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OVERSIGHT HEARING ON THE TOXIC SUBSTANCES CONTROL ACT
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UNITED STATES SENATE

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INTRODUCTION

Mr. Chairman and Members of the Committee, thank you for the invitation to appear before you today. It is my privilege to represent the U.S. Environmental Protection Agency (EPA) during this oversight discussion on the Toxic Substances Control Act (TSCA).

KEY ACCOMPLISHMENTS

EPA takes very seriously its commitment to implementing TSCA and to protecting both the American public and our environment from the adverse effects of chemicals. We are also extremely proud of the many accomplishments we have achieved in the past 3 decades and the progress that has been made in protecting human health and the environment.

TSCA provides the Agency with the necessary authority to ensure that new chemicals are adequately reviewed, that EPA can require reporting or development of information needed to assess existing chemicals, and that those chemicals that pose an unreasonable risk can be effectively controlled. Using TSCA as the foundation for our efforts, EPA has, over the decades, developed a wide array of regulatory and voluntary approaches and tools to assist us in our goal to protect both human health and the environment. Using the strengths of both regulatory and partnership approaches we have ensured effective, timely chemical management decisions. We

have developed sophisticated modeling programs which assist both the Agency and industry in developing, reviewing, and manufacturing safer chemicals. We have incorporated broad pollution prevention approaches into both our regulatory work and numerous highly successful voluntary programs which have considerably increased the speed at which we have been able to achieve environmental results. We have worked cooperatively with the regulated community, our stakeholders, our counterparts in other federal agencies, States and Tribes, and the public on a broad range of programs and activities, in order to make informed and transparent chemical management decisions. We have also worked closely with the international community on chemical management issues because we recognize that global coordination and harmonization is critically important in ensuring a level playing field for all. I would like to take a few moments to share with you some of the highlights of the progress and achievements of our TSCA-related activities.

EPA's Regulatory Accomplishments

When TSCA was passed almost 30 years ago, there were 62,000 chemicals on the TSCA Chemical Substance Inventory of existing chemicals. Since that time, under Section 5 of TSCA (which addresses new chemical review and control), EPA has reviewed more than 45,000 new chemical submissions. EPA has regulated more than 1,800 of these new chemicals. An additional 1,700 have been withdrawn by industry. Approximately 20,000 chemicals have gone into production and have been added to the Inventory. The remaining new chemical submissions have either not gone into production or were the subject of applications for review as exemptions from Premanufacture Notification (e.g., Low Volume Exemptions). Voluntary environmental stewardship programs also play a significant role in our efforts to promote the development of

safer and greener new chemicals, and innovative programs like Sustainable Futures and the Persistent, Bioaccumulative, and Toxic (PBT) Profiler are key contributors in this regard,

Under Section 4 of TSCA, EPA has issued test rules or used Enforceable Consent Agreements to require the generation of testing on more than 200 chemicals. EPA has also successfully utilized voluntary stewardship approaches to address existing chemicals. In 1998, EPA, working cooperatively with the chemical industry and the environmental community, under the High Production Volume (HPV) Challenge Program, sought commitments from chemical manufacturers to make basic health and safety data publicly available on the chemicals produced in the U.S. at over a million pounds a year. While annual production volumes vary substantially over the current Inventory of some 80,000 chemicals, these approximately 2,800 HPV chemicals account for more than 93% of the production volume from the chemicals we track on the Inventory. This program has also been coordinated with international testing programs which has resulted in greater participation and has ensured that U.S. manufacturers not bear the entire burden of developing this critical data. Under the Bush Administration priority implementation of the HPV Challenge Program has continued and, to date, more than 370 chemical manufacturers, either individually or as part of an industry consortia, have stepped forward to sponsor more than 1,400 chemicals under the HPV Challenge, and over 800 chemicals have been sponsored under the complementary international effort. Data have been submitted for over 97% of HPV Challenge chemicals and the international effort will continue to contribute information. EPA is reviewing and assessing the data submitted on approximately 1700 HPV chemicals to date, to identify chemicals that may warrant additional follow-up action or assessment.

This past Spring, EPA also made good on its 1998 commitment to make the HPV data publicly available with its release of the internet-accessible HPV Information System. Building on this effort, EPA will co-host a conference this December with NEWMOA, the Northeast Waste Management Officials' Association, which will provide an opportunity for a wide range of stakeholders and interested parties to share experiences in using and accessing the HPV data.

Recognizing the success of the HPV Challenge Program, chemical industry leaders, through the American Chemistry Council, the Soap and Detergent Association, and the Synthetic Organic Chemical Manufacturers Association, came together to extend the HPV program by announcing in late 2005, their intention to develop these health and safety data on an additional 500 HPV chemicals. EPA is very encouraged by this effort and will work closely with the participants as their effort proceeds.

TSCA also provides the agency with the authority to address unreasonable risks through Section 6. To date, the agency has regulated five existing chemicals or chemical categories and four new chemicals under Section 6.

TSCA, through Section 8 requirements, provides the agency with the ability to require recordkeeping and reporting on a wide range of data, including production volume information, health and safety data, and substantial risk information. For example, more than 50,000 health effects, environmental effects, and environmental fate studies have been submitted to the Agency. This information helps not only EPA, but a number of other Federal Agencies in their efforts to assess chemicals. EPA also receives industry submissions under TSCA section 8(e), of "substantial risk" information which alerts EPA to critical new test data and which, when appropriate, is referred to other Agencies, industry, and stakeholder groups.

Section 12 of TSCA ensures that the U.S. notifies other countries when certain chemicals are exported. Section 13 prohibits the import of chemicals that would not be in compliance with TSCA. Section 14 puts in place requirements for handling confidential business information submitted by companies, and Section 21 sets forth a process that allows the public to petition the Agency to take action on specific chemical issues.

Voluntary Efforts

Recently, a number of voluntary phase-out actions by chemical companies have been given regulatory effect through the use of TSCA authority. Several high-profile examples include one company's decision in May, 2000 to voluntarily cease production by 2002 of 88 "PFOS"-related perfluorinated chemicals, which were widely used in many soil and stain resistant products.. EPA, under the Bush Administration, took prompt regulatory action under Section 5 of TSCA by issuing Significant New Use Rules (SNURs) to ensure that new uses of these chemicals will be reviewed by the Agency prior to manufacture or re-introduction in the marketplace. EPA subsequently proposed a SNUR for an additional 183 PFOS- related chemicals which would subject them to the same requirements. In 2004, following discussions with EPA, another U. S. chemical company announced its decision to withdraw "PentaBDE" and "OctaBDE," polybrominated diphenyl ether (PBDE) flame retardants used in furniture foam and other products, from production by the end of 2004. The Agency also followed up this voluntary action with a SNUR that will ensure that new uses of these chemicals are reviewed by the Agency prior to introduction into the marketplace.

During its work on PFOS, the Agency, through Section 8(e) reporting, became aware of concerns with a related perfluorinated chemical, "PFOA," which is used as a processing aid in

the production of a wide range of stick-resistant consumer products. EPA began the development of a risk assessment and, recognizing we do not currently have the data necessary to understand the sources and pathways of human exposure to PFOA, launched a formal process with industry and other interested parties to develop needed information utilizing specific testing agreements, including Memoranda of Understanding and TSCA Section 4 Enforceable Consent Agreements. EPA is thus working to develop the scientific information needed to fully understand how people are being exposed to PFOA and what, if any, concerns those exposures may pose. Industry has responded by initiating new studies, including through enforceable as well as voluntary testing efforts. EPA recognized that the science was still coming in but the concern was there, so EPA Administrator Stephen Johnson asked eight chemical companies to join the Agency in an environmental stewardship program that has resulted in the industry committing to a 95 percent reduction in PFOA emissions and product content by no later than 2010, and to work toward eliminating PFOA exposure from these sources by no later than 2015. The effort to gather exposure data will continue in parallel to the stewardship program. It is clear from the accomplishments I have just outlined that TSCA provides broad authority to the Agency to adequately control new and existing chemicals, and the ability to address emerging chemical issues as they arise. The Agency's recent efforts on PFOS, PFOA, and PBDEs, provide clear examples demonstrating this point.

Nanotechnology

In addition, we believe TSCA is adequate for addressing issues that may arise with emerging technologies, such as nanotechnology. The use of nanotechnology has enormous potential for a wide array of applications. At this early stage, there are few detailed studies on

the effects of nanomaterials in the body or the environment. However, based on early results, it is clear that it is not yet possible to make broad conclusions about which nanomaterials may pose risks. The Agency is moving expeditiously, but thoughtfully, to ensure appropriate oversight of this emerging technology, without impeding its development. TSCA provides the Agency with the regulatory authority needed to help ensure that this emerging technology is used safely. We are using our authorities to regulate new chemical substances under Section 5 of TSCA, which require that all new chemical substances are submitted to the Agency for review prior to manufacture and introduction into commerce. We are also considering developing a stewardship program to increase understanding of both TSCA new and existing chemical nanomaterials to complement our on-going new chemical efforts, assemble existing data and information from manufacturers and processors of these materials,, and encourage the development of test data needed to provide a firm scientific foundation for future work and regulatory and policy decisions. We believe that this approach will ensure that the Agency will be positioned to meet our mandate to protect both the public and the environment from any unreasonable risks.

TSCA OVERSIGHT

While I appreciate the opportunity to share with you the highlights of much of our work on TSCA over the past three decades, we recognize that no statute is perfect. For this reason, we are most appreciative of the on-going interest of this Committee in TSCA and the work of the United States Government Accountability Office (GAO) in their recent reports on chemical regulation under TSCA and chemical regulation in the U.S., Canada and the European Union. It is clear that there are different statutory approaches to ensure that chemicals are manufactured and used safely and that the public and the environment are adequately protected. As I stated at

the beginning of my testimony, I believe that TSCA provides EPA with the statutory tools necessary to achieve these goals. We are committed to using sound science to make risk-based decisions, to complementing these actions with successful collaborative environmental stewardship programs, and to working with governments around the world on chemical management programs.

CONCLUSION

The Agency looks forward to continuing to work closely with Members of this Committee and your staff, and the GAO on their reviews of TSCA as we work together to protect human health and the environment. There are many dedicated engineers, chemists, biologists, toxicologists, economists, statisticians, attorneys and other civil servants who work directly on TSCA issues at EPA. They are among the most scientifically capable and talented staff at EPA and they work extremely hard to effectively implement the myriad of TSCA related activities that I have just shared with you. As an organization, they have demonstrated with the outcomes of their work the benefits of innovation, collaboration and sound science. I am extremely proud of their achievements and to be newly associated with them. Again, I thank you for the opportunity to be here today and to provide you with this information. I am happy to answer any questions.