WRITTEN TESTIMONY OF WILLIAM K. RAWSON

PARTNER AND CHAIR OF THE ENVIRONMENT,
LAND & RESOURCES DEPARTMENT IN WASHINGTON, D.C.

LATHAM & WATKINS

BEFORE THE

COMMITTEE ON ENVIRONMENT & PUBLIC WORKS

OF THE

UNITED STATES SENATE

JULY 24, 2012

Madam Chair, distinguished members of the Committee and staff – good morning. Thank you for inviting me to testify today on the topic of EPA's legal authorities and activities to assess exposures and risks to toxic chemicals, including flame retardants. I hope my testimony will prove useful to the Committee.

I am a partner in the law firm of Latham & Watkins and chair its environmental practice in Washington, D.C. I have co-authored a deskbook on the Toxic Substances Control Act (TSCA) published by the Environmental Law Institute, and have been involved in numerous rulemaking proceedings and other activities arising under various sections of TSCA. I have been asked to testify today by Albemarle Corporation, a domestic producer of flame retardants, and ICL-IP, an Israeli company that produces and imports flame retardants. My testimony will reflect my experience representing and counseling companies and trade associations on issues arising under TSCA and other chemical regulation statutes over the last 25 years.

My testimony will focus primarily on EPA's experience implementing its authorities under TSCA. It is important to keep in mind, however, that TSCA is only part of the story. EPA regulates the use, release and disposal of chemical substances under many other environmental statutes. Other federal agencies, including OSHA, FDA and CPSC, also have substantial responsibility for ensuring the safe handling and use of chemicals under their respective statutory authorities.

Additionally, chemical manufacturers have implemented various voluntary initiatives and product stewardship programs to support the safe manufacture and use of their products. Many of the industry's voluntary initiatives have been undertaken in collaboration with EPA and other stakeholders. These initiatives and product stewardship programs help meet the objectives of TSCA.

I also would like to express strong appreciation for EPA's mission. I have worked closely with many EPA managers and staff over the years on numerous challenging issues, and have great respect for their efforts in support of EPA's mission.

TSCA

All major stakeholders appear to agree that amendments to TSCA are needed. Stakeholders have divergent views, however, about what needs to be fixed and why. To make progress toward amendments, we need to find common ground.

A useful starting point for analysis is Executive Order No. 13563, signed by President Barack Obama on January 11, 2011. That EO states: "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." TSCA amendments should meet those objectives.

The EO also states that our regulatory system must "identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative." EO No. 13563 directs each agency to "propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs." It compels each agency to "tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives." One possible framework for evaluating proposed amendments to TSCA, then, would be to ask how well the legislative proposals would promote the objectives stated in the President's Executive Order.

I will focus my testimony on three sections of TSCA: section 5, which governs approvals of new chemicals; section 4 which governs testing of existing chemicals; and section 6 which provides authority to regulate existing chemicals.

Section 5. EPA has taken a flexible approach to data requirements for new chemicals, in some cases requiring very little information, and in other cases requiring more information. EPA has imposed restrictions on manufacture and use where it has considered restrictions necessary to protect health or the environment. While companies often negotiate over data requirements or proposed restrictions, in every case since TSCA was enacted in 1976, the company seeking approval of a new chemical has either agreed to EPA's data requirements and restrictions, or withdrawn its premanufacture notice. Several thousand chemicals have either been approved with restrictions or not approved at all. There has been no litigation under TSCA section 5.

The strength of §5 lies in its flexibility. Chemicals are not all alike. Some can very easily be determined to pose low risks. Others require more data and closer scrutiny, and may require restrictions to ensure safe use. The flexibility in §5 allows EPA to raise or lower the scrutiny, and raise or lower the restrictions, according to the properties of the chemical.

I believe Section 5 is doing a reasonably good job meeting the multiple objectives of EO 13563. In my view, those who were involved in the enactment of TSCA in 1976 should be pleased with what has been accomplished under Section 5. This section fundamentally changed how companies that manufacture chemicals bring new products to market.

Under the Senate bill – the Safe Chemicals Act of 2011 -- every new use of a previously approved chemical, and every significant increase in use of an existing chemical, would require another round of EPA review. Under the current statute, EPA has authority to determine when a new use would be sufficiently significant to require another round of review, based on consideration of relevant factors. The regulatory burdens associated with requiring new review for every new use, and every significant increase in use, would be enormous. The implications of the Senate proposal for EPA's overburdened EPA resources, for EPA's ability to prioritize, and for industry's ability to innovate, would be very significant.

Section 4. EPA has two ways under TSCA to require toxicity testing of existing chemicals. The first requires EPA to find that a chemical "may present" an unreasonable risk. The second is an exposure-based approach, where EPA can base testing requirements on production volume and a finding of significant or substantial human exposure or substantial releases to the environment. In each case, EPA must also find that existing data are insufficient to evaluate potential risks, and that the specific proposed testing is necessary to evaluate potential risks. Case law shows that the burden is very low. There is no Catch-22, as some have suggested. The "may present" a risk finding can and has been met with very limited toxicity data and only circumstantial evidence of potential exposure, such as, for example, that a chemical is handled in the workplace.

I believe the TSCA §4 criteria provide a sound basis for deciding what testing is necessary to protect human health and the environment. These criteria are appropriate not only for test rules under TSCA, but for industry decisions about what testing to conduct voluntarily.

Why aren't there more test rules? One reason is that industry conducts a large amount of testing voluntarily, without the need for any rulemaking action by EPA. Also, many chemicals have been evaluated for testing under TSCA and have been determined to be a low priority for testing or not to need any testing at all. The volume of testing and the amount of information available to EPA is not accurately measured by counting the number of test rules and section 4 testing consent orders.

There have been implementation issues with section 4 that have caused a number of rulemakings to get bogged down. I believe a greater willingness on EPA's part to use tiered approaches to testing would have helped resolve some of the disputes that have arisen in the past.

The Senate bill would not require EPA to consider potential for exposure before considering the necessity of testing. EPA has stated expressly in the Federal Register that: "The level, frequency, and duration of exposure to a chemical should always be considered when determining the sufficiency of existing data and the necessity of additional testing." One might ask, would it be appropriate to eliminate testing criteria that EPA has expressively stated are appropriate?

The goal of amendments should not be to make it easier for EPA to impose testing requirements. The goal should be to ensure that statutory criteria produce scientifically-sound and ethical testing decisions. If the current criteria do that, changes to the criteria are not needed. The emphasis should not be on the number of test rules that have been promulgated, but on

ensuring that EPA has the information it needs to perform its risk management functions, whether that information is gained through test rules, voluntary testing initiatives, or otherwise.

Section 6. Very few regulations have been promulgated under §6. That is not necessarily the right metric for evaluating the adequacy of the statute. Rulemakings take time and money. If product stewardship and/or voluntary initiatives render formal action under §6 unnecessary, that should be considered a good outcome. Nevertheless, I acknowledge that there has been an erosion of public confidence in TSCA, and in particular section 6. So we must ask: how can that be addressed, and what changes might improve public confidence in TSCA?

I will first address the failed effort to ban uses of asbestos, which has been cited as evidence that the evidentiary burden EPA must meet under section 6 is too high. A careful reading of the court's decision overturning portions of the asbestos ban shows that EPA made procedural and substantive errors of a nature that would require any final rule under any environmental statute to be set aside. EPA did not give proper public notice of a key element of its exposure analysis, that in some cases "completely altered" EPA's assessment, until after the hearings were closed. [1] In the case of asbestos-containing friction products (primarily replacement drum and disk brakes),[2] which accounted for "the lion's share of the proposed benefits of the asbestos regulation," a study commissioned *by EPA* raised significant concerns about the effectiveness of substitute products. One of the study authors testified that the "replacement/substitution of asbestos-based with non-asbestos brake linings will produce grave risks," and that "'the expected increase of skid-related highway accidents and resultant traffic deaths would certainly be expected to overshadow any potential health-related benefits of fiber substitution.'"[3] Other equally significant errors are noted in the court's opinion. The court ruling certainly was disappointing to EPA, which had spent 10 years on the asbestos rulemaking, but the court's decision should not be misunderstood. The asbestos rulemaking failed not because of the statute, but because of errors in the rulemaking.

I believe the failure of the asbestos rulemaking has led to an overstatement of the burdens associated with promulgation of a §6 rule. EPA successfully promulgated several §6 rules before the failed asbestos effort, without becoming embroiled in legal challenges, and without conducting a quantitative risk assessment for every alternative control measure. I believe we should look at that experience before concluding that section 6 can never work.

Section 6 requires EPA to adopt the "least burdensome requirements" necessary to address the identified health or environmental risks. This precludes a ban of a product if a less burdensome approach would protect human health and the environment. Recall that EO 13563 directs agencies to use the "least burdensome tools for achieving regulatory ends."

The "unreasonable risk" standard in section 6 standard is not unique to TSCA. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires EPA to consider "any unreasonable risk to man or the environment" and take "into account the economic, social, and

---

1 *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1212-13 (5th Cir. 1991).

2 The court's opinion related to after-market brakes and the difficulty of installing non-asbestos replacement brakes in vehicles designed to use asbestos brakes. At the time, most new cars were already engineered for non-asbestos brakes.

3 *Id.* at 1224 n. 25 (citing written testimony).

environmental costs and benefits of the use of any pesticide." EO 13563 similarly directs agencies to "take into account benefits and costs, both quantitative and qualitative."

The Senate bill would apply a "reasonable certainty of no harm" safety standard, which EPA uses for food-use pesticides and FDA uses for food contact materials. The bill would require EPA to consider aggregate exposure from all sources, including those outside its jurisdiction. The level of effort that would be required and implications for EPA resources are enormous. Application of this standard to all chemicals regulated under TSCA, regardless of their uses and physical, chemical and toxicological properties, would appear unrealistic.

The Senate bill would provide that an EPA decision that a chemical fails to meet the safety determination would be immune from judicial challenge. Even arbitrary and capricious decision-making could not be overturned. I find that a very troubling concept.

Section 6 of TSCA places the burden on EPA to demonstrate the need for regulation. This is not unique. When EPA promulgates an air quality or emission standard under the CAA, for example, it typically carries the burden of demonstrating the need for the level of protection and/or specific control measures that are proposed. Courts typically give EPA wide latitude to make these kinds of judgments. While the burden should be on industry to develop the information EPA needs to perform its risk management functions, it is not unreasonable, nor out of line with other environmental statutes, to expect EPA to support a proposed regulation under TSCA with good science.

All stakeholders recognize the need for EPA to prioritize its resources. I believe a rational prioritization scheme with reasonable timelines would give greater confidence to the public that significant risks are being addressed in a systematic and timely manner. I offer this as an example of an important area where all stakeholders might be able to get together, and craft a more comprehensive approach to risk management under TSCA.

To conclude my general remarks about TSCA, all stakeholders agree TSCA amendments are needed. We need to understand which perceived shortcomings derive from the statute, which derive from implementation, and make sure the proposed solutions match the problems. Amendments should produce better decisions, not just easier decisions. I cite the EO because I believe TSCA should live by the same principles that govern other statutes and fundamentally should remain risk-based. Important risk management decisions under TSCA should remain subject to judicial review, just as occurs under other environmental statutes.

DecaBDE

I would like to offer a few comments about EPA activities regulating decaBDE, one of the polybrominated diphenyl ethers, under TSCA.

The three major producers and importers of decaBDE in December, 2009 submitted letters to EPA committing to phase out production and importation over a four year period. Some uses could be phased out relatively quickly; some require much longer lead times, and for some even the four-year phase-out might be very challenging or might yet prove infeasible.

EPA has proposed to issue a Significant New Use Rule (SNUR) under TSCA section 5 that would apply to imports of articles containing decaBDE, and also has proposed to require testing of any companies that wish to continue manufacture or import of decaBDE or articles containing decaBDE. The three companies that submitted voluntary commitments to discontinue production and importation of decaBDE generally support these regulatory proposals.

Thus within a reasonable period of time, it appears that manufacture and use of decaDBE in the United States will have been ended, without any action under TSCA section 6. Having said that, I wish to dispel some misunderstandings about decaBDE, and make clear that there has been no failure of TSCA with respect to decaBDE.

First, DecaBDE has been extensively tested. Much of the toxicity testing has been conducted voluntarily by industry and made publicly available, without the need for any test rule under TSCA. A substantial amount of exposure information is available as well.

Second, the available test data and exposure information supports the conclusion that decaBDE can be used safely as a flame retardant. Levels that have been detected in humans are far below levels that might present a concern. Potential exposures from dust are far below levels that might present a concern. DecaBDE does not accumulate in the body. Health Canada recently released a draft health assessment document that found adequate margins of exposure for the most highly exposed age groups of children.

Third, much of the concern about decaBDE originated with a study that used a novel protocol and that has been shown in the published literature to have significant flaws. EPA used this study in 2008 to calculate a safe daily exposure level. Since then the companies funded a much more robust study, following internationally-accepted and EPA-approved protocols, that failed to replicate the findings of the earlier, flawed study. This robust guideline study was published in the peer-reviewed literature in 2011. This study and other published literature support a considerably higher safe daily level than EPA has calculated. The National Academy of Sciences in 2004 calculated a safe daily level that is approximately a 1000-fold higher than the level calculated by EPA. The producers believe the safe daily level calculated by NAS is a scientifically sound value.

Fourth, the companies agreed to sponsor DecaDBE under EPA's Voluntary Children's Chemical Evaluation Program (VCCEP). That effort ended at the end of Tier 1 when EPA and the companies did not reach agreement on whether certain additional environmental fate and transport testing was needed. EPA's testing requests to the companies were rendered moot by their decision to phase out production. However, at the same time, the companies conducted the guideline study described above, without any need for a test rule under TSCA.

Fifth, the companies voluntarily committed to stop production of decaBDE not because they thought the product posed significant risks to health or the environment. Concerns had been raised in the marketplace by state ban bills, and by the flawed study described above. The companies responded to those concerns.

Sixth, CPSC has not conducted any tests that call into question the efficacy of decaBDE as a flame retardant. Rather, a very robust literature supports the use of flame retardants like

decaBDE to slow the spread of flames and increase escape time, and thereby to save lives, not just in household furniture but in many other applications, including electronics, aviation and other transportation.

In summary, the companies committed to end production and importation of decaBDE without EPA taking any action under TSCA section 6. Substantial testing has been conducted by the companies without the need for any test rule under TSCA section 4. The companies support EPA's efforts to promulgate a SNUR under TSCA section 5 that would apply to imported articles containing decaBDE.

I hope my testimony is helpful to the Committee.

Thank you.