S. each year. The EPA will build on and apply the results of EPA's work on the High-Production Volume (HPV) chemicals (produced or imported in the U.S. in quantities of 1 million pounds or more per year), the information gathered in the 2006 Inventory Update Reporting Rule, or IUR, as well as Canada's categorization work. These efforts will be extended to Moderate Production Volume (MPV) chemicals (produced or imported in the U.S. in quantities above 25,000 and less than 1 million pounds per year).

For the more than 2,200 HPV chemicals that were part of the HPV Challenge Program, the Agency began, in 2007, to develop and post interim screening-level hazard characterizations. In 2008, EPA updated these and combined them with use and exposure data under the 2006 IUR Rule to develop and post Risk-Based Prioritizations (RBPs) (www.epa.gov/hpv). The RBPs summarize basic hazard and exposure information, detail the preliminary evaluation of potential risks and identify additional data or testing that may be needed to better characterize the chemical. This process enables the EPA to make judgments as to whether control measures should be pursued to address potential exposure risks or whether the chemical is a low priority for further action.

Through this process, EPA is making judgments on whether a chemical presents either a high, medium or low priority and what further action it requires. If it is concluded that a chemical is a priority for action, and that additional information is needed to clarify EPA's assessment, or if regulatory control action may be needed, there are several steps the agency can initiate under TSCA. They can informally request additional information from manufacturers or importers. They can also issue reporting rules under Section 8 of TSCA, Significant New Use Rules and/or test rules. They can also pursue product stewardship approaches or Challenge programs, as well as initiate efforts to identify and consider safer substitutes under the Design for the Environment program.

Action on high and medium priority cases will be taken, especially on cases where particularly serious issues are identified: high priority special concern cases. Additional exposure and use information will be sought for these cases to clarify or resolve the risk issues identified in the RBP. Once this has been received, further action will be determined. For cases identified as high priority but not "special concern," follow-up action will be initiated by 2012. Most medium priority cases will be dealt with after 2012.

For the almost 4,000 moderate volume chemicals, or MPVs, hazard based prioritizations, or HBPs will be developed. There is no HPV Challenge data or IUR use and exposure information for most of the MPV chemicals, so the approach relies on existing available test data, structure activity relationship (SAR) analyses, and the results of the Canadian categorization work, when available, to prepare the HBPs, which also will identify next steps, where needed. Next steps will focus on gaining additional exposure information to provide a risk context. In most cases, follow-up action will be deferred until after 2012 unless prompt action is needed.

In Sept 2008, it was announced that as part of ChAMP, the TSCA Inventory of industrial chemicals will be reset. At present there are more than 83,000 chemicals on the inventory, and a great many of these are no longer being produced or imported so an update will reflect only those chemical substances currently manufactured or imported in the U.S., as called for under TSCA section 8(b). Chemicals would be removed that are no longer being manufactured or imported. Companies will be invited to certify they have manufactured or imported specific chemicals. Chemicals that remain on the reset TSCA inventory would maintain their current status. A new chemical notice would only be needed if a company decided, at a later date, to produce a chemical no longer on the reset inventory. Periodic resets in the future would continue to keep the Inventory current.

It was also announced in September 2008, that as part of ChAMP, a phased Inorganic HPV Challenge approach will proceed, allowing EPA to obtain, review and evaluate hazard and use information on the HPV inorganic chemicals. An initial "development" phase will allow EPA to take full advantage of the work completed or underway by the OECD, Canada's categorization efforts, and future REACH work. The implementation phase will likely include sponsorship opportunities but a vigorous use of test rules will be pursued in the absence of this to ensure submission of quality data sets.

Following a 2-3 year data development period, after 2012, a ChAMP-type prioritization assessment of the inorganic HPV chemicals will begin. This assessment would apply the IUR exposure / use reporting on inorganics which will be received in 2011. Preparation of prioritization assessments on Moderate Production Volume inorganic chemicals would follow, informing decisions on any needed next steps for these chemicals.

2. Programs on Safer Product Design

EPA has initiated several programs designed to ensure that safer chemicals come to market and that safer alternatives are available to chemicals identified as higher concern. These programs include:

Sustainable Futures Initiative: The Sustainable Futures Initiative is a voluntary pilot project initiated in 2002, the goal of which is to make new chemicals safer, available faster, and at lower cost. It works by giving chemical developers the same risk-screening and safer chemical design models that EPA uses to evaluate new chemicals before they enter the market. Sustainable Futures promotes pollution prevention in chemical design and processing. Employees of participating firms must undergo training sessions to ensure their comprehension of the project, and the firm must show that principles of pollution prevention influence decision-making, in

addition to providing examples of PMN notices that successfully used screening tools to assess chemical hazards and worker exposure. Participating businesses are rewarded for these efforts with expedited reviews of future PMNs, or some flexibility in the form which the PMN can be submitted.

Pollution Prevention Partnerships: The *Pollution Prevention Act* of 1990 elevated pollution prevention as the fundamental goal of the environmental protection efforts in the U.S. While the Act did not prescribe any particular agency actions, it has led to the establishment of a number of EPA voluntary research and outreach efforts. Pollution prevention represents an important and indirect route to chemicals management — production process redesign and product design change can result in a substantial reduction or substitution of problem materials. EPA's efforts on pollution prevention have ranged from voluntary sector or use based initiatives to examine alternatives to problem substances or process changes to reduce waste or emissions, to procurement guidelines, to product labelling initiatives, to design challenges.

Design for Environment: The Design for Environment (DfE) program is a series of partnerships with industry to prevent chemical exposures through educated business decisions. As an overall program, DfE identifies a range of technologies, products, and processes that can be used to prevent pollution; evaluate and compare hazards, performance, and cost tradeoffs of the alternatives; encourage and enable use of subsequent information by providing mechanisms and incentives to institutionalize continuous environmental improvement; and distribute this information to the industrial community. Three initiatives of particular note are the Furniture Flame Retardant Partnership, designed to identify safer alternatives to Penta-BDE; the Printed Circuit Board Partnership, designed to identify safer alternatives to Tetrabromobisphenol-A; and the Formulators Project, designed to support formulators to reformulate products to be environmentally safer, cost-competitive, and effective (focused to date on surfactants, solvents and in the future fragrances). The Safer Detergents Stewardship Initiative is a voluntary program to recognize companies that voluntarily switch to safer surfactants (those that break down quickly to non-polluting compounds and help protect aquatic life in both fresh and salt water), in particular nonylphenol ethoxylates.

Green Chemistry: Green Chemistry is the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. Green Chemistry applies across the life cycle, including the design, manufacture, and use of a chemical product. The EPA has undertaken a range of Green Chemistry initiatives: (1) The Presidential Green Chemistry Challenge. The Challenge offers individuals, groups or organizations rewards for innovations that help benefit human or environmental health. Grants and awards are given jointly through an EPA/National Science Foundation partnership. (2) Educational materials. EPA and American Chemical Society have partnered in efforts to ensure that green chemistry innovations are being incorporated into students' education of chemistry. (3) The Synthetic Methodology Assessment for Reduction Techniques program (SMART). The Program is used by the Office of Pollution Prevention and Toxic Substances (OPPTS) to review manufacturing methods in new chemical submissions and is designed to complement the New Chemicals Program. Based on the review, EPA may suggest methods for pollution prevention that invoke the principles of Green Chemistry. (4) The Green Chemistry Institute. A partnership between the American Chemical Society (ACS) and EPA precipitated the Institute, a non-profit entity that promotes

environmentally friendly chemistry by means of research, education, and communication and conveyance of information to government, advocacy, educational and corporate institutions.

Critiques of TSCA and Other Voluntary Programs

Below we provide additional details on specific critiques of TSCA and its Implementation through various programs.

1) Unequal Treatment of "New" and "Existing" Chemicals: For Existing Chemicals, those on the TSCA inventory, there are no automatic testing or review requirements. These substances are subject to significant risk notification requirements under TSCA Section 8(e) and various data provision requirements under Section 8(a), such as the Inventory Update Rule. They can also be subjected to Significant New Use Rules which would require pre-manufacture notification if a particular substance or use ceases.

However, to restrict an existing chemical in commerce, EPA must demonstrate an unreasonable risk – which includes strong toxicological evidence as well as showing that the benefits of regulation outweigh the risks of not regulating and that the least burdensome means to reduce risk was chosen. While this burden is reduced for restrictions that do not involve bans, it is a high administrative hurdle. Given this burden, as well as an appeals court decision from 1990, EPA has not committed the resources to apply these regulatory authorities under TSCA. Instead, the Agency has engaged in voluntary commitments with industries, when possible and has used other tools such as test rules and Significant New Use Rules.

Example: Asbestos and the limits of TSCA.

The EPA's experience in attempting to regulate asbestos in 1990, demonstrates the near impossibility for EPA to restrict chemicals in commerce through regulatory means. Following ten years of research, public meetings, and regulatory impact analyses in 1989, the EPA issued a final rule under Section 6 of TSCA to prohibit the future manufacture, importation, processing and distribution of asbestos in almost all products. The asbestos industry challenged the EPA's ban and took its appeal to the Fifth Circuit Court of Appeals. In a landmark case (*Corrosion Proof Fittings v. EPA)*, the court held that the EPA had presented insufficient evidence (including risk information) to justify its asbestos ban. The court found that: (1) the agency had not used the least burdensome regulation to achieve its goal of minimizing risk, (2) had not demonstrated a reasonable basis for the regulatory action, and (3) had not adequately balanced the benefits of the restriction against the costs to industry. In its conclusions the court held that "the EPA's regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA" and that "EPA, in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA equation." Such a sharp reprimand from the court has placed a chill on efforts by the EPA to use its Section 6 authority to restrict chemical production or use.

For new chemicals, EPA has significant influence and ability to control chemicals before they come to market through the New Chemicals Program. The new chemicals provisions of TSCA apply at the pre-manufacture stage (before any marketing has occurred) and place a low initial threshold for agency action: "may present an unreasonable risk to human health or the environment or substantial exposure throughout their production, use, and disposal." In conducting the pre-manufacture reviews, the EPA uses a multidisciplinary lifecycle review approach involving long-standing agency scientists to rapidly assess the risks associated with new chemicals. Through deterrence from potentially harmful chemicals and guidance toward safer chemicals and production methods, the EPA is able to provide strong signals to manufacturers as to types of chemicals that might present an unreasonable risk and types of chemicals and synthesis pathways that will reduce risks. These mechanisms include:

- *Categories of chemicals*. The EPA has used its "Chemical Categories" list to indicate the types of chemicals and risks that are of concern to the agency and the types of data the agency needs to evaluate those risks. As a result, companies are more likely to present data to avoid the possibility of regulatory orders or to avoid certain chemicals of concern (i.e, the EPA has issued guidance providing strong signals to avoid bringing persistent, bioaccumlative, and toxic substances to market).
- *Informal communication and negotiation with submitters*. The EPA regularly discusses concerns with pre-manufacture notification submitters. If EPA staff express concern, submitters are not likely to question those concerns because they generally do not have the data to refute them. They either withdraw the chemical or come up with the data (a large percentage of pre-manufacture notifications are withdrawn and many chemicals never go to market or come to market with changes in design and use). Further, EPA informally advises submitters to modify production process or substances to minimize risks, placing the burden on industry to make such changes.
- *Pollution prevention initiatives.* EPA has initiated voluntary programs to encourage the development of safer chemical products and production systems, including providing software to firms to understand chemical risks and safer syntheses. These help to internalize considerations of safety at the earliest points of the research and design phase of chemicals.

Despite these successes, there are some particular limits of the program, including the short time period for EPA review (90 days, extendable to 180) which places EPA on a treadmill with thousands of pre-manufacture notifications to review each year and allows manufacturers to commence manufacture if EPA has not responded in the 90 day timeframe; the fact that there is no minimum set of pre-manufacture data requirements; and that there are rarely tiered data/follow-up requirements once chemicals actually become marketed (when they are subject to the higher burdens under TSCA section 6), which could lead to repeating the current problems of existing chemicals.

Once a new chemical is on the market (on the TSCA inventory), unless there is some restriction on use, the chemical may be used by any company for any use, since production and use information is not binding on the PMN submitter or future manufacturers. The burden to act ("will present an unreasonable risk" for limitations or "may present an unreasonable risk" for a testing rule) is completely on EPA. EPA can continue vigilance over new chemicals once they

enter the market with the lower threshold for action through a Significant New Use Rule. While the term Significant New Use is broadly defined, the burden is on EPA to imagine, at the pre-manufacturing stage, any significant new uses or exposures and whether they have the potential to pose an unreasonable risk. This can be extremely difficult in the face of missing information about production processes or market potential of the substance. The difficulty of issuing a SNUR is perhaps one of the greatest weaknesses in the New Chemicals Program, in that a chemical may end up being used in a way that results in much higher exposures than originally envisioned. SNURs have been developed for less than 5% of PMNs[211] [212]. As of 2002, about 900 SNURs had been issued. For existing chemicals, which make up the vast majority by volume of new uses of chemicals, SNURs are rarely used, meaning that there is little ability of EPA to track how chemical uses change over time or their subsequent risks.

Congress noted that, "as chemical substances frequently are not manufactured in large volumes for a large number of uses initially, the authority to require notification for these substances as uses mount or as volumes increase is extremely important.[213]" SNURs are a means to require toxicity testing at a more logical stage in the lifecycle of a chemical, when that substance has achieved economic viability.[214] They provide a "safety net by which we would be able to return to and reconsider the appropriateness of levels of use and types of exposure for a chemical about which we had reason to be concerned" but did not give rise to sufficient concerns for action.[215] The Government Accounting Office found that because of the uncertainties in EPA's toxicity and exposure assessments (due to limited data), as well as unforeseen changes in chemical use, unless EPA monitors new chemicals after they complete the pre-manufacture review process it will not achieve the Act's "objective of identifying and controlling unreasonable risks from new chemicals before they occur or become widespread."[216]

2) Limited Information on Chemicals in Commerce: TSCA requires industry to submit only limited data on chemical hazards and use. As such, studies from the 1990s found only limited amounts of basic toxicological data on the most widely used chemicals in commerce.[217] The

---

[211] GAO - United States General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective,* (Washington, DC: U.S. General Accounting Office, September 1994). GAO/RCED-94-103.

[212] Elizabeth Brown, Julia Hatcher, Carolyne Hathaway, William Rawson, and Robert Sussman, "A Practitioner's Guide to the *Toxic Substances Control Act*," in *TSCA Deskbook*, ed. Environmental Law Institute and Latham & Watkins, (Washington, DC: Environmental Law Institute, 1999), 7-81.

[213] United States Congress - Staff House Committee on Interstate and Foreign Commerce, 94th Congress 2nd Session. 1976, *Legislative History of the Toxic Substances Control Act*, (Washington, DC: Government Printing Office, December 1976).

[214] Conservation Foundation, *Significant New Use Rules (SNURs) for Existing Chemicals*, (Washington, DC: Conservation Foundation, 1983).

[215] Ellen Silbergeld, Testimony before the United States Senate Committee on Environment and Public Works - Subcommittee on Toxic Substances, Research, and Development, *Reauthorization of the Toxic Substances Control Act*, (May 17 and July 13, 1994a).

[216] GAO – U.S. General Accounting Office, *Assessment of New Chemical Regulation Under the Toxic Substances Control Act*, (Washington, DC: U.S. General Accounting Office, June 15, 1984). GAO/RCED-84-84.

[217] Environmental Defense Fund, *Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States*, (Washington, DC: Environmental Defense Fund, 1997); U.S.EPA - United States Environmental Protection Agency, *What Do We Really Know about the Safety of High Production Volume (HPV) Chemicals*, (Washington, DC: United States Environmental Protection Agency, Office of Pollution Prevention and Toxics, 1998).

HPV Challenge program found that a significant amount of unpublished data existed in industry files. Similarly, data on chemical uses and exposures along supply chains have been limited at best. While risk data have been developed as a result of Significant Risk Notifications under Section 8e of TSCA, these may not include the actual substance name or manufacturer identify. Further, under TSCA manufacturers are required to share only limited information on chemical toxicity and potential exposures along supply chains to product manufacturers, retailers, or the public. Only the Occupational Safety and Health Administration implemented Hazard Communication Standard, requires that MSDS sheets be prepared for chemical products and shared with workers. However, MSDSs are often incomplete and inadequate for proper decision-making about safer substances.

This lack of information extends to new chemicals. Since there are no test data requirements for the most part for new chemicals, historically only very small percentage (less than 50% and less than 10% for some end points) of pre-manufacture notifications contain actual test data. Toxicity data increase with chemicals in "chemical categories" where EPA provides indications of requested data. To build a dataset to analyze chemical risks in the face of missing data, EPA scientists have developed elaborate models and methods, which some critics believe have limitations. The main area of criticism is in the Agency's systematic reliance on Structure Activity Relationships to assess potential risk for new chemicals, unless further data are requested from manufacturers through Section 5e actions. Several validation exercises have demonstrated that for many ecotoxicity endpoints and many physical characteristics of chemicals, QSAR analysis is a reasonably accurate method for predicting chemical properties.[218] [219] However, estimates for some physical characteristics and human health endpoints have not proven as successful[220]. Some evidence exists to indicate that SAR analysis may under-predict risks some of the time.[221] In some cases, however, QSARs overestimate risks. It is clear that TSCA cannot serve its protective purposes if SAR does not accurately predict hazard.[222] Nonetheless, the SAR process is combined with the professional judgment of a multi-disciplinary group of agency scientists who have combined hundreds of years of experience in the agency. A concern is whether this "institutional memory" will be lost when these scientists retire in the coming 5-10 years.

---

[218] U.S.EPA – U.S. Environmental Protection Agency, *U.S. EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships*, (Washington DC: Office of Pollution Prevention and Toxics, United States Environmental Protection Agency, March 1994). 743-R-94-001.

[219] Maurice Zeeman, "Ecotoxicity Testing and Estimation Methods Developed Under Section 5 of the *Toxic Substances Control Act* (TSCA)," in *Fundamentals of Aquatic Toxicology*, ed. Gary Rand, (London: Taylor and Francis, 1995) 703-715.

[220] U.S.EPA – U.S. Environmental Protection Agency, *U.S. EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships*, (Washington DC: Office of Pollution Prevention and Toxics, United States Environmental Protection Agency, March 1994). 743-R-94-001.

[221] GAO - United States General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, (Washington, DC: U.S. General Accounting Office, September 1994). GAO/RCED-94-103.

[222] David Durenburger, Opening statement before the Subcommittee on Toxic Substances and Environmental Oversight of the Committee on Environment and Public Works, United States Senate, *Toxic Substances Control Act* Oversight, July 27, 29, and August 1, 1983.

EPA has attempted to fill toxicological data gaps for existing chemicals with large voluntary initiatives such as the High Production Volume (HPV) Challenge. The HPV challenge has resulted in a significant amount of data compiled from manufacturer files and some new data generated on chemicals and chemical categories. While significant additional data have been developed as a result of this program, numerous limitations have been identified, including: (1) slow speed of completing program elements. The EPA has taken years to complete hazard characterizations under the program and is only now beginning to complete risk characterizations and has delayed testing rules for "orphan" chemicals (of 270 orphan chemicals only 16 have been subjected to test rules after 5 years, though some may not be currently in use); (2) at least 30% of the hazard characterizations EPA has posted as of May 2008 had identified gaps in the datasets provided by sponsors, even though these are claimed to be final; (3) there are nearly 600 chemicals that have reached HPV status since the Challenge was launched but are not included in it. Despite industry assurances that these would be covered in an additional Extended HPV Program, only about 1/3 of them have been sponsored. As such there are hundreds of high production volume chemicals which still lack basic testing information.[223] Despite these gaps, EPA has moved forward with the Chemical Assessment and Management Program (CHAMP) to fill in data gaps for mid-production volume chemicals using structure activity relationship data and loose clustering of chemicals, reaching broad hazard conclusions without clearly identifying data gaps. A new Inorganic HPV program proposed under ChAMP may not make sense given the delays in the current HPV program.

EPA has attempted to fill in data on chemical use and exposure through its Inventory Update Rule requirements. However, there are significant gaps in this data, including extensive claims of confidential business information (see below) which inhibits any public use of the data as well the fact that reportable information elements are only required if they are "readily obtainable" by the manufacturers. Yet despite these limits EPA is using this data (to the exception of other contradictory exposure and use data) to develop risk characterizations for HPV chemicals, which has the potential to underestimate chemical risks.[224] While EPA may use conservative exposure scenarios in absence of exposure data, such scenarios may not fully capture possible exposures if data on use types is weak or non-existent. For example, where data are deemed not readily obtainable, those exposures may be ignored in the analysis; in other words, lack of data can possibly be equated with evidence of safety.[225]

EPA's ability to provide public information on chemical production and risk has also been hindered by strict confidential business information provisions of TSCA. Disclosure of CBI is generally prohibited except where necessary to protect human health. And such information cannot be shared outside the federal government (other than contractors). During the early history of TSCA, industry had to substantiate confidentiality claims; claiming confidential information now requires little more than a routine check-off procedure. A 1998 EPA analysis found that 65 percent of the information in industry filings to the agency under TSCA was

---

[223] See Richard Denison, *Environmental Defense Fund's Comments on ChAMP: EPA.s Recent Commitments and Possible New Initiatives for Existing Chemicals: Docket EPA-HQ-OPPT-2008-0319*, (May 2, 2008). Accessed at: www.edf.org/documents/7871_Comments_ChAMP_May08.pdf.

[224] Richard Denison, *Environmental Defense Fund's Comments on ChAMP: EPA.s Recent Commitments and Possible New Initiatives for Existing Chemicals: Docket EPA-HQ-OPPT-2008-0319*, (May 2, 2008). Accessed at: www.edf.org/documents/7871_Comments_ChAMP_May08.pdf.

[225] *Ibid.*

claimed as confidential.[226] About 40 percent of substantial risk notifications claim chemical identity as confidential. Further, EPA is not required to review CBI requests and must challenge each one individually. Such claims do not have expiration dates and while health and safety studies cannot be claimed as CBI, chemical and submitter identity generally can be.[227] EPA has the burden of demonstrating that such confidentiality claims are unfounded, a lengthy and expensive process.[228] [229] [230]

3) Slow and Cumbersome Chemical-by-Chemical Risk Assessment and Management Processes: EPA's ability to issue regulations for testing of chemicals is limited by the scientific and legal evidence the agency must amass before it can act. As a result of this burden, EPA has required testing on less than 250 existing chemicals and 1000 new chemicals. Despite a legislative history and TSCA Section 2b stating that a lack of data on chemical risks should trigger a requirement that industry provide that information, EPA and the courts have interpreted TSCA to require some evidence through actual test data or modeling that the substance (or surrogates) may present an unreasonable risk or substantial exposure before the agency can initiate testing orders under Section 4 or 5(e). In Chemical Manufacturers Association v. EPA (1988), the DC Circuit concluded that in establishing a test rule, the Agency must "find a more-than-theoretical basis for concluding that the substance is sufficiently toxic, and human exposure to it is sufficient in amount, to generate an unreasonable risk of injury to health." As of 2008, EPA had issued test rules for only a small percentage of the "orphan" HPV chemicals, likely due to the administrative challenges and costs of issuing them. Even though most PMNs have no actual test data, EPA does have an upper hand in informally requesting test data for new chemicals as the agency has the ability to "stop" the 90 day PMN clock. Nonetheless, the percentage of Section 5(e) rules and Significant New Use Rules is relatively small.

While data are increasing, particularly for existing chemicals, as a result of the HPV and CHAMP processes, the process of moving from test data to risk assessment to risk management action is still cumbersome, costly, and time consuming and only done on a chemical by chemical basis for the most part.

---

[226] L. Goldman, "Preventing Pollution? U.S. Toxic Chemicals and Pesticides Policies and Sustainable Development," *Environmental Law Reporter*, 32 (2002), 11018-11041.
[227] Richard Denison, *Not That Innocent: A Comparative Analysis of Canadian, European, and U.S. Policies on Industrial Chemicals*, (Washington, DC: Environmental Defense, 2007).
[228] Warren Muir, Testimony before the United States Senate Committee on Environment and Public Works - Subcommittee on Toxic Substances, Research, and Development. Reauthorization of the *Toxic Substances Control Act*, May 17 and July 13, 1994.
[229] GAO - United States General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, (Washington, DC: U.S. General Accounting Office, September 1994). GAO/RCED-94-103.
[230] Lynn Goldman, Testimony before the United States Senate Committee on Environment and Public Works - Subcommittee on Toxic Substances, Research, and Development. Reauthorization of the *Toxic Substances Control Act*, (July 13, 1994).

Appendix C: Consumer Product Safety Legislation and Its Implementation

The two main laws regulating consumer product safety are the *Consumer Product Safety Act* (CPSA) and the *Federal Hazardous Substances Act* (FHSA). Under the *Federal Hazardous Substances Act*, a hazardous substance is: "Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." This definition of a hazardous substance has been interpreted to include both acute and chronic toxicity.

Thus, for a toxic substance to be considered hazardous under the FHSA, it must not only be toxic but people must also be exposed to the substance, it must be bioavailable (can enter the body) and there must be a significant risk of an adverse health effect associated with the customary handling and use of the substance.

In general, companies make the determination as to whether their product contains a hazardous substance, though in some rare cases, the CPSC may issue a regulation defining a particular chemical or substance as hazardous. The CPSC has developed regulatory definitions of acute toxicity as well as voluntary, though interpretable, guidelines to assist companies in determining the hazards of substances in their products (so as to comply with FHSA) including carcinogenicity, neurotoxicity, reproductive/developmental toxicity, exposure, bioavailability, risk assessment, and acceptable risk. For example, in its guidance on lead in consumer products, the CPSC states: “In evaluating the potential hazard associated with products that contain lead, the Commission staff considers these major factors on a case-by-case basis: that the total amount of lead contained in a product, the bioavailability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product.”

As such, the law requires that evidence that a substance may cause substantial illness be demonstrated before it is labelled as hazardous, although there is little guidance as to what is meant by “substantial” (i.e. of medical or toxicological significance). This strict risk-based definition means that many toxic chemicals that are components of consumer products, but may leach out during normal use, would be unlikely to meet the standard of a hazardous substance due to a lack of information demonstrating a substantial risk. Thus, the mere presence of a hazardous chemical in a product and the potential for leaching would not be sufficient to meet this standard. Indeed for many substances, as noted previously, very little direct toxicological data exists, though it is unclear whether data based on SAR/QSAR would be sufficient to meet this standard. If data do not exist to document a risk, then under the law the substance is not considered hazardous.

These two laws authorize CPSC activities in the following areas:

Testing: There are no mandatory pre-market testing required for consumer products, rather the law requires manufacturers to ensure that their products are not hazardous or are properly labelled. CPSC may selectively test certain product types for restricted or prohibited substances such as lead on a periodic basis. Or it may request that EPA initiate testing on a particular chemical or undertake its own risk assessment activities (for example on phthalates).

Product Safety Standards: The CPSC has authority to promulgate mandatory federal safety standards for specific consumer products deemed to be unreasonably dangerous to the public. Most of the consumer product safety standards are set to avoid injury or acute hazards such as choking, burns, etc. There are less than 20 mandatory federal standards for toxic chemicals in toys and consumer products, the most notable being lead in paint.[231] Safety standards and regulations can range from outright bans to restrictions to voluntary actions, and from written guidance to consumer information and outreach. The 1981 amendments to the *Consumer Product Safety Act* require CPSC to defer to a voluntary standard—rather than issue a mandatory regulation—if CPSC determines that the voluntary standard adequately addresses the hazard in question and where there is likely to be considerable compliance with the voluntary standard.

Labelling: Whether or not a product must be labelled depends on its contents (if it contains a hazardous substance as defined above) and the likelihood that consumers will be exposed to any hazards it presents. To require labelling, a product must meet the definition of a hazardous substance: toxicity, exposure, and potential for harm. Manufacturers, distributors, and /or importers make determinations on if and how to label their products in accordance with FHSA requirements (which requires that hazardous substances in products be labelled). It is the company's responsibility to comply with these requirements. Companies are only required to list the hazardous ingredients in their products.

Recalls: The CPSC has authority to recall products either because they contain a defect, which makes them unsafe, or because they violate an existing consumer product safety rule. Voluntary recalls are the CPSC's preferred method of enforcement given the legal burdens of issuing mandatory recall regulations.

[231] See www.cpsc.gov/businfo/reg1.html or www.access.gpo.gov/nara/cfr/waisidx_04/16cfrv2_04.html for a list of products for which safety standards have been developed.

Appendix D: U.S. Case Studies on Policies and Programs Relevant to Great Lakes Chemicals of Concern

Case Study: Perfluorinated compounds (PFCs)

Perfluorinated compounds (PFCs) have been produced and used since the 1950s and are commonly used in numerous applications including stain- and water-repellent finishes to clothing, carpets and furniture, non-stick coatings for kitchenware, and cleaning products. They are persistent, bioaccumulative substances, many of which are toxic to humans and animals. Degradation products of PFC chemicals have been found in human and animal blood samples, water, and soil throughout the world. These breakdown products are highly persistent and resistant to degradation. PFCs can be released into the environment through the manufacturing, use, and disposal of the chemical.[232] Human exposures can also occur in each stage of the life cycle.

PFCs are a group of synthetic organic substances characterized by a carbon chain in which hydrogen atoms have been replaced with fluorine atoms. Carbon-fluorine bonds are exceptionally strong, creating compounds that are highly persistent and resistant to degradation. The properties that make PFC-based products effective in their numerous applications also result in their long-lived persistence in the environment.[233]

Two primary classes of PFCs are used to impart these properties, e.g. water resistance to textiles are perfluorooctane sulphonates (PFOS) and fluorotelomers. Fluorotelomers (also called fluortelomer alcohols, telomers or fluorpolymers) are commercial chemicals produced using a class of chemicals called perfluorinated carboxylic acids (PFCAs). Fluorotelomers also breakdown into PFCAs, including the chemical perflourooctanoic acid (PFOA).[234]

In the environment, PFCs are highly persistent, bioaccumulative and toxic. They have been found in remote locations such as the Canadian Arctic.[235] Results of a study released in 2004 detecting perfluorooctane surfactants in Great Lakes water showed concentrations of PFOS and PFOA in Lake Erie and Ontario ranging from 21-70 and 27-50ng/L respectively.[236]" A study released in 2007 measured concentrations of perfluorinated carboxylates (PFCAs) and perfluorinated sulfonates (PFSAs) in 4 year-old lake trout in all five Great Lakes. Data showed

---

[232] See for example, Department of Environmental Health, Boston University School of Public Health (under the direction of the International Joint Commission's Health Professionals Task Force), "Perflourinated Compounds (PFCs)," (Boston: Department of Environmental Health, Spring 2005). Accessed at: www.ijc.org/rel/pdf/health_effects_spring2005.pdf on Sept. 15, 2008.

[233] KemI (Swedish Chemicals Agency), "Perflourinated Substances and their Uses in Sweden," Report Nr 7/06, (Sweden: KemI, 2006).

[234] KemI, "Perfluronated Substances and their Uses in Sweden," Report NR 7/06, (Sweden: KemI, 2006).

[235] See for example, Government of Canada. "Perfluorinated Carboxylic Acids (PFCAs) and Their Precursors (Including Fluorotelomers)." Accessed at: www.chemicalsubstanceschimiques.gc.ca/interest-interet/pfca-acp_e.html on Sept. 17, 2008; and KemI (Swedish Chemicals Agency), "Perflourinated Substances and their Uses in Sweden," Report Nr 7/06, (Sweden: KemI, 2006).

[236] B. Boulanger, J. Vargo, J.L. Schnoor, K.C. Hornbuckle, "Detection of Perfluorooctane Surfactants in Great Lakes Water," *Environmental Science & Technology,* 38 no. 15 (2004), 4064-4070.

the major contributor to the sum concentrations of perfluorinated carboxylates (PFCAs) was from PFOA.[237] A recent study documented a decline in PFOS concentrations in human blood in the U.S. (from 2000 to 2006) which the researchers attribute in part to the decline of PFOS manufacturing and use[238].

PFCs have been found in human[239] and animal blood samples throughout the world. In tests on laboratory animals PFOA has been shown to cause cancer in rats and adverse effects on the immune system in mice. PFOA can also display reproductive or developmental toxicity in rodents at moderate levels of exposure, and moderate to high systemic toxicity in rodents and monkeys following long-term exposure.[240]

PFOA appears to remain in the human body for a long time.[241] In the mid to late 1990's, employees at U.S. manufacturing plants had measured blood levels of PFOA ranging from 0.1 to 81.3 ppm. Exposed workers had levels approximately ten times greater than those found in the general population.[242] Studies also point to the risk for heart attack and stroke from exposures to PFOA, including a study showing elevated cholesterol levels in workers exposed to the Teflon chemical.[243244] PFOS accumulates in the body and studies have shown PFOS to cause liver and developmental toxicity.[245] In 2006, the U.S. EPA's Science Advisory Board classified PFOA as a likely human carcinogen.[246]

---

[237]V.I. Furdui, N.L. Stock, D.A. Ellis, C.M. Butt, D.M. Whittle, P.W. Crozier, E.J. Reiner, D.C.G. Muir, and S.A. Mabury, "Spatial Distribution of Perfluoroalkyl Contaminants in Lake Trout from the Great Lakes," *Environmental Science & Technology*, 41 no. 5 (2007), 1554-1559.

[238] G. Olsen, et al., "Decline in Perfluorooctanesulfonate and Other Polyfluoroalkyl Chemicals in American Red Cross Adult Blood Donors, 2000−2006," *Environ. Sci. Technol.,* 42 no. 13 (2008), 4989–4995.

[239] See for example, Department of Environmental Health, Boston University School of Public Health (under the direction of the International Joint Commission's Health Professionals Task Force), "Perflourinated Compounds (PFCs)," (Boston: Department of Environmental Health, Spring 2005). Accessed at: www.ijc.org/rel/pdf/health_effects_spring2005.pdf on Sept. 15, 2008.

240 Government of Canada, "Perfluorinated Carboxylic Acids (PFCAs) and Their Precursors (Including Fluorotelomers)." Accessed at: www.chemicalsubstanceschimiques.gc.ca/interest-interet/pfca-acp_e.html on Sept. 17, 2008.

241 U.S. Environmental Protection Agency, "Basic Information on PFCs." Accessed at: www.epa.gov/opptintr/pfoa/pubs/pfoainfo.htm#concerns on Sept. 17, 2008.

242 Department of Environmental Health, Boston University School of Public Health (under the direction of the International Joint Commission's Health Professionals Task Force), "Perflourinated Compounds (PFCs)," (Boston: Department of Environmental Health, Spring 2005). Accessed at: www.ijc.org/rel/pdf/health_effects_spring2005.pdf on Sept. 15, 2008.

243 T. Kropp, and J. Houlihan, *Evaluating Human Health Risks from Exposure to Perfluorooctanoic Acid (PFOA): Recommendations to the Science Advisory Board's PFOA Review Panel*, (2005).

244 S. Fields, "Chemical Exposures: PFOA Alters Liver Gene Expression," *Environmental Health Perspectives*, 114 no. 8 (August 2006), A464.

245 European Food Safety Authority, "Perfluorooctane sulfonate (PFOS), Perfluorooctanoic Acid (PFOA) and Their Salts Scientific Opinion of the Panel on Contaminants in the Food Chain" (2008). Accessed at: www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902012410.htm, on Oct. 10, 2008.

246 U.S. Environmental Protection Agency, "SAB Review of EPA's Draft Risk Assessment of Potential Human Health Effects Associated with PFOA and Its Salts," (May 30, 2006). EPA-SAB-06-006. Accessed at: www.epa.gov/sab/pdf/sab_06_006.pdf on Sept. 17, 2008.

Canada, the U.S., and the EU have begun to take regulatory actions to address the hazards posed by PFCs. Concerns about PFOA in the United States began in 1999 with studies from 3M indicating the build up of the chemical in workers, communities around production plants and ultimately the entire U.S. This finding led the manufacturer to voluntarily phase out PFOA. Following this, in March 2002, EPA issued a SNUR concerning 13 known discontinued PFOS chemicals. The SNUR made any new manufacture or import of any of the 13 substances a significant new use extending this to 75 additional chemicals and excluding from the definition of "significant new use" specifically defined low volume, controlled exposure uses in: semiconductor manufacture, aviation hydraulics, and photography.[247]

For example, in 2006, the Canadian government proposed regulations to permanently ban four fluorotelomers from manufacturing, sale and importation. However these proposals do not expect to address imported products that may contain these chemicals.[248] Similarly, in the same year the government of Canada proposed and passed regulations to ban the sale, import and manufacture of PFOS compounds.[249] Unlike the proposed regulations on fluorotelomer based chemicals, the regulations on PFOS included ban on import products containing PFOS. The regulations, however, outlined a number of limited five year exemptions on specific uses of PFOS.[250] In 2006, the U.S. EPA initiated a voluntary PFOA Stewardship Program, in which the eight major companies in the industry committed voluntarily to reduce facility emissions and product content of PFOA and related chemicals on a global basis by 95 percent no later than 2010, and to work toward eliminating emissions and product content of these chemicals by 2015.[251] PFOS and its precursor PFOSF (perfluorooctanesulfonyl fluoride, the primary intermediate for synthesis of PFOS and PFOS-related substances) is under consideration for a global ban (with exemption for a number of critical uses) within the *Stockholm Convention on Persistent Organic Pollutants* (POPs).

DuPont's settlement in February 2005 of more than $100 million for its management of PFOA used in the production of Teflon® and grease resistant coatings for food packaging and carpets however, suggest that regulatory, not just voluntary steps may be needed. DuPont has also agreed to settle an EPA civil action for $16.5 million to address an EPA complaint that the company had failed to report adverse effects from PFOA "in a timely manner" and it is facing a related criminal investigation. A $5 billion class action lawsuit has been filed claiming that

[247] U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics. "Overview: Office of Pollution Prevention and Toxics Programs," (December 24, 2003).
[248] Government of Canada. *Toxic Substances Regulations, 2005 (Four NewFluorotelomer-based Substances)* C. Gaz. I, 140, no. 24 (June 17, 2006).
[249] Government of Canada. *Perfluorooctane Sulfonate and its Salts and Certain other Compound Regulations*, C. Gaz.II, 142, No. 12, Statutory Instruments 2008 Textes réglementaires 2008, SOR/2008-172 to 183 and SI/2008-59 to 62.
[250] *Ibid.*
[251] Government of Canada, "Order Adding Toxic Substances to Schedule 1 to the *Canadian Environmental Protection Act*, 1999," C. Gaz.I, 140 no. 24 (June 17, 2006). See canadagazette.gc.ca/partI/2006/20060617/html/regle1-e.html. Accessed Sept. 15, 2008; and U.S. Environmental Protection Agency, "2010/15 PFOA Stewardship Program," Accessed 10/11/2008 at: www.epa.gov/oppt/pfoa/pubs/pfoastewardship.htm.

DuPont failed to warn consumers of health risks associated with Teflon® cookware.[252] DuPont maintains that "Extensive scientific testing shows that our products including those that are branded Teflon® are safe for consumers."[253]

Exposures to PFOA and PFOS are the result of a mixture of facility based and product exposures. These substances are still widely used in products and it is expected that exposures will continue for some time. Regulatory action on these substances which do not break down in the environment has been slow. Some governments are beginning to take action to regulate PFCs, but these efforts are lagging behind the continued dispersion of these chemicals into the environment.

Case Study: Polybrominated diphenyl ethers

Polybrominated diphenyl ethers or PBDE started to be used commercially as flame retardants in 1960. They are organic compounds that are members of a broader class of brominated chemicals used as flame retardants; these are called brominated flame retardants, or BFRs. These chemicals are major components of commercial formulations often used as flame retardants in furniture foam (pentaBDE), plastics for TV cabinets, consumer electronics, wire insulation, back coatings for draperies and upholstery (decaBDE), and plastics for personal computers and small appliances (octaBDE).

The chemical structure of PBDE is simple. It is composed of two rings (phenyl rings) linked by an oxygen bridge (ether linkage). "Poly" means many. "Bromine" is a type of mineral (a halogen). There are up to ten locations where a bromine atom can attach to a carbon on the rings. If a PBDE has ten bromines, it's called a deca-BDE; five bromines is a penta-BDE.[254] The three major types of PBDE mixes are named for the predominant BDE: Penta; Octa; and Deca. When products containing PBDEs are exposed to a certain level of heat, the bromine atoms come off the rings and quench the fire.

The general public is exposed to PBDEs through the use of consumer products in homes, offices, cars and schools. Exposures to PBDEs in some occupational settings, e.g., in computer recycling facilities, can be much higher than those of the general public. As consumer products are used and after they are discarded, PBDEs are released into the environment where they can bioaccumulate in wildlife and food animals. PBDEs have been measured in house and office dust, indoor air, plant and animal-based foods, terrestrial and marine animals, and in human breast milk, blood and fat. The levels of PBDEs measured in humans in the United States and Canada are typically at least 10 times higher than those in Europe, and appear to be doubling every few years.[255] Specific to the Great Lakes region, a study released in 2005 dated sediment

[252] These developments are summarized in Sanford Lewis for DuPont Shareholders for Fair Value, "The Shareholder's Right to Know More: 2006 Update: Despite DuPont's Recent Concessions to EPA, Shareholder Value Remains at Risk from PFOA," (Stanford Lewis, 2006). Accessed at: www.ohiocitizen.org/campaigns/dupont_c8/marketreport.pdf.
[253] Dupont website, "Information on PFOA," (Dupont, 2008). See www2.dupont.com/PFOA/en_US/index.html.
[254] Suzanne Snedeker, "PBDEs – Polybrominated Diphenyl Ethers," (Cornell University Sprecher Institute for Comparative Cancer Research, February 2007). See envirocancer.cornell.edu/pbde/brief.pdf.
[255] California Dept of Toxic Substances Control website, "Emerging Chemicals of Concern." See www.dtsc.ca.gov/AssessingRisk/EmergingContaminants.cfm.

cores to see trends in PBDEs and PBBs (Polybrominated Biphenyls). The study showed higher concentrations in Lake Michigan than Lake Erie, and Lake Superior. The study also showed rapid increase in both PBDEs and PBBs in sediments, concurrent with market increase in demand for these flame retardants. The total burdens of these compounds in the sediment of Lakes Michigan and Erie were 110 and 10 metric tons, respectively. The estimated total burden of these compounds in all of the Great Lakes was approximately 200 tons.[256]

PBDEs have structural similarities to some of the polybrominated and polychlorinated biphenyls (PBBs and PCBs) and in the limited toxicity testing to date, they have produced some of the toxic effects and physiologic changes typical of the PBBs and PCBs. These effects include developmental and nervous system toxicity, as well as mimicry of estrogen and interference with the activity of thyroid hormone. Specific studies include: a single dose of PBDEs given to mice in early development causing effects on learning and memory, spontaneous motor behavior and habitutation capability that worsened with age;[257] a low dose of PBDEs given to mice in early development leading to changes in behaviour;[258] a single dose of PBDEs given to mice in early development significantly impairing spontaneous motor behaviour;[259] PBDEs as an endocrine disruptor during development;[260] and a single very low dose of PBDEs given to rats in early development causing decreased sperm count in adult offspring.[261]

In June 2006, the U.S. EPA promulgated a Significant New Use Rule (SNUR) in the Federal Register to require notification to EPA ninety days prior to U.S. manufacture or import, for any use, of the commercial products pentaBDE and octaBDE after January 1, 2005.[262] Thus before the chemical can be manufactured or imported for the significant new use, the company would be required to provide advance notification to EPA under Section 5 of TSCA. This action builds on the November 3, 2003, announcement by the Great Lakes Chemical Corporation, the only U.S. manufacturer of these chemicals, who agreed to voluntarily phase-out PentaBDE and OctaBDE production by December 31, 2004. In Europe, the European Union enacted a ban on PentaBDE and OctaBDE in all products which took effect on August 15, 2004. Scientists working for the United Nations Environment Program are reviewing nine chemicals that could be added to the original "dirty dozen" list of banned toxic chemicals: pentaBDE and octaBDE are

[256] L. Y. Zhu and R.A. Hites, "Brominated Flame Retardants in Sediment Cores from Lakes Michigan and Erie," *Environmental Science & Technology*, 39 (2005), 3488-3494; erratum 39 (2005), 5904.
[257] P. Eriksson, E. Jakobsson, A. Fredriksson, "Brominated Flame Retardants: A Novel Class of Developmental Neurotoxicants in our Environment?" *Environmental Health Perspectives*, 109 no. 9 (September 2001), 903-8.
[258] I. Branchi, E. Alleva, L.G. Costa, "Effects of Perinatal Exposure to a Polybrominated Diphenyl Ether (PBDE 99) on Mouse Neurobehavioural Development," *Neurotoxicology*, 23 no. 3 (Sepetmber 2002), 375-384.
[259] P. Eriksson, H. Viberg, E. Jakobsson, U. Orn, A.A. Fredriksson, "Brominated Flame Retardant, 2,2',4,4',5-Pentabromodiphenyl Ether: Uptake, Retention, and Induction of Neurobehavioral Alterations in Mice During a Critical Phase of Neonatal Brain Development," *Toxicological Sciences*. 67 no. 1 (May 2002), 98-103.
[260] T. Zhou, M.M. Taylor, M.J. DeVito, K.M. Crofton, "Developmental Exposure to Brominated Diphenyl Ethers Results in Thyroid Hormone Disruption," *Toxicological Sciences*, 66 no. 1 (March 2002), 105-16.
[261] S. Kuriyama, and I. Chahoud, "Maternal Exposure to Low Dose 2,2'4,4',5 Pentabromo Diphenyl Ether (PBDE 99) Impairs Male Reproductive Performance in Adult Male Offspring," *Organohologen Compounds*, 61 (2003), 92-95.
[262] U.S. Environmental Protection Agency website, "Polybrominated diphenylethers (PBDEs)" See www.epa.gov/oppt/pbde/.

two of these.[263] A PBDE regulation was finalized in Canada on July 9th, 2008. As originally proposed, the final regulation bans the manufacture of all PBDEs and the import and use of tetra- through hexaBDE (ingredients in the discontinued Penta and Octa commercial mixtures) but fails to ban heptaBDE through to decaBDE and thus the DecaBDE commercial mixture.[264]

The U.S. EPA's Design for Environment Program hosts a Furniture Flame Retardancy Partnership helping industry factor environmental and human health considerations into their decision-making as they choose chemical flame retardants for fire safe furniture foam. This broad, multi-stakeholder partnership was formed as the result of concerns about the worldwide occurrence of pentaBDE in the environment and human tissues and works to develop and disseminate information on alternative technologies for achieving furniture fire safety standards.

At the state level, eleven states (California, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, New York, Oregon, Rhode Island, and Washington) have enacted and eleven states (Alaska, California, Connecticut, Hawaii, Illinois, Maryland, Michigan, Minnesota, Montana, New York, and Vermont) have proposed legislation prohibiting the use of PBDEs. Of the states that have enacted legislation, two (Maine and Washington) restrict pentaBDE, octaBDE, and decaBDE, four (Illinois, Maryland, Minnesota, and Rhode Island) restrict pentaBDE and octaBDE and require further study of decaBDE, and five (California, Hawaii, Michigan, New York, and Oregon) restrict pentaBDE and octaBDE. Of the states that have proposed legislation, three states (Alaska, Montana and Vermont) have proposed bills restricting pentaBDE, octaBDE, and decaBDE, seven states (California, Hawaii, Illinois, Maryland, Michigan, Minnesota, and New York) have proposed bills to restrict decaBDE, and one state (Connecticut) has proposed a bill restricting certain PBDEs.

Many issues and challenges remain: landfill disposal and release of PBDEs into the air and wastewater are major, unresolved issues; electronic equipment recycling plants are sources of PBDE release; and levels of PBDEs in people and wildlife need to be monitored to characterize trends over time. The potential of these substances to do harm, even if based on limited evidence, combined with documentation of their presence in breast milk and cord blood should be sufficient to trigger a search for alternative ways to obtain the flame retarding properties of these chemicals. And, if safer alternative ways of providing the same flame retarding function can be found, then the substitution should not have to wait for quantitative evidence showing that the estimated risk of potential health outcome exceeds an "acceptable" risk threshold.[265]

A critical lesson from the case of PBDEs is to think beyond chemical by chemical substitution and examine the functionality that one is trying to achieve, its need, and how that functionality can be achieved through safer chemistries or material designs. Further, given the transition from

---

[263] The Daily Green website,"Adding the 'Nasty Nine' to the 'Dirty Dozen. The United Nations Considers Expanding Toxic Chemical Ban by 75%," (October 14, 2008). See www.thedailygreen.com/environmental-news/latest/toxic-chemicals-47101403.

[264] Canadian Environmental Law Association website, "Groups Call for Ban on All PBDEs." See www.cela.ca/newsevents/detail.shtml?x=3950.

[265] J. Tickner, and D. Kriebel, "The Role of Science and Precaution in Environmental and Public Health Policy," in *The Precautionary Principle and Public Policy Decision-making: A Prospective Analysis of the Role of the Precautionary Principle for Emerging Scientific and Technological Fields in Different Regions of the World*, ed. Fisher, Jones and von Schomberg, (London: Edward Elgar, 2006).

PBDEs to other brominated flame retardants that are being identified as chemicals of concern by some government bodies and in the scientific literature (tetrabromobisphenol-a – TPPBA and hexachlorobromo dodecane – HCBD) and that exhibit persistence, it is critical to take a broad approach to substitution to ensure that one problem is not substituted with another. Further, despite their benefits in flame retardancy, one approach may be a class based approach to avoid all chlorinated and brominated flame retardants given their propensity to be persistent, bioaccumulative and toxic (an approach to reduction of persistent and bioaccumulative chemicals recommended by the IJC in the past) when safer, functional alternatives have been identified. This is the approach being taken by some major corporations such as Dell and Apple.

Case Study: Triclosan

Triclosan is an antimicrobial pesticide traditionally only used in hospital settings. Today its more than 40 formulations have been approved for use in 140 kinds of consumer products, mainly in hand soaps and dish detergents. Triclosan falls under the regulatory direction of the *Federal Insecticide, Fungicide, and Rodenticide Act* which requires evidence of its antimicrobial properties, and the *Food Drug and Cosmetics Act* which oversees its antimicrobial use in over-the-counter applications such as toothpaste.[266] Further, FDA regulates antimicrobial products, such as triclosan, differently depending on its use in a consumer product. If it kills germs for health purposes (gingivitis, for example) it is regulated as a pharmaceutical, if it is intended for cosmetic purposes, (deodorant, for example) it is regulated as a cosmetic, while if it is not intended for the human body, rather for use in a household cleaner, it is regulated as a pesticide by EPA.[267] However the prevalence of triclosan in the environment and in the human body provides evidence that question the efficacy of current regulatory protections: 97 percent of women tested found triclosan in their breast milk; 75 percent of Americans over age 6 tested found triclosan in their urine; and 58 percent of rivers and streams tested have shown the presence of triclosan.[268]

Triclosan is increasingly being added to consumer products, often without consumer knowledge. One such consumer product is toothpaste, to which the American Dental Association has stated: "The use of antimicrobial agents such as triclosan in consumer products has not been studied extensively. No data exist to support their efficacy when used in such products or any need for them…it may be prudent to avoid use of antimicrobial products in consumer products."[269] The widespread-presence of triclosan has led some to worry that its constant use could lead to microbial resistance, and worse still, that antimicrobials may not protect us from bacteria and viruses any better than plain soap and water.[270]

---

[266] Ann Blake, "Antimicrobials in Wastewater: Triclosan and Quats," (Presented to National NAHMMA, October 15, 2008).
[267] Aviva Galaser, "The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed," *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.
[268] Environmental Working Group website, "Pesticide in Soap, Toothpaste and Breastmilk - Is it Kid-Safe?" (2007-2009). See www.ewg.org/reports/triclosan.
[269] Aviva Galaser, "The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed," *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.
[270] Ann Blake, "Antimicrobials in Wastewater: Triclosan and Quats," (Presented to National NAHMMA, October 15, 2008).

In 2002 it was estimated that 95% of triclosan was used in consumer products which were used or disposed of through household drains and into wastewater treatment plants.[271] This increase in use has resulted in an increase in the amount of triclosan that is sequestered in the sludge of wastewater treatment plants, quantities that have increased by 5 orders of magnitude since it was first used in consumer products. When these biosolids are used as fertilizer or otherwise applied to land surfaces, triclosan can degrade into chloroform or the carcinogen dioxin when exposed to sunlight. Triclosan in the human body has been shown to disrupt the body's hormones, particularly testosterone and estrogen.[272]

As early as 2000, similar findings in Europe led policy makers to publicly state that antimicrobial products were not only unnecessary for household use but were detrimental to aquatic environments and could lead to the creation of "super bugs" such as those seen after the overuse of penicillin.[273] In the case of triclosan, its widespread use in an array of often-used products can contribute to the creation of antibacterial/antimicrobial resistant bacteria. Moreover, because triclosan persists in the environment, even diluted concentrations in the environment can lead to resistance over time.[274]

[271] Aviva Galaser, "The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed," *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.
[272] Ann Blake, "Antimicrobials in Wastewater: Triclosan and Quats," (Presented to National NAHMMA, October 15, 2008).
[273] Aviva Galaser, "The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed," *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.
[274] Teresa M. Barbosa, and Stuart B. Levy, "The Impact of Antibiotic Use on Resistance Development and Persistence," *Drug Resistances Updates*, 3 (2000), 303-311.