

STATEMENT OF
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BEFORE
THE U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

AT A HEARING ON
TITLE I OF THE TOXIC SUBSTANCES CONTROL ACT; UNDERSTANDING ITS HISTORY
AND REVIEWING ITS IMPACT

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Thank you for the opportunity to testify at this hearing on the topic: “Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact.”

As you know, the Toxic Substances Control Act (TSCA) was enacted in October, 1976 – the end product of attempts to enact a statute over five years. The initial proposal for the law that ended up becoming TSCA came from the Council of Environmental Quality (CEQ) under the Nixon Administration. In 1971, the CEQ issued a report on the state of regulation of toxic chemicals in the U.S. and found there was “a high-priority need for a program of testing and control of toxic substances....We should no longer be limited to repairing damage after it is done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory.”

TSCA is focused on the manufacturing, processing, distribution, use and disposal of industrial chemicals, including those used in many commercial and consumer products. Excluded from the jurisdiction of TSCA are substances whose uses are otherwise regulated including pharmaceuticals, pesticides, nuclear materials, tobacco, and radioactive materials.

Whether or not it was widely understood at the time, the final enacted version of TSCA contained several major flaws that have contributed to the law’s ineffectiveness and overall lack of success. These flaws include:

- grandfathering of the 62,000 chemicals then in use without a mandate for EPA to require testing and review chemicals to meet a safety standard,
- placing the burden of proof on EPA to prove the harm of a chemical, rather than on the chemical industry to prove its safety (as is required for pesticides and pharmaceuticals);
- failure to require a minimum data set sufficient for the evaluation of new chemicals;
- limitations on EPA’s ability to require testing other than via a rulemaking,

- a safety standard of “unreasonable risk,” further burdened and weakened by the “least burdensome” test;
- allowing Confidential Business Information (CBI) to be claimed without upfront justification (and review by EPA) and without a nominal sunset date absent re-justification.

Taken together, these elements have led to a program that has done almost nothing to regulate or protect the public from existing chemicals; and has approved the use of thousands of new chemicals, based on estimates of their safety that have relied on incomplete information.

The law did contain at least one positive element: a specific Congressional phase-out of the production and distribution of poly chlorinated biphenyls (PCBs) a persistent, bioaccumulative toxin. PCBs have been classified as probable human carcinogens by EPA, the U.S. National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC). They have been shown to cause cancer in humans as well as non-cancer effects including effects on the immune system, reproductive system, nervous system and endocrine system. It was Congressman John Dingell who led the successful effort to add the ban on PCBs on the floor of the House in 1976.

In the years after enactment, EPA established the “TSCA inventory” a list of chemicals manufactured, imported or processed in the United States. The inventory of existing chemicals in 1982 was approximately 62,000 substances. Over the past 30 years, approximately 22,000 additional chemicals have been added to the inventory through the new chemicals program, for an approximate total of 84,000 chemicals on the inventory.

On balance, both the assessment and regulation of existing and new chemicals over the life of TSCA has been extremely limited – a point made repeatedly by the Government Accountability Office, as well as many other commentators, including EPA.

Existing chemicals

As noted above, TSCA grandfathered all of the chemicals in use, or available for use, at the time it was enacted, -- roughly 62,000 chemicals, without requiring that they meet a safety standard, or that EPA require testing of those substances. The law contained no general mandate for EPA to review the safety of those chemicals, and no minimum performance requirements or deadlines for performing such reviews. With a few exceptions, TSCA's existing chemicals program has been almost a dead letter since the day it was enacted. Since 1976, EPA has taken Section 6 action on only 5 substances. In addition to the steps taken to implement the phase out of PCBs required by Congress, these include: prohibiting the transfer of dioxin waste from a facility in Arkansas and requiring notice of disposal of TCDD wastes, phasing out the non-essential use of fully halogenated chlorofluoroalkanes as propellants in aerosol spray containers, banning the use of hexavalent chromium in comfort cooling towers, and an attempted ban on new and existing uses of asbestos.

EPA's attempt to ban asbestos and the subsequent overturning of its ban on existing uses is perhaps the central historical moment of TSCA, and one that remains the subject of dispute more than 20 years later. Asbestos is a known cause of several types of deadly illness including lung cancer and mesothelioma. As little as one single day of exposure to asbestos has been associated with deadly cancer which may not manifest itself for decades. The threat is not only posed to those industrial workers who are exposed on the job, but also to family members exposed when the fibers come home on a worker's clothes. Approximately 10,000 people are estimated to die each year in the United States from asbestos-related illnesses.

EPA spent ten years on its asbestos rulemaking, building an administrative record of more than 45,000 pages, demonstrating that asbestos posed an unreasonable risk to human health and the environment.

EPA concluded that only a phase-out of most uses of asbestos would be sufficient to protect the public, and the agency finalized a rule mandating such a phase-out.

EPA's final rulemaking was challenged in court and heard by the U.S. Court of Appeals for the Fifth Circuit in a decision known as the *Corrosion Proof Fittings* case. In that decision, the court ruled that EPA had not sufficiently demonstrated that it had chosen the "least-burdensome" approach to regulating asbestos, to meet the "unreasonable risk" standard. The court also criticized EPA from not considering the safety and cost of proposed alternatives to asbestos. The court rejected EPA's ban on existing uses of asbestos, and upheld its ban on any future new uses and any past but not current uses.

Since the court's decision in *Corrosion Proof Fittings* in 1991, EPA has not attempted another regulatory action for an existing chemical under Section 6 of TSCA. The court imposed a strict requirement for cost-benefit analysis, -- including an analysis of the costs and benefits of each of the regulatory options that are articulated in the law -- which commentators believe is the primary reason no additional regulatory actions under Section 6 have been attempted¹.

There are a range of views on the merits of court's decision in *Corrosion Proof Fittings*. What is clear though is that more than three-and-a-half decades after TSCA was enacted EPA has taken no regulatory action on virtually the entire inventory of 62,000 chemicals that were grandfathered, including existing uses of asbestos. Products containing asbestos are still imported into the U.S., and people continue to be exposed. Meanwhile, more than 50 other countries have adopted asbestos bans.

There are hundreds of chemicals besides asbestos that we already know are unsafe, or that are subject of ongoing study and concern. These include known and probable carcinogens, neurotoxicants, and

¹ See Testimony of Lisa Heinzerling before the Subcommittee on Environment and Hazardous Materials of the Committee on Energy and Commerce, U.S. House of Representatives, Hearing on "POPs, PIC, and LRTAP: The Role of the U.S. in Draft Legislation to Implement These International Conventions" July 13, 2004 and Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 Tex. L. Rev. 525, 541-49 (1997).

reproductive toxicants. It is astounding to many people to learn that EPA has taken no action to regulate the use of these and other chemicals under TSCA. TSCA needs to be amended to make it easier to take regulatory action on chemicals of concern – ranging from requiring labeling, use limitations, record retention, disposal limits up to and including bans and phase outs.

New Chemicals

Although the new chemicals program has managed to function better than the program for assessing and regulating existing chemicals, it has been hindered by key constraints that have limited its ability to ensure the safety of new chemicals entering the marketplace. These include the short period allowed for EPA to review pre-manufacture notices, , EPA's lack of authority to designate a minimum data set necessary for assessing the safety of new chemicals, and its inability to require testing by order rather than rulemaking or voluntary consent. In addition, the burden is on EPA to prove that a proposed new chemical may pose an unreasonable risk to human health or the environment rather than the burden being placed on chemical manufacturers to demonstrate the safety of their products. EPA has done its best with these limitations of the law to assess the safety of new chemicals and protect the public. In a limited number of cases EPA has imposed conditions of use on new chemicals, or raised concerns that have led to a company to withdraw its pre-manufacturing notice and forego production of the chemical. EPA has also developed methods for reviewing new chemicals for safety in the absence of easy access to the underlying data they might otherwise have. This includes comparing proposed chemicals with other known chemicals for structural similarities to help predict how they might behave in the environment and in people. While these methods can be useful for determining certain characteristics like persistence, bioaccumulation and ecotoxicity, they fall short in other areas including anticipating harmful impacts on mammals such as reproductive and developmental toxicity. Unlike under TSCA,

virtually all other industrial countries require potential manufacturers of a chemical to provide a minimum set of data up front with which the reviewing government can assess the chemical.

A further limitation under TSCA is that once a new chemical is added to the TSCA inventory – unless a Significant New Use Rule (SNUR) has been adopted at the outset – anyone may then produce the chemical, in whatever quantity, and for any number of uses – which may or may not have been considered under the original pre-manufacturing review by EPA – and with no notice to EPA required. This is one reason we now are in a situation where we don't have a clear picture of how many chemicals are actually in use in commerce, at what volumes, and for what uses. While the EPA's newly revised Chemical Data Reporting (CDR) requirements for periodically updating the TSCA inventory will provide some additional information, it is still very much an incomplete picture.

One other significant aspect of TSCA that must be mentioned is the current protections for Confidential Business Information (CBI). Let's stipulate up front that there is a category of information that most people agree should be considered CBI, at least for a reasonable period of time, and a category of information that does not qualify as CBI. There is a third category where there is less agreement, and is subject to debate. Unfortunately, under the existing TSCA, the CBI provisions are written and implemented in a way that allows information from all three categories to be swept into the protection of CBI, with no sunset for those information protections – resulting in the public having less access to information about chemicals, their uses, and their potential health effects than they should. The identity of some 16,000 chemicals on the TSCA inventory remains protected as CBI.

While EPA is thus severely constrained from regulating either new or existing chemicals under the current TSCA, the Administrator does have the authority to publish a list of chemicals of concern, based on a finding that such chemicals present or may present an unreasonable risk of injury to health and the environment. This provision allows EPA to inform the public, even when no regulatory action is

contemplated. However, the so-called “chemicals of concern” provision (which, in the early days of TSCA was also referred to as the “risk list”) has never been exercised by EPA. The previous Administrator of EPA was the first to attempt to use the provision, but EPA’s proposed rule to initiate notice and comment on a proposal has been “under review” at the Office of Management and Budget for three years.

These and other problems with TSCA have led the Government Accountability Office (GAO) to issue more than a dozen reports and testimony on the problems and ineffectiveness of TSCA since its enactment, culminating in its 2009 designation of EPA’s programs to assess the safety of chemicals as being at “high risk” of failure.

Science has not stood still

Meanwhile, over the 35 years that virtually no regulation of chemicals has taken place, the science raising concerns about the potential health effects of individual chemicals, as well as classes of chemicals, has exploded. Since 1976, scientists have linked exposure to toxic chemicals to a wide array of health risks. It is increasingly understood that exposure to low doses of certain chemicals, particularly in the womb or during early childhood, can result in irreversible and life-long impacts on health. It is now commonly known that some toxic chemicals persist in the environment, sometimes for decades, and build up in the food chain and in our bodies. It is now well-recognized that some chemicals are able to disturb our hormonal, reproductive, and immune systems and that multiple chemicals that individually may be at low levels considered to be “safe” can act in concert to harm health.

This broadening in understanding of the scope of possible health effects, as well as exposures, has occurred amidst increased public concern over the rising rates of a number of chronic illnesses and disabilities including certain types of cancer, types of mental illness and learning disabilities, asthma and Parkinson’s disease. At the same time, in the past few years the National Academies of Science (NAS)

has issued several reports containing recommendations on how EPA (and other agencies) can conduct better risk assessments of chemicals.

The explosion of science, coupled with the rise in chronic illness and disease has prompted growing calls for reform of our federal program for assessing and regulating chemicals by medical and health organizations, including the President's Cancer Panel (appointed by George W. Bush), American Medical Association, the American Academy of Pediatrics, the National Medical Association, the American Nurses Association, the American Congress of Obstetricians and Gynecologists, the Endocrine Society, the Bladder Cancer Advocacy Network, the Learning Disabilities Association, the American Fertility Association, and others.

Legacy of TSCA

Although other laws have been controversial, and battles over their implementation and reauthorization have been hard fought, there are undeniable accomplishments – with real- world benefits for public health and the environment – that can be ascribed to most of our other major environmental laws including the Clean Air Act, the Clean Water Act, Food Quality Protection Act, Safe Drinking Water Act, Superfund, and The Resource Conservation and Recovery Act (RCRA). Virtually nobody makes any such claims for TSCA. The chemical industry had long viewed TSCA as a success. However, starting around 2009, the industry position shifted and concerns began to be raised about the effectiveness of TSCA and its failure to ensure a needed level of consumer confidence in the safety of chemicals, particularly those used in commercial and consumer products. What caused the shift?

In the absence of any meaningful regulation, and little by way of disclosure of uses or potential concerns about chemicals used in hundreds or thousands of products, action devolved to the state level, and to the marketplace, where a combination of state legislative and administrative actions, and consumer pressure on major retail companies as well as some chemical processors has led to a sustained, and

growing, upheaval across the country. Public dissatisfaction with the lack of a coherent and effective federal regulatory system for chemicals is being expressed in manifest ways, in dozens of states, with hundreds of chemicals as targets for concern. This movement has had concrete results – including:

- Announcements from major chemical processors that it will stop using specific chemicals in certain products – for example, Johnson and Johnson removing formaldehyde from baby shampoo, and Procter and Gamble removing 1,4 dioxane from Tide laundry soap.
- Big box retailers refusing to carry products on their shelves containing certain chemicals – for example, Wal-Mart’s ban on products containing PBDE flame retardants.
- States across the country have acted to ban the use of certain chemicals in specific products, particularly those marketed for children, including bans of Bisphenol A (bpa) in 12 states, as well as phthalates, cadmium, PBDEs (and Tris) and lead among others. These are in addition to more than 175 policies addressing mercury in 34 states.
- At least 10 states have adopted green cleaning policies – leading school districts around the U.S. to use less toxic cleaning supplies.
- Several states have also adopted programs requiring the public disclosure of chemicals used in specific products, and the development of lists of chemicals of concern which might then be regulated by individual states.

The success of these diverse activities – usually with the support of largely bi-partisan votes by state legislatures – which are both a sign of the high degree of public concern, and lack of consumer confidence in the safety of products in their homes, automobiles, workplaces and schoolrooms – have contributed to two phenomenon dreaded by chemical processors and consumer products companies: (1) an increasingly complex “patchwork” of state-level (and, in some cases local) regulation of chemicals,

(2) so-called “retail regulation” in which companies are forced to modify their products to comply with the requirements of large-scale retailers.

And it is these developments that have led the chemical industry to reassess its own satisfaction with the way TSCA has operated for 35 years.

At least some chemical companies are now of the view that reform of TSCA is necessary to stem the tide of state and retail-level activity and to restore consumer confidence in chemicals and the everyday products which contain them. This shift has led to more discussion of potential reform of TSCA in the past few years than at any time since it was enacted. But reform of TSCA must entail serious and timely review of the safety of chemicals based on sufficient data, and allow EPA to impose restrictions as necessary to protect the public. Revisions to TSCA that won't ensure real action is taken by EPA, while at the same time preempting action at the state level, will not protect the public nor re-instill consumer confidence. Such legislation would not constitute real reform. It is possible to establish a federal program to review the safety of chemicals, and establish controls on those chemicals necessary to protect public health and the environment, while protecting the role of states and maintaining the continued success of the chemical manufacturers, processors and downstream users – and create a market for innovative companies producing safe and effective chemicals. And after more than three decades since TSCA was enacted, it is long past time that we do so.