

Testimony
Toxic Substances Control Act

Senate Environment and Public Works Committee
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Mr. Chairman and members of the Committee on Environment and Public Works, it is my honor to testify today about the Toxic Substances Control Act.

I am Dean of the School of Public Health and Health Services at The George Washington University School of Public Health and Health Services. I am a pediatrician and an epidemiologist, and serve on the Board for the Children's Environmental Health Network and as a member of the Board of Trustees of the Environmental Defense Fund. From 1993-98, I served as Assistant Administrator for Prevention, Pesticides and Toxic Substances at the US Environmental Protection Agency (EPA). While serving in that position I was responsible for the implementation of the Toxic Substances Control Act. Prior to joining the EPA I worked for eight years in public health with the California Department of Health Services. However, my testimony represents my own views and not the views of these other organizations.

When TSCA was passed in 1976, there were great expectations that it would improve our understanding of chemical risks and address these risks in a comprehensive multi-media framework. But, for a variety of reasons, TSCA has not been able to fully live up to these expectations. The people in the Toxics program at the EPA do an excellent job with the tools that they have but they have neither the legislative tools nor the resources that are needed. There are several symptoms that all is not well with TSCA. First is the rising tide of chemicals being regulated on a state-by-state basis. While I support the right of states to take action to protect their citizenry only federal actions protect all US citizens. Second is the enormous gap that is forming between TSCA and the new chemicals legislation (REACH) in the European Union. And third is the dwindling away of personnel and resources in the EPA devoted to core TSCA efforts.

Today, I will focus on a discussion of a number of areas of concern – and opportunity for change. These include: risk evaluation, protection of vulnerable populations, risk management, precaution, new chemicals, right to know, pollution prevention, international management of chemicals and priority-setting.

Risk Evaluation:

To evaluate risk requires the availability of data on hazards and exposures. The Chemical Testing Program was established to carry out the policy expressed in TSCA that adequate data should be developed with respect to the health and environmental effects of chemical substances and that the development of these data should be the responsibility of chemical manufacturers and processors. Unfortunately the analytic burden required of EPA to write TSCA 4 Test Rules and to defend them from litigation has resulted in a situation such that, repeatedly, over the past two decades, the Government Accountability Office (GAO), the Congress, and others have noted a lack of productivity and the absence of a clear agenda for testing. EPA has tried to overcome this problem in a number of ways, including: use of Enforceable Consent Agreements rather than test rules; development of a Master Testing List and voluntary approaches for screening high volume chemicals in cooperation with the chemicals industry and the OECD (Organization for Economic Cooperation and Development). These voluntary

programs are good programs but it is not at all clear how and when EPA will move from screening to more extensive testing of chemicals for adverse endpoints.

Another important information gathering provision is TSCA Section 8(e), a critically important information-gathering tool that serves as an "early warning" mechanism for keeping the Agency apprised of significant new chemical hazards and exposures, and for satisfying the public's right to know about these hazards. EPA's longstanding policy has been, appropriately, that if certain serious health effects are discovered, that information should be considered for immediate reporting to EPA without further evaluation. Over and over again, across the decades, it comes to pass that companies may misinterpret TSCA Section 8(e) and EPA's corresponding policy. EPA has tried to remedy this situation in several ways including by providing guidance documents and via the voluntary Compliance Audit Program (CAP) which, in 1992, allowed participating companies to submit delinquent Section 8(e) information and pay stipulated penalties up to a \$1 million ceiling. Yet, this problem has recurred again and again. Some recent examples of significant information being withheld from EPA include: chromium, diacetyl and PFOA.

EPA collects little to no information about chemical exposures yet such information is essential to the evaluation of risk. TSCA needs to be reformed to give EPA clear expectation for testing of risks of existing chemicals. TSCA also needs to provide for exposure monitoring, by EPA or in collaboration with others such as the CDC. The structure of TSCA should reward companies for the generation of information about chemicals and exposures, through more rapid approvals and/or avoidance of penalties.

Protection of Vulnerable Populations

TSCA does not require the protection of sensitive populations, including children. Several other statutes, the Clean Air Act, the Safe Drinking Water Act and the Food Quality Protection Act all contain provisions making it clear that such populations should be protected. Children are often more highly exposed to chemicals in the environment, via diet, inhalation, crawling on the floor, mouthing hands and objects in the environment, and route such as transfer from mother to baby in utero or in breast milk. Children are often more susceptible. "Windows of exposure" during development cause susceptibility to irreversible effects like birth defects, neurobehavioral outcomes, and other developmental alterations, and cancer. Parents are not aware that the products in their homes are made with chemicals, many of which have not been assessed at all for risks to children (or even adults). Because the fetus and child are often more exposed and can be more susceptible to adverse effects of chemicals during critical life stages, this is a particularly important vulnerable group. Other groups include people who have genetic differences in response or metabolism of chemicals; the elderly, and people with preexisting conditions. TSCA should explicitly require the protection of vulnerable populations. Exposure and response patterns of vulnerable populations should be included in risk analyses for chemicals and additional uncertainty factors employed where such information is both missing and relevant.

Risk Management

In terms of managing the risks of toxic chemicals, the EPA never has recovered from the Fifth Circuit Court of Appeals decision to remand the 1989 Asbestos Ban and Phaseout Rule to EPA. In this case, the court's decision imposed a burden of proof on EPA that significantly increased the level of analysis on potential substitutes and on identifying the least burdensome approach for any future Section 6 action. Second, the court's interpretation of least burdensome alternative under Section 6 appears to define end-of-pipe solutions, where toxic substances are controlled after they are distributed into the environment, as less burdensome than pollution prevention solutions, where toxic substances are reduced or eliminated at their source. End-of-pipe solutions are in conflict with the pollution prevention approach and are more costly over time. EPA needs for Congress to restore its ability to take regulatory action to manage risks of chemicals. Strengthening EPA's ability to manage chemicals risks is this is the single most effective way that Congress could turn the tide on state-by-state regulatory actions on chemicals.

Precaution

Decisions about chemical risks should be made based on a stronger, more health based safety standard or goal. The current safety standard is to avoid "unreasonable risk to health or the environment", which means that decisions are based on risk benefit balancing. The standard for pesticides in food is one of a "reasonable certainty of no harm". This is a public health standard. Such a standard is needed for chemicals to which we are exposed in our daily lives, just as it is needed to protect us from residues of pesticides in food. Additionally, existing chemicals on the market should be reviewed to assure that they are safe. Certain categories of chemicals, such as persistent chemicals should be given highest priority (as has been done by Canada). Such a precautionary approach would tend to shift the "burden of proof" onto manufacturers, to prove that chemicals are safe rather than on EPA to prove that they are unsafe. Such an approach is in contrast t the "least burdensome" provision of current law, which made the banning of asbestos impossible.

New Chemicals

Section 5 of TSCA requires that anyone who intends to manufacture or import a new chemical substance in the United States notify EPA 90 days before commencing that activity. The EPA new chemicals program has over the years reviewed thousands of new chemical substances. In many cases EPA has made decisions to prevent risk before a harmful substance enters commerce. The U.S.'s new chemicals program is unique in that it requires review of chemicals prior to manufacture rather than prior to marketing as in most other countries with such systems. I think that there is general agreement among the chemicals regulators worldwide that what would make more sense is a system that gives different types of approvals for R&D and for marketing chemicals. This would help the EPA focus more efficiently on the chemicals which are actually destined for the market. In the case of TSCA, the thousands of chemicals that are submitted and the 90-day review period are challenging. On top of that, the new chemicals program in the United

States does not require any testing prior to PMN submission and therefore over half of all PMNs are submitted without any test data. Ever resourceful, the Agency has developed tools to use Structure Activity Relationships (SAR) to predict and assess the fate and effects of new chemicals. Other systems, most notably the “pre-REACH” Pre-marketing Notification scheme used in the European Union (EU), require a “base set” of testing on new chemicals. In the 1990s the US and EU evaluated the utility of SAR and found that it worked for some endpoints but not others, particularly a number of chronic health effects. Today the EPA and others have been working on the development of new tools to predict toxicity using computational modeling. These new approaches will allow the EPA to even more accurately predict the hazards of new chemicals but only if they are able to request the information that is needed to conduct the modeling.

When EPA determines that there is a risk associated with a PMN it has tools that can be used to manage those risks. TSCA Section 5 gives EPA the ability to require additional tests or other measures such as disposal controls and worker protection. Over the years, the new chemicals program has made wonderful efforts to inform the chemical industry about the criteria used to assess chemicals. These efforts have encouraged development of safer chemicals, and I believe have caused the industry to screen out “bad actors” before presenting them to the EPA in the first instance.

TSCA’s new chemical provisions would be improved if EPA’s effort were focused premarket rather than premanufacture approvals and would benefit greatly from the addition of risk related data to the agency’s determinations.

Right to Know

Empowering the public with information is a powerful tool for environmental progress. The creation of the Toxics Release Inventory (TRI), established in Section 313 of the Emergency Planning and Community Right-to-Know (EPCRA), led the way to a new era of public disclosure and a more constructive dialogue between citizens and industry on emissions reduction and pollution prevention. For a toxic chemicals program, it is almost inevitable that the “right to know” ethic will expand to other chemical information. The public release of environmental data gives everyone the ability to participate in the broader national effort to set a toxics agenda and address chemical issues based on the extent of risk posed. The states, local governments, industry, labor unions, public interest groups and grass-roots community groups are increasingly finding ways to work together on environmental improvements. All problems of chemical management cannot be solved through direct EPA action. As one example of this, the EPA has unsuccessfully attempted to foster and enhance the participation of individual states in chemical management by providing them with TSCA derived chemical data. As a former state regulator, I know the value of site specific information in risk assessment and priority setting. Yet, the language of the law has been interpreted to say that such information cannot be shared with state officials if it has been declared as “confidential business information”. In relation to this problem, there is a large amount of information reported to the EPA under TSCA information claimed as confidential business information; studies have found that much of which does not deserve such protection.

EPA has attempted to reform the CBI process but such efforts have foundered on resource limitations and the language of the law, which gives manufacturers too much leeway. Some examples from a survey of the data conducted by EPA in 1998:

- In 1998, more than 65 % of the information filings directed to the Agency through TSCA were claimed as confidential.
- Submissions under the former Inventory Update Rule show that about 20 % of facility identities were claimed as confidential.
- In 1998, 40 % of Section 8(e) substantial risk notices had chemical identity claimed as confidential.

There is a need to reform the CBI provisions in TSCA. Also Congress needs to rethink the role of the states, which has expanded greatly since 1976, and identify ways to provide them not only with more information but also with more opportunities to participate in chemicals management efforts

Pollution Prevention

Preventing pollution offers significant opportunities for protecting the environment and public health in a cost effective manner. The adoption of a pollution prevention ethic is a logical development in a toxic chemicals program, given the focus on improving environmental protection through changes in the manufacture, processing and use of chemicals in our society. Fundamentally, we need to encourage use of safer chemicals and processes in our industrial sector. In order to achieve this TSCA would need to be altered in a number of fundamental ways. First, EPA needs stronger coordination among its “media” offices when it comes to chemicals to prevent the movement of harmful substances from air to water to waste. Second, TSCA does not reward the development of newer safer alternatives. Newer chemicals are reviewed more carefully than existing ones and the lack of regulation of hazardous existing chemicals does not create an incentive to remove them from the market. Congress needs to examine ways to create incentives for greener chemicals and chemical use patterns. TSCA should support and reward companies for research and development and for creating safer substitutes through tools such as exemptions and more rapid approvals for market. TSCA should be a tool to break down the “silos” at EPA to assure that chemicals are managed properly from cradle to grave and not inappropriately shifted from one medium to another (for example, from water to air).

International Management of Chemicals

Increasingly it is recognized that a number of very persistent and/or very hazardous chemicals need to be managed globally. In 1992 the Rio Conference adopted Agenda 21, which contained a number of goals for international management of toxic substances. Since that time we have seen the development of many new institutions including: the Intergovernmental Forum on Chemical Safety, a global treaty on prior informed consent for the import of highly toxic chemicals (the Rotterdam convention or PIC) and the global treaty on Persistent Organic Pollutants (POPs). Yet the US has been

slow to join these issues and in fact has not ratified the POPs and PIC conventions. Ratification is needed so that the US can fully participate in these important efforts to protect the health of the global community. Only a very limited TSCA change is made to allow ratification.

Priority Setting

Because there are so many chemicals on the market that have yet to be evaluated, what is needed is for Congress to set a clear agenda for priorities in evaluation and management of chemicals, as well as clear expectations for action. Some factors that might be considered include:

- Children's exposure pathways and uses that are likely to expose children
- Biomonitoring and environmental data; which chemicals are in peoples bodies
- Cancer, developmental, reproductive and ecological effects and chemicals classes associated with such effects
- Higher production volumes
- Bioaccumulative or environmental persistence properties
- Use patterns; chemicals uses more likely to result in exposures to humans and the environment

Along these lines, there are numerous chemicals that we already know have potential risks. TSCA needs to provide the EPA with the tools to address the risks as they are identified. It would be a mistake to hamstring the agency with requirements to do comprehensive assessments and reassessments of all chemicals before any action is taken.

Practical Advice

Last year I, in collaboration with three other former EPA officials who have served under both democrats and republicans, wrote a paper for the American Bar Association that I have submitted for the record ("Practical Advice for TSCA Reform: An Insider Perspective"). The paper provides "practical advice" for TSCA reform, is included as an appendix to my testimony.

1. There is much to be recommended in the approach in the Food Quality Protection Act (FQPA), especially the safety standard, which is clear and public health-based. However, for regulating the thousands of toxic chemicals on the market EPA will need a more flexible and prioritized system.
2. Second EPA's Toxics program has limited organizational capacity. Any new legislation will need to address this problem. It will be important to have a reasonable phase-in period, provision for fee-supports and clear and reasonable schedules.
3. Third, all chemicals are not created equally. Congress needs to assure that the EPA first focuses on the several hundred chemicals that are in most need of control. We guesstimate this to be about 5-10% of 6,200 non-polymeric chemicals with significant (>2,500 lbs/yr) annual production.
4. Fourth, there are areas within the current chemical regulatory system that need to be continued. The chemical inventory, the new chemicals review process, the use

- of the Significant New Use Rule (SNUR), and EPA's current efforts to focus on the riskiest chemicals are all examples of efforts that have been successful and should be sustained and enhanced.
5. Fifth, chemicals are increasingly managed internationally. The data that are being produced by industry under the EU REACH program should be made available to the EPA and will be a valuable resource for a reformed TSCA. TSCA needs provisions that allow the US to fully participate in international chemical management schemes, including the Stockholm and Rotterdam conventions (mentioned above), as well as other efforts like the Globally Harmonized System for classification and labeling of chemicals and the Strategic Approach to International Chemicals Management. New TSCA amendments should affirmatively recognize and embrace these growing global realities.
 6. Finally, we caution against efforts to prescribe how the regulatory science is conducted or evaluated under TSCA. No matter how well driven by current scientific approaches, any specific approaches are likely to soon be outmoded. Rather, EPA needs to evolve its approaches over time, in recognition of the inevitable changing science behind chemical evaluation and assessment as well as the regulatory options that might be available in the future.

Conclusion

In summary, overhaul of TSCA is long overdue. EPA needs clear requirements and regulatory authority that requires placing a high priority on protecting health (especially for vulnerable populations) and the environment. Minus congressional action on TSCA we will continue to see the erosion of federal management of chemicals on many levels. We will see more states taking action to manage chemicals, thereby creating confusion in the markets and unequal levels of protection state by state. We also will continue to see the dwindling down of activities on the federal level with a commensurate increase in the risk that "bad actors" will get through the net. And we will increasingly see the European Union and others move into the lead in this area, thus putting us at a competitive disadvantage. This is a complicated area but at the end of the day there is one simple principle that should be kept foremost, which is assuring the American public that the products on the market, the air they breathe, the food and the water, are safe. Fortunately, at this time there is a major opportunity for reform. Not only EPA but also a number of stakeholder groups, including industry, have put forward principles for reform. The need for change is clear. It now is time to bring the parties together to craft a reasonable, science-based and health protective overhaul of TSCA.