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

"REGULATION OF EXISTING CHEMICALS AND THE ROLE OF PRE-EMPTION UNDER SECTIONS 6 AND 18 OF THE TOXIC SUBSTANCES CONTROL ACT"

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INTRODUCTION

Mr. Chairman and distinguished members of the Committee – good afternoon. I would like to begin by thanking the Committee for inviting me to testify today. I consider it a privilege to have this opportunity to contribute to the public discourse on the Toxic Substances Control Act (TSCA). I hope my testimony will prove useful to the Committee.

I am a partner in the law firm of Latham & Watkins LLP. I have practiced in the environmental area, with an emphasis on chemical regulation under TSCA and other environmental statutes, since 1987. I have co-authored two editions of a TSCA Deskbook published by the Environmental Law Institute. My testimony is based on my experience representing and counseling companies and trade associations on issues arising under TSCA and other environmental statutes over the last 26 years. However, I am testifying today solely on my own behalf.

All major stakeholders agree that improvements to TSCA are necessary to achieve the objectives of the statute and increase public confidence in federal chemical regulatory programs. Divergent views have been expressed in prior hearings before this Committee concerning what needs to be fixed and why. I understand the purpose of this hearing is not to advocate any specific

amendments to TSCA or to address any specific legislative proposals, but rather to share perspectives on the current statute.

As directed, my testimony will focus on EPA's experience assessing and regulating existing chemicals under TSCA section 6, and experience under TSCA section 18 pertaining to preemption. It is important to keep in mind 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 mandates.

Additionally, chemical manufacturers have implemented various voluntary initiatives and product stewardship programs over the years to support the safe manufacture and use of their products. Many of these voluntary initiatives have been undertaken in collaboration with EPA and other stakeholders. These initiatives and product stewardship programs help meet the objectives of TSCA, and provide additional context for a discussion about experience regulating chemicals under TSCA.

Section 2 of TSCA states that it is the policy of the United States that "Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." Similarly, Executive Order No. 13563, signed by President Obama on January 11, 2011, states: "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." These similar pronouncements, made 35 years apart, give some indication of the concerns this Committee must address as it considers what amendments to TSCA might best promote the objectives of the statute.

SECTION 6: REGULATION OF EXISTING CHEMICALS

Few rulemaking actions have been taken under section 6 (excluding regulation of PCBs). This has contributed significantly to the erosion of public confidence in TSCA, and is cited as evidence that the burdens on EPA when attempting to regulate under section 6 are too high. The failed attempt to regulate asbestos-containing products also is cited as evidence that section 6 is not workable. I will address first the issue of statutory authority. I then will address what I consider to be the greatest concern relating to EPA's exercise of its section 6 authority, which is the backlog of EPA assessments of existing chemicals. I believe EPA needs a stronger mandate to set priorities and complete safety assessments of chemicals in commerce, to determine whether and how chemicals should be regulated.

Section 6(a) of TSCA gives EPA authority to regulate the manufacture, processing, distribution, use or disposal of a chemical if the Agency has a "reasonable basis" to believe the chemical "presents or will present an unreasonable risk to health or the environment." Section 6 enumerates various regulatory options – from an outright ban to warning and labeling requirements – and provides that EPA may impose one or more of the enumerated requirements "to the extent necessary to protect adequately against such risk using the least burdensome requirements."

When promulgating rules under section 6, EPA must take into account the health and environmental effects of the substance, the magnitude of exposure, the benefits of the substance, the availability of substitutes and their potential health and environmental impacts, and the reasonably ascertainable economic consequences of the proposed rule. Specific hearing requirements are set forth in section 6(c), and any rule that is promulgated must be supported by "substantial evidence" in the rulemaking record considered as a whole.

The Agency also must determine whether the concern could be better addressed by EPA or another agency under another statute. If the risk of injury to health or the environment can be

eliminated or reduced under another statute administered by EPA, then section 6(c) requires EPA to utilize its authority under that statute unless the Agency determines that it is in the public interest to act under TSCA. If the chemical risk may be prevented or sufficiently reduced by action under a federal law not administered by EPA, the Agency must refer information on the chemical's risk to the agency administering the other law. Pursuant to section 9(a), EPA may not take action under TSCA Section 6 if the other agency finds no unreasonable risk or initiates regulatory action.

As noted, 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. Similarly, Executive Order 13563 directs executive agencies to "identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends." The Executive Order compels each agency to "tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives."

The "unreasonable risk" standard in section 6 is not unique to TSCA. For example, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for non-food use pesticides requires EPA to consider "any unreasonable risk to man or the environment" and take "into account the economic, social, and environmental costs and benefits of the use of any pesticide." Executive Order 13563 similarly directs EPA and other executive agencies in their regulations to "take into account benefits and costs, both quantitative and qualitative." The Executive Order directs each agency to "propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs."

Section 6 of TSCA places the burden on EPA to demonstrate the need for regulation. This also is not unique. When EPA promulgates an air quality or emission standard under the Clean Air Act, 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.

EPA applies numerous health-protective assumptions when making "unreasonable risk" findings, whether under TSCA or other environmental statutes. EPA typically sets the safe level in humans at a level 100- to 1000-fold (or more) below a dose that produced no adverse effect in the most sensitive animal study, and uses conservative assumptions concerning level, frequency and duration of exposure. The end result is that EPA regulates based on theoretical upper bound estimates of risk, with the understanding that true risks are likely to be much lower than upper bound estimates, and could be zero. EPA has stated this explicitly in rulemakings under the Clean Air Act, for example. Again, courts give EPA considerable latitude to make these kinds of judgments.

The failed effort to ban uses of asbestos is often cited as evidence that TSCA does not give EPA sufficient authority to regulate chemicals. A careful reading of the court's decision shows that EPA made procedural and substantive errors that compelled the court to set portions of the rule 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] Asbestos-containing friction products (primarily replacement drum and disk brakes) accounted for "the lion's share of the proposed benefits of the asbestos regulation," but 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

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

benefits of fiber substitution.'"[2] Other equally significant errors are noted in the court's opinion. The ruling certainly was disappointing to EPA, which had spent 10 years on the asbestos rulemaking, but I would urge careful review of the court's decision before any conclusions are drawn.

Before the failed asbestos rulemaking, EPA had successfully promulgated several section 6 rules, albeit on a much smaller scale, without legal challenges, and without conducting a quantitative risk assessment for every alternative control measure (one of the complaints emanating from the *Corrosion Prof Fittings* decision). Further, the court in *Corrosion Proof Fittings* did not completely vacate the asbestos rule; it upheld EPA's ban on products not currently being produced in the United States, and the ban on unknown, future uses of asbestos. The court actually started with a "presumption of validity" in favor of EPA's rule, but found such fundamental errors in the rulemaking that all product-specific bans were struck down.

Witnesses at the prior hearings of this Committee have noted that conducting a rulemaking, whether under TSCA or any other environmental statute, can be time-consuming and challenging for the Agency and can take several years. Nevertheless, I would submit that one lesson of *Corrosion Proof Fittings* is that procedural requirements and substantive criteria should not be lightly set aside, as they help ensure the quality and objectivity of regulatory decisions.

Section 6 of TSCA was crafted to support sound regulatory decisions that protect human health and the environment while not placing undue economic burdens on companies that manufacture, process or use chemicals. The similarities to several provisions in Executive Order 13563 are noteworthy and provide context for evaluating the requirements of TSCA section 6. Changes to section 6 should not simply make it easier for EPA to ban the use of chemicals, but should support sound regulatory decisions that meet all the objectives of the statute. Decisions

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[2] *Id.* at 1224 n. 25 (citing written testimony).

made under TSCA should be governed by the same principles that govern other environmental statutes, and fundamentally should remain risk-based.

It remains true that very few rulemaking actions have been taken by EPA under section 6. That is not necessarily the right metric for evaluating the adequacy of the statute as a whole, as it does not account for assessments of existing chemicals and uses by EPA that did not result in regulation because chemicals or activities were found not to present significant risks or to be of low concern for further evaluation. It also ignores accomplishments under other sections of the statute, including significant new use rules promulgated under section 5(a) to curb uses of some existing chemicals. Further, it ignores voluntary product stewardship actions and other voluntary initiatives that have at times rendered formal action under section 6 unnecessary. Many of these activities addressing existing chemicals are described on EPA's website, and they are substantial. They have often involved partnerships with industry and other stakeholders, and international cooperation. But the lack of rulemaking actions under section 6 receives more attention, and continues to undermine public confidence.

This leads to the concern I expressed at the beginning of this section of my testimony. There is still a backlog in EPA's assessment of existing chemicals. I believe addressing this backlog should be the top priority for bringing EPA's regulation of existing chemicals in line with regulation of new chemicals. A clear mandate and adequate resources are needed to enable EPA to assess in a timely manner the potential risks to health and the environment from chemicals that are present in commerce in significant quantities. Once risks have been assessed, action can be taken where necessary. Additionally, the public also can take comfort with respect to those chemicals and uses that EPA determines present low concern.

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 identified and addressed in a systematic and timely manner. Some chemicals and uses can be quickly identified as low concern. Others require more effort to characterize potential risks and ensure safety. Any new mandate should give EPA flexibility (indeed, should require EPA) to set priorities and direct resources accordingly, so that the greatest number of high priority chemicals can be assessed within reasonable timeframes.

In a prior Administration, EPA announced a Chemical Assessment Management Program (ChAMP) that was intended to accelerate dramatically the preparation of screening-level assessments for approximately 7,000 chemicals for which periodic exposure information reporting was being required under the Inventory Update Rule, now called the Chemical Data Reporting Rule. EPA did this on its own, with no statutory mandate and no change in its authority under section 6. The initiative was replaced in the current Administration in favor of Chemical Action Plans that focused on a very short list of chemicals, and more recently EPA has implemented a TSCA Work Plan which also will address a relatively small subset of existing chemicals. This is not the first time EPA has abandoned one chemical risk management initiative for another. I believe it would be very helpful for EPA to have a strong mandate to increase the rate at which it identifies and assesses high priority compounds, with follow-through to completion.

SECTION 18: PREEMPTION

As you are aware, the concept of preemption is rooted in Article VI of the Constitution, which provides that the laws of the United States shall be the supreme law of the land, notwithstanding the laws of any states. The purpose of preemption is to prevent state and local laws that might thwart the effectiveness of a national legislative and regulatory scheme. Preemption discourages state law requirements that would hinder interstate commerce by placing varying requirements on companies operating across more than one state. Preemption provisions are found in several different Federal laws regulating products, including the Consumer Product

Safety Act (CPSA), the Food, Drug, and Cosmetic Act (FDCA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

TSCA section 18 preempts state and local law only when EPA has issued a rule under section 4 (testing), 5 (approval of new chemicals), or 6 (regulation of existing chemicals). If EPA has not acted, states and localities are free to act. If, however, EPA has issued a rule under section 4, 5, or 6, states and localities must apply to EPA for an exemption from preemption prior to enacting additional restrictions. EPA may grant the exemption only if the state or local law would provide a higher degree of protection from risk of injury to human health or the environment than the TSCA rule and would not unduly burden interstate commerce. The state or local law also must not cause the manufacturing, processing, or distribution in commerce of the substance, mixture or article to be a violation of any TSCA requirement.

Notably, several types of state laws are not subject to preemption and the exemption process. State or local laws governing the manner or method of disposal of toxic substances are not preempted where EPA has issued a relevant disposal rule pursuant to TSCA section 6(a)(6). State or local laws that are identical to a rule issued by EPA under section 5 or 6 are not subject to preemption. State or local laws that were adopted under the authority of another federal law such as the Clean Air Act also are not preempted. Additionally, a state or local law may prohibit the use of a substance or mixture, other than its use in the manufacture or processing of other substances or mixtures.

As a practical matter, preemption has rarely come into play under TSCA because EPA has promulgated few rules under section 6 (other than regulation of PCBs), and states generally have not been in the business of regulating new chemicals (TSCA section 5) or requiring testing of existing chemicals (section 4). One TSCA preemption case is *Rollins Environmental Services (FS), Inc. v. The Parish of St. James*, in which the Fifth Circuit Court of Appeals found that

preemption applied to a St. James Parish, Louisiana, ordinance prohibiting commercial solvent cleaning in certain areas as part of an effort to ban PCB disposal activities.[3] EPA had promulgated comprehensive PCB disposal regulations under TSCA section 6(e)(1), and St. James Parish did not apply for an exemption. The court found that "[i]f every locality were able to dodge responsibility for and participation in this program through artfully designed ordinances, the national goal of safe, environmentally sound toxic waste disposal would surely be frustrated."[4] Thus, preemption in this case met the goal of not allowing state law to thwart a national regulatory scheme.

As noted, the CPSA, FDCA, and FIFRA also contain preemption provisions. A brief overview of these preemption provisions will provide context for evaluating preemption under TSCA.

Preemption under the CPSA works in a manner similar to preemption under TSCA.[5] If the CPSC has issued a rule pursuant to the CPSA that addresses the risk of injury associated with a consumer product, non-identical state and local standards relating to product performance, composition, packaging, labeling, etc., that address the same risks addressed by the CPSC are preempted. As with TSCA, states and localities are free to act if the CPSC has not. The CPSC may exempt non-identical state and local standards so long as the standard does not unduly burden interstate commerce and provides a significantly higher degree of protection from risk of injury than the CPSC's consumer product safety standard.

Under the FDCA, no state or locality may establish any requirement that is not identical to an FDA regulation governing over the counter (OTC) drugs and medical devices.[6] States and

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[3] *Rollins Environmental Services (FS), Inc. v. The Parish of St. James*, 775 F.2d 627 (5th Cir. 1985).

[4] *Id.* at 637.

[5] 15 U.S.C. § 2075.

[6] 21 U.S.C. § 360k, 379r.

localities are free to act if FDA has not acted. States and localities may apply to the FDA for an exemption from preemption. The preemption provision for OTC drugs contains an exemption for product liability actions.

Under FIFRA, a state may not regulate the sale or use of any federally registered pesticides or impose any packaging or labeling requirements that are different from those required by EPA under FIFRA.[7] However, a state may permit registration for additional uses of federally registered pesticides to meet special local needs, subject to a right of cancellation by EPA.

These other statutes demonstrate that preemption is an important concept, particularly in the area of product regulation where state laws or regulations could create conflicts with federal requirements or otherwise pose significant burdens on interstate commerce.

I hope my testimony is helpful to the Committee.

Thank you.

[7] 7 U.S.C. § 136v.