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OF THE

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INTRODUCTION

Mr. Chairman, distinguished members of the Committee and staff – good morning. 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). This is an important subject, and I hope that my comments 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 been with the firm since 1982, and have practiced in the environmental area, with an emphasis on chemical regulation under TSCA and other environmental statutes, since 1987. I have co-authored a *TSCA Deskbook* published by the Environmental Law Institute, and have been involved in numerous rulemaking proceedings arising under various sections of TSCA. My testimony is based on my experience representing and counseling companies and trade associations on issues arising under TSCA and other chemical regulation statutes over the last 19 years. However, the views I will express today are solely my own.

TSCA section 2 states that it is the policy of the United States that:

- (1) Adequate data should be developed with respect the effect of chemical substances and mixtures on health and the environment;
- (2) Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment; and
- (3) 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.

The question before the Committee today is whether the provisions of TSCA give EPA the authority it needs to achieve these objectives. I believe the answer is “yes.”

In my judgment, TSCA is a well-crafted statute that has stood the test of time quite well.

SCOPE OF TESTIMONY

My testimony will focus on three sections of the statute:

- **Section 5** pertaining to review, testing and control of new chemicals;
- **Section 4** pertaining to the testing of existing chemicals; and
- **Section 6** pertaining to the regulation of existing chemicals.

I will discuss whether the statutory language in each section is appropriate and sufficient to enable EPA to perform its functions under the Act. There are a number of issues concerning how EPA has implemented each of these sections of TSCA; for the most part, I will not discuss those implementation issues, except insofar as they are relevant to assessing the adequacy of the statutory language. I do believe EPA could improve its performance under TSCA by addressing some of the implementation issues.

Also, it is important to understand that TSCA does not stand alone, and actions taken by EPA under TSCA represent only a small part of the total chemical management story in the United States. 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 manufacture and use of chemicals under their respective statutory authorities.

Additionally, chemical manufacturers have adopted 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. Again, I will focus primarily on the language of the statute, and defer to others to address the voluntary initiatives and product stewardship efforts that help meet the objectives of TSCA.

This testimony assumes the reader is generally familiar with the provisions of TSCA and EPA’s principal accomplishments under each section, as much of that information has been provided elsewhere.

Finally, I 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.

SECTION 5: NEW CHEMICALS

The strength of section 5 of TSCA lies in its flexibility. The provisions of section 5 recognize implicitly that industrial chemicals are not all alike; some are readily determined to have low toxicity and to be relatively innocuous, while others present significant toxicity concerns that require close scrutiny before commercial manufacture is allowed to commence. Section 5 gives EPA flexibility to vary its assessments of new chemicals according to the attributes and expected uses of each substance. In this way, EPA is able to ensure that the introduction of new chemicals into commerce does not pose unreasonable risks, without imposing undue economic burdens or unnecessary barriers to innovation.

Many new chemicals qualify for complete or partial exemptions from the premanufacture notice (PMN) requirements. Section 5 expressly authorizes exemptions for substances manufactured or processed only in small quantities solely for R&D, for substances manufactured or processed for test marketing purposes, and for non-isolated intermediates. Section 5(h)(4) also authorizes EPA to promulgate rules exempting other categories of new chemical substances from all or part of the PMN requirements, if the Agency has determined that the substances “will not present an unreasonable risk of injury to health or the environment.”

EPA has used this authority to create additional partial exemptions for polymers, chemicals that will be produced only in low volumes, and chemicals for which the manufacturer is able to demonstrate low release and exposure. EPA also has created exemptions for certain categories of chemicals that are produced but have no separate commercial purpose, such as impurities. Thus, section 5 gives EPA authority to streamline the new chemical review process for categories of chemicals that can be determined upfront not to pose unreasonable risks to health or the environment. In this way, section 5 promotes the efficient use of EPA resources, and also avoids imposing unnecessary burdens on industry.

Some new chemical substances do not qualify for an exemption, but can readily be determined to pose little or no risk to health or the environment based on information provided with the PMN, use of EPA models, and comparison to other previously approved substances (using a methodology known as structure activity relationship, or SAR). In fact, according to EPA officials, the majority of new chemicals submitted for review can be screened out as not requiring further review based on screening models that show low potential for toxicity, or based on other information (anticipated uses, potential for releases and exposures) demonstrating low potential risks.¹ Again, section 5 allows EPA the flexibility to make these judgments, and to adjust the new chemical review process accordingly.

Many new chemical substances, however, do require close scrutiny before they enter commerce. With regard to these substances, some stakeholders have expressed a concern that there is no minimum base set of tests that must be submitted with the PMN, to facilitate EPA review. However, section 5 effectively gives EPA the authority to require the PMN submitter to conduct the testing that EPA deems necessary in each case to support a determination whether the

¹ GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, at 12 (June 2005) [hereinafter *GAO Report*].

manufacture or use of the PMN substance will pose unreasonable risks. Thus, additional authority is not necessary.

Specifically, section 5(e) gives EPA authority to prohibit or limit the manufacture and use of any new chemical substance where: (1) existing information is insufficient to permit a “reasoned evaluation” of the substance’s health and environmental effects; and (2) *either* the substance may present an unreasonable risk of injury to health or the environment, *or* the substance will be produced in substantial quantities and there will or may be substantial human or environmental exposure. EPA has used its authority under section 5(e) to require testing of numerous PMN substances. EPA also has developed a guidance document that identifies numerous chemical categories of concern, and identifies the type of test data that typically will be required for a PMN substance in each category.

In some cases, the PMN submitter has agreed to conduct the testing during the PMN review process (by also agreeing to suspend the statutory PMN review period during the conduct of the testing). In other cases, the testing requirements have been incorporated into a consent order issued under section 5(e). In either event, EPA has received the information that it has deemed necessary to assess the potential risks associated with the new chemical.

Additionally, EPA has authority under section 5(a) of TSCA to promulgate a significant new use rule (SNUR) for a PMN substance, and thereby to require a company to submit a significant new use notice (SNUN) to EPA before engaging in uses identified in the SNUR. SNUNs operate much like PMNs; they enable EPA to evaluate new uses of a chemical substance before they are undertaken and decide whether such uses should be subject to special regulations. EPA has used its SNUR authority to codify the restrictions in section 5(e) orders so they apply to subsequent manufacturers of the chemical, and also to control the uses of existing, TSCA inventory-listed chemicals that raise concern.

EPA’s relatively recent use of SNURs in connection with the voluntary phase-out of perfluoroalkyl sulfonate (PFAS) substances is a good example of how EPA can use a SNUR to address hazards associated with an Inventory-listed substance. In May 2000, the sole U.S. manufacturer of perfluorooctanyl sulfonate (PFOS) announced it would voluntarily withdraw production. The phase-out was completed in 2002. Following this, the EPA issued a SNUR in March 2002 limiting any new manufacturing or importing of 13 PFAS chemicals that were being produced by 3M.² In December 2002, the EPA issued a second SNUR adding 75 additional chemicals, but excluding “low volume, controlled exposure uses in: semiconductor manufacture,

² 67 Fed. Reg. 11,014, 11,020 (Mar. 11, 2002) (Perfluoroalkyl Sulfonates. Proposed Significant New Use Rule) (“EPA determined that the proposed SNUR should be promulgated as final for the 13 chemicals, employed principally in coatings for textiles, carpet, apparel, leather, and paper, on which no comments were received and which 3M, the sole manufacturer, confirmed were discontinued from manufacture before Dec. 31, 2000.”). In the original proposed SNUR, these chemicals were referred to collectively as perfluorooctylsulfonates, or PFOS, but commenters noted that this generic usage of the term PFOS was inconsistent with the use by the manufacturer of PFOS to refer only to chemicals with an eight-carbon, or C8, chain length.

aviation hydraulics, and photography.”³ Thus, through close cooperation with industry and use of its authority under section 5(a)(2), the EPA was able to extend the voluntary phase-out by the sole manufacturer to all prospective producers and importers of the subject compounds.

Also, under section 5(f) of TSCA, if EPA determines a new chemical substance “presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 2605 [section 6] of this title can protect against such risk,” the Agency may issue a proposed rule under TSCA section 6(a) that is effective upon its publication in the Federal Register, or alternatively may issue an order or may apply for an injunction in federal court to prohibit the manufacture, processing, or distribution in commerce of the substance.

As of September 30, 2002, EPA had taken the following actions:

- Issued 1243 section 5(e) orders (500 with SNURs, and 743 without);
- Promulgated an additional 437 non-section 5(e) SNURs; and
- Taken four actions under section 5(f).

Further, 1552 PMNs had been withdrawn in the face of impending EPA action. Thus, it is clear that EPA has exercised its authority under section 5 to give careful scrutiny to new chemical substances where appropriate. EPA in fact has imposed substantial controls or effectively prohibited the manufacture of more than 3200 chemical substances.⁴

It is noteworthy that under section 5(e)(1)(C), a PMN submitter may file objections with EPA to a proposed 5(e) order, and EPA is then forced to go to court to obtain an injunction to prohibit or limit the manufacture or use of the PMN substance (unless EPA determines that the objections have merit and alters or withdraws the proposed order). To my knowledge, no PMN submitter has ever forced EPA to go to court to obtain such an injunction. In other words, no PMN submitter has ever challenged a 5(e) order judicially; the PMN submitter has either complied or withdrawn the PMN. This means in every case EPA’s data requirements and control requirements have been met, or the PMN has been withdrawn.

PMN submitters have not always been pleased with EPA’s proposed testing requirements or control requirements. Some PMNs have been withdrawn because the PMN submitter did not agree with the proposed testing or control requirements, and the costs associated with those requirements rendered commercialization impractical. But there has never been a legal challenge. Thus, while there may be issues around the edges pertaining to how EPA has implemented section 5 of TSCA, there does not appear to be any basis for arguing that EPA lacks authority to assess or regulate new chemical substances. To the contrary, the provisions of section 5 appear well-designed to give EPA the necessary flexibility and discretion to give each

³ Battelle, *Overview: Office of Pollution Prevention and Toxics Programs*, at 18-19 (Dec. 24, 2003) [hereinafter *Battelle Report*]; see also 67 Fed. Reg. 72,854, 72,859 (Dec. 9, 2002) (Perfluoroalkyl Sulfonates; Significant New Use Rule).

⁴ *Battelle Report*, *supra* n.3, at 11.

PMN substance the level of scrutiny it merits, and to impose such restrictions on manufacture and use as are necessary to prevent unreasonable risks to health and the environment.

SECTION 4: TESTING OF EXISTING CHEMICALS

TSCA section 4 provides EPA with authority to impose health and environmental effects testing requirements on chemical manufacturers and processors. EPA has authority to require testing of existing chemicals under two circumstances: when a chemical “may present an unreasonable risk” (the 4(a)(1)(A) or “A” finding), or when a chemical “is or will be produced in substantial quantities” and either “enters or may reasonably be anticipated to enter the environment in substantial quantities,” or “there is or may be significant or substantial human exposure” (the 4(a)(1)(B) or “B” finding). In each case, EPA also must show that (i) there is insufficient data or experience to determine whether manufacture and use pose unreasonable risks to health or the environment, and (ii) testing is necessary to develop this data. Over the years, EPA has made significant progress in developing testing programs for existing chemicals and has issued detailed regulations governing development of test rules, negotiation of enforceable testing consent agreements, and compliance with testing requirements under test rules and consent orders.

EPA has obtained test data for more than 200 substances under TSCA section 4 test rules or enforceable consent agreements. Many more chemicals have been screened for testing and determined by EPA or the Interagency Testing Committee (ITC) to be low priority for testing or not to require further testing, and testing of many more substances has occurred on a voluntary basis without the need for a test rule. The High Production Volume Challenge Program, which involved more than 2100 substances, is certainly a noteworthy example of a voluntary testing initiative, but many individual substances also have been the subject of voluntary testing that has made action under section 4 of TSCA unnecessary.

There has been some suggestion that the findings required by section 4 of TSCA are overly burdensome on EPA, and render section 4 an ineffective vehicle for obtaining test data.⁵ I find these arguments unpersuasive. The burden of proof that EPA must meet to support a test rule in fact is quite modest under both the “A” finding and the “B” finding.

As already described, the statute only requires EPA to show that a substance *may* present an unreasonable risk, or *may* reasonably be anticipated to enter the environment in substantial quantities, or that there is or *may* be significant or substantial human exposure. When evaluating “unreasonable risk” under section 4, the EPA has stated that its determination of whether a chemical “may present” a hazard would not be based on definitive scientific data, but of necessity would involve reasonable scientific assumptions, extrapolations and interpolations.

The EPA has also stated that it is sufficient to show that exposure *may* arise because of activities associated with the manufacture, use, etc. of the chemical. The D.C. Circuit Court of Appeals endorsed the Agency’s contention that the mere *potential* for human exposure is sufficient to

⁵ GAO Report, *supra* n.1, at 26.

support a “may present an unreasonable risk” finding under section 4.⁶ The minimum burden that the court required was that the EPA show the risk is “a more-than-theoretical probability,” and the court said that EPA may demonstrate the potential for exposure based on circumstantial evidence.⁷ Once the EPA has established this “more-than-theoretical probability,” the burden shifts to industry to rebut this by presenting evidence to the contrary.

In 1990, industry challenged the cumene test rule which was based on a “B” finding. The Fifth Circuit found the EPA’s explanation of the basis for its “B” finding inadequate and remanded.⁸ On remand, EPA released the B Policy⁹ and applied it to the test rule that had been challenged. No further legal challenge was pursued. (The court had declined to stay testing, so testing had in fact already been completed.) The B Policy establishes standards and criteria for making “B” findings. EPA defined substantial production as one million pounds or more per year. EPA defined “substantial” human exposure differently for three classes of people: workers (1,000 people), consumers (10,000 people), or the general population (100,000 people). EPA defined “significant” human exposure in terms of the nature of the exposure (i.e., if the exposure is more direct than typical exposure. Since then, these criteria have proven relatively easy to apply).

I do not agree with the suggestion that EPA should be permitted to require testing based solely on a production volume trigger and a determination that testing is necessary.¹⁰ Such an approach would effectively negate consideration of potential exposure.¹¹ EPA’s B Policy expressly recognizes that “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.¹² Eliminating consideration of the potential for human or environmental exposure would make it marginally easier for EPA to promulgate test rules, but it would not provide a more scientifically sound basis for making testing decisions. Such a change also would not be consistent with EPA’s current policies and practices under TSCA section 4.

I do believe EPA could improve its performance under TSCA section 4 in a number of ways. EPA has issued few test rules in recent years (perhaps because substantial resources have been devoted to the HPV Challenge Program), and some testing proposals have languished unfinished for many years. Some suggestions for improvement include:

⁶ Chem. Mfrs. Ass’n v. EPA, 859 F.2d 977 (D.C. Cir 1988).

⁷ *Id.* at 984-88.

⁸ Chem. Mfrs. Ass’n v. EPA, 899 F.2d 344 (5th Cir. 1990).

⁹ EPA, *TSCA Section 4(a)(1)(B) Final Statement of Policy: Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure*, 58 Fed. Reg. 28,736 (May 14, 1993) [hereinafter, “B Policy”].

¹⁰ *GAO Report, supra* n.1, at 27.

¹¹ EPA has recognized on many occasions that production volume is not a surrogate for exposure or even potential exposure.

¹² *B Policy, supra* n. 9, at 28,742.

More timely responses to industry alternative testing proposals. I have worked with numerous chemical industry groups that have submitted alternative testing proposals to EPA in response to testing proposals issued under TSCA section 4. The testing proposals have been intended to meet EPA's objectives in a more cost-effective manner, sometimes by making greater use of existing studies. EPA has sometimes taken as much as two years to respond to such proposals. More timely responses would help improve EPA's track record under section 4.

More flexibility in testing approaches. Perhaps because of the time and expense associated with the development of proposed test rules, EPA at times has not seemed open to alternative approaches. I have worked with chemical industry groups that have proposed that EPA permit testing to proceed in phases, such that the companies would conduct a portion of the proposed testing initially, and then ask EPA to reconsider, based on the results of the initial testing, whether the balance of the proposed testing was still necessary. These proposals have all been rejected (sometimes after an extended period of delay). In these cases, I believe more flexibility on the part of the Agency would have allowed testing on the subject chemicals to commence in a reasonable and cost-effective manner, without compromising the Agency's ability to obtain the test data that it deemed necessary.

I believe following the foregoing suggestions would lead to better testing decisions, and would improve EPA's track record under section 4. However, I do not believe the statutory criteria need to be modified. I believe the criteria in the statute provide a sound basis for making scientifically appropriate testing decisions.

There have been very few legal challenges to test rules promulgated under section 4. Indeed, there has been relatively little litigation under TSCA generally, especially compared to the steady drumbeat of litigation under other environmental statutes, such as the Clean Air Act. The few legal challenges under TSCA section 4 have generally affirmed EPA's broad authority to require testing.

SECTION 6: REGULATION OF EXISTING CHEMICALS

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*" (emphasis added).

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 the reasonably ascertainable economic consequences of the proposed rule. A rule promulgated under section 6 must be supported by "substantial evidence" in the rulemaking record considered as a whole. Before EPA can regulate under section 6(a), the Agency also must determine whether the problem could be better addressed by EPA or another agency under another statute.

EPA's ability to regulate effectively under TSCA section 6 has been called into question over the years because of the Fifth Circuit's decision in *Corrosion Proof Fittings v. EPA*,¹³ which overturned a ban on certain asbestos-containing products. If EPA cannot ban asbestos, the argument goes, then what can it ban? The Government Accountability Office (GAO) has suggested ways that the legal requirements of section 6 might be loosened, ostensibly to make EPA's job easier.¹⁴ However, as will be demonstrated below, the failures in the asbestos rulemaking were failures in implementation, and not caused by deficiencies in the statute.

EPA regulated several substances under section 6(a) during the early years of TSCA. Starting in 1978, EPA used section 6(a) to ban nonessential uses of fully halogenated chlorofluoroalkanes, which were used primarily as propellants for aerosols. In 1980, EPA issued a rule regulating disposal of wastes containing TCDD, a form of dioxin. In 1990, EPA issued a final rule prohibiting the use of hexavalent chromium-based water treatment chemicals in comfort cooling towers. In 1984, EPA issued three immediately effective proposed rules under section 6(a) to address unreasonable risks identified during the review of PMNs. The three chemical substances affected by the rules were intended for use in metalworking fluids, and EPA was concerned that the addition of certain nitrosating agents could lead to the formation of a substance shown to be carcinogenic in animals. Accordingly, EPA banned the use of nitrosating agents in metalworking fluids containing the PMN substances. EPA used its authority under section 5(f)(2) to make the proposed rules under section 6(a) effective immediately.

EPA was not as successful with its attempt to regulate asbestos. EPA's asbestos rule under section 6 was promulgated in 1989 and banned most uses of asbestos still in commerce, including asbestos-containing floor materials, clothing, roofing and other building materials, pipeline wrap, friction products (e.g. brakes), and other automotive products. EPA also banned all new uses of asbestos, and all existing uses that were not currently in production in the U.S.

In handing down its decision in *Corrosion Proof Fittings*, the court upheld EPA's determination to proceed under section 6, instead of deferring to other federal agencies under TSCA section 9. The court also upheld EPA's ban on products not being produced in the United States currently, and the ban on unknown, future uses of asbestos. Concerning the bans on existing asbestos-containing products, the court articulated a "presumption of validity" in favor of EPA's rule, and rejected a number of arguments advanced by industry petitioners challenging the bans. However, the court found such fundamental errors in EPA's methodology and rationale for banning asbestos-containing products that all product-specific bans were struck down in their entirety. The asbestos rule and the court's decision are described more fully in an attachment to this testimony. A few of the Agency's errors are highlighted in the following paragraphs.

Inadequate notice of a key element of EPA's analysis. EPA used "analogous exposure" data – exposure data obtained under comparable circumstances to the circumstances being addressed – to calculate expected benefits of the asbestos bans. The court found that for some products, use of the analogous exposure estimates constituted the bulk of EPA's analysis,¹⁵ and in some cases

¹³ 947 F.2d 1201 (5th Cir. 1991).

¹⁴ *GAO Report*, supra n.1, at 34.

¹⁵ *Corrosion Proof Fittings*, 947 F.2d at 1212.

the analogous exposure analysis “completely altered the EPA’s calculus and multiplied four-or five-fold the anticipated benefits.”¹⁶ Yet EPA did not disclose that it was relying on “analogous exposure” data until after the hearings were closed.

Failure to justify not pursuing less burdensome alternatives. The Court found EPA gave inadequate consideration of less burdensome alternatives. EPA did give some consideration to labeling asbestos products and stricter workplace rules. However, the court found EPA’s analysis inadequate, because EPA “rejected calculating how many lives a less burdensome regulation would save, and at what cost.”¹⁷ EPA failed to consider adequately the less burdensome options because it believed there was no level of asbestos exposure that would pose zero risk. However, as the court correctly noted, “[r]educing risk to zero . . . was not the task that Congress set for the EPA in enacting TSCA.”¹⁸ EPA misconstrued its authority under section 6 – aiming for zero risk instead of eliminating “unreasonable risk” – and as a result failed to address adequately the statutory requirement that it employ the *least burdensome* alternative necessary to protect against *unreasonable* risks.

The court’s opinion should not be construed to require a *quantitative* assessment of the costs and benefits of every regulatory option, starting with the least burdensome, in every section 6 rulemaking. In other successful section 6 rulemakings, EPA has considered and rejected less burdensome alternatives without undertaking such a quantitative analysis.

Inflated Estimates of Benefits. When calculating the workplace benefits of the bans, the court found that did not consider currently available control technologies that could have provided improved workplace conditions. Additionally, the court criticized EPA’s method of calculating the present value of future health benefits, which the court believed inflated potential health benefits from the product bans.

Failure to Consider Harm From Use of Substitutes. In the case of asbestos-containing friction products (primarily replacement drum and disk brakes),¹⁹ 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 and potential health risks 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.”²⁰ Further, many of the EPA’s own witnesses conceded on cross-examination that the non-asbestos fibrous substitutes would pose cancer risks upon inhalation. Ultimately, the court concluded that “a death is a

¹⁶ *Id.* at 1213 n.11.

¹⁷ *Id.* at 1216.

¹⁸ *Id.* at 1217.

¹⁹ Notably, 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 engineered for non-asbestos brakes.

²⁰ *Id.* at 1224 n.25 (citing written testimony).

death, whether occasioned by asbestos or by a toxic substitute product.”²¹ EPA could not ignore the risks and possible toxic effects of the proposed substitutes for asbestos once the potential concerns were brought to the Agency’s attention.

Other equally significant errors are noted in the court’s opinion. It is apparent that the asbestos rule did not fail because of the requirements of section 6. As the court stated in its conclusion, EPA’s product-specific bans were rejected because of “the agency’s reliance upon flawed methodology and its failure to consider factors and alternatives that TSCA explicitly requires it to consider.” One gets the impression, from reading the opinion, that the court was deeply troubled by the number of ways the reasoning in the final rule was skewed in favor of its proposed outcome, as reflected by the court’s repeated references to “flawed methodology” and “ cursory,” “cavalier” and “meaningless” treatment of data. I say this not to be critical of EPA, but because it is important that the court’s decision not be misunderstood.

The lesson that should be learned from *Corrosion Proof Fittings* is not that section 6 cannot work. The lesson is that no matter what the product, when acting under section 6, EPA must consider all relevant information, conduct proper procedures, and present a reasonable basis for its decision.

The GAO Recommendations

“Least Burdensome Requirements” test. GAO has suggested that TSCA section 6 might be amended to eliminate the requirement to demonstrate that the regulatory option chosen is the “least burdensome requirement” necessary to address the identified health or environmental risks. However, before EPA bans the use of a product, it is not unreasonable to require the Agency to show that there is no less burdensome alternative that would be sufficient to protect human health and the environment. Stated differently, if there is a less burdensome alternative that would be adequately protective of human health and the environment, there would seem to be no justification for not using it, and no justification for banning a product that has proven to be valuable in commerce. Further, notwithstanding the result in *Corrosion Proof Fittings*, if EPA determines that a ban is the least burdensome requirement, the Agency should not be concerned that its judgments will be easily second-guessed by the courts. To the contrary, if regulations imposed under section 6 are based on consideration of the relevant factors, adequately explained and promulgated through proper procedures, they will receive deferential treatment by courts.²² EPA made the “least burdensome requirement” determination successfully in each of its other section 6(a) final rules.

“Unreasonable Risk” standard. GAO also has suggested that section 6 might be amended to replace the requirement to demonstrate an “unreasonable risk” with a requirement to show a

²¹ *Id.* at 1221.

²² *Corrosion Proof Fittings*, 947 F.2d at 1214 (citing *Envtl. Defense Fund v. EPA*, 636 F.2d 1267, 1277 (D.C. Cir. 1980) (“Under the substantial evidence standard, a reviewing court must give careful scrutiny to agency findings and, at the same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise.”)).

“significant risk.” GAO indicates that finding “significant risk” would require EPA to show that the “risks are substantial or serious.” Moving from “unreasonable” to “significant” risk, however, would be inconsistent with several other provisions of TSCA, which also use the phrase “unreasonable risk” and clearly reflect congressional intent that EPA consider health and environmental impacts *and* social and economic impacts when regulating under TSCA.²³ This congressional intent is stated explicitly in section 2(c): “[i]t is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter.”²⁴

The “unreasonable risk” standard requires a balancing of the nature of the potential harm being addressed, the probability of the harm occurring, and the harm that would result from the rule. Thus, full consideration is given to the nature of the potential adverse health or environmental effects being addressed, and the likelihood of that harm occurring. To suggest, however, that EPA might consider imposing a ban on valuable commercial products without any consideration of the potential social or economic impacts of the ban clearly is not consistent with congressional intent for how EPA should implement its authority under TSCA. The asbestos rule, in fact, demonstrates the importance of considering the potential impacts of any product ban, given that there was credible evidence, supported by an EPA-sponsored study and EPA witnesses, that the ban on asbestos brakes for after-market use could cost more lives than it was projected to save.

TSCA is by no means unusual in requiring EPA to consider potential social and economic impacts of its regulatory actions. For example, 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 environmental costs and benefits of the use of any pesticide.” Pesticides are subject to very rigorous scrutiny, perhaps more so than any other category of products, and to my knowledge the “unreasonable risk” standard has not prevented EPA from exercising its authority in a prudent and health-protective manner.

In short, GAO’s suggestion that the “unreasonable risk” standard in section 6 be replaced with a “significant risk” standard would be inconsistent with other provisions of TSCA and contrary to clear congressional intent, and also is not necessary to protect human health or the environment.

“Presents or Will Present” Test. GAO also suggested that section 6 might be amended to require that EPA demonstrate only that a chemical “may present” an unreasonable risk, rather than requiring a demonstration that a chemical “presents or will present” an unreasonable risk. However, experience under section 4 of TSCA does not support this recommendation. Under that section, EPA has authority to require testing of a chemical that “may present an unreasonable risk” to health or the environment. As described earlier in this testimony, the “may present” standard has proven to be a very low threshold, and requires only a “more-than-

²³ See, e.g., sections 4(a) (testing authority for existing chemicals); 5(e) (allowing regulation of new chemicals pending development of information); and 5(f) (allowing immediate regulation to prevent against unreasonable risk).

²⁴ 15 U.S.C. § 2601(c).

theoretical basis for suspecting that some amount of exposure takes place,”²⁵ and hazard information that supports merely a suspicion of toxicity.²⁶ Such a low standard may be entirely appropriate within the context of section 4, where EPA is deciding whether additional data should be collected. However, such a low standard would be inappropriate under section 6, where the Agency has the ability to ban a chemical. Moreover, if the “may present” standard were incorporated into section 6, it would be possible for the Agency to skip the testing step and proceed directly to a ban merely on the suspicion of a hazard and a “more-than-theoretical basis” for believing that exposure might be occurring, rendering section 4 meaningless.

Conclusions About Section 6

There has been a tendency among critics of TSCA to judge EPA by the number of chemicals that have been banned under section 6. I believe that is an unduly narrow way of looking at EPA’s accomplishments – under section 6 and under TSCA generally.

The EPA took a unique, but instructive approach in a case where they proposed a rule to prohibit the manufacture, distribution, and use of acrylamide grout to protect workers from exposure to acrylamide and another chemical. After eleven years, the proposal was withdrawn because the development of personal protective equipment (PPEs) made the rule unnecessary. A lower cost alternative was available to protect workers from exposure to the acrylamide and other chemicals in these grouts.²⁷ Since EPA’s concerns were addressed, this action should be considered a success, notwithstanding that no ban was implemented.

Also, as noted earlier in this testimony, EPA has used its authority under section 5(a)(2) to issue SNURs as another way to address concerns related to Inventory-listed substances. The PFAS case described earlier is just one example; there are many others.

Thus, section 6 is not the only mechanism for addressing unreasonable risks. Good product stewardship is a much more efficient approach and is the first line of defense. It is important that EPA have a means to address unreasonable risks when necessary, and section 6 as it is currently designed does provide that authority, but the industry must continue to act responsibly and the EPA, when it takes action, must do so within the statutory guidelines laid out in section 6.

In sum, I believe EPA can regulate effectively under TSCA section 6 as it is currently written, as evidenced by EPA’s successes during the first decade after TSCA was enacted. EPA’s asbestos rule was struck down because in that case, EPA used flawed methodology and failed to consider

²⁵ *Chem. Manuf. Ass’n v. EPA*, 859 F.2d at 984.

²⁶ 45 Fed. Reg. 48,524, 48,528 (July 18, 1980) (Chloromethane and Chlorinated Benzenes Proposed Test Rule; Amendment to Proposed Health Effects Standards) (“EPA’s conclusion that the chemical may present a hazard will not be based on definitive scientific data. This is inevitable; if EPA knew in detail the types of hazards a chemical posed, there would be no need to test. Thus, determinations of hazard potential under Section 4 by their very nature must involve reasonable scientific assumptions, extrapolations, and interpolations.”).

²⁷ For more details, see *Battelle Report*, *supra* n.3, at 21.

relevant factors, not because of problems with section 6 itself. GAO's suggested revisions of section 6 are not necessary, in my judgment, to support effective regulation, and would not improve the statutory framework for making regulatory decisions. I believe the language of section 6 provides a sound basis for EPA decision-making, and does not impose unreasonable burdens on the Agency. To the contrary, it highlights the key factors that should be considered by EPA when contemplating whether to ban or restrict the use of products.

CONCLUSION

Thank you for giving me the opportunity to testify today. In my judgment, TSCA is a well-crafted statute and provides the EPA ample authority to achieve the objectives set forth in the statute. EPA has accomplished a great deal over the years under TSCA (including under section 8, though not discussed in this testimony). I believe EPA could accomplish even more through improved implementation, but I do not believe revisions to the statute are necessary. I hope you find this testimony helpful in your deliberations.

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Education

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Mr. Rawson is qualified to practice before the District of Columbia bar.

Areas of Expertise

William K. Rawson is a partner in the Washington, D.C., office of Latham & Watkins and chairs the firm's Environment, Land & Resources Department in that office. Mr. Rawson has represented companies and industry groups in petitions, agency rulemaking proceedings and litigations covering a wide variety of topics, including the Toxic Substances Control Act (TSCA), Emergency Planning and Community Right-to-Know Act (EPCRA), FIFRA, the OSH Act, the Clean Air Act, the Clean Water Act, RCRA, the Safe Drinking Water Act, and the Federal Hazardous Substances Act.

Mr. Rawson has extensive experience dealing with complex issues pertaining to hazard, exposure and risk assessment and risk communication, and has counseled clients on these issues before various state as well as federal agencies and also in connection with high visibility coverage by national news media. Before joining the Environment, Land & Resources Department, Mr. Rawson spent several years in the firm's Litigation Department and handled a variety of matters in various state and federal jurisdictions.

Mr. Rawson has lectured on TSCA, EPCRA, OSHA and other topics, and co-authored (with other Latham attorneys) a handbook on TSCA published by the Environmental Law Institute. Mr. Rawson also co-authored an article on chemicals in the body that was the cover story for the July 2004 issue of *European Chemical News*.

Before joining the firm in 1982, he served as a law clerk to the Hon. Jerome J. Farris of the U.S. Court of Appeals for the Ninth Circuit.



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