

**Testimony of Mark Greenwood
Before the U.S. House of Representatives Energy and Commerce
Subcommittee on Environment and the Economy**

**Hearing on
“Regulation of Existing Chemicals and the Role of Preemption
under Sections 6 and 18 of the Toxic Substances Control Act”**

September 18, 2013

Chairman Shimkus, Ranking Member Tonko and members of the Committee, I thank you for the invitation to testify today on the implementation of Section 6 of the Toxic Substances Control Act (“TSCA”), the principal legal authority under which the U.S. Environmental Protection Agency (“EPA”) is authorized to regulate existing chemicals in commerce.

My name is Mark Greenwood. I am an attorney practicing environmental law through my firm Greenwood Environmental Counsel. I am appearing here today to offer my personal views on the implementation of TSCA, and do not represent the interests or views of any particular client. My comments are informed by my experience in private practice as well as my experience at EPA. From 1988 to 1990 I was Associate General Counsel for Pesticides and Toxic Substances, and from 1990 to 1994 I served as Director of the Office of Pollution Prevention and Toxics (“OPPT”). In these roles I was directly involved in EPA’s efforts to address the risks of existing chemicals, including the challenges presented by EPA’s asbestos ban and phase-out rule, the litigation surrounding

that rule and the program aftermath when the rule was vacated by the U.S. Court of Appeals for the Fifth Circuit.

My testimony will focus on the key elements of Section 6 that commenters on TSCA often cite when arguing that the EPA existing chemical program has failed to achieve its intended objectives. My goal is to provide members of the committee with contextual information surrounding the regulation of existing chemicals under TSCA that I hope will assist your evaluation of this subject.

Overview of EPA Experience with TSCA Section 6

When TSCA was originally enacted in 1976, the statute was viewed by many people in EPA and outside the Agency as the cutting edge of environmental law. In 1971 the Nixon Administration submitted the first version of the Toxic Substances Control Act to Congress. In support of the legislation, the Council on Environmental Quality submitted a report indicating that this bill was intended to provide a “New System” for addressing the environmental challenges of the time that would not be limited by the jurisdictional limits of media-specific statutes for air and water pollution or of statutes that only looked at certain materials, such as pesticides. This new system would allow EPA to address health and environmental risk in an integrated and comprehensive way. Regarding the regulation of existing chemicals, the CEQ report characterized the new role for EPA as follows:

The Administrator of the Environmental Protection Agency would be empowered to restrict or prohibit the use or distribution of a chemical substance if such restriction were necessary to protect health or the environment. In imposing such

a restriction, the Administrator would be required to consider not only the adverse effects of the substance but also the benefits to be derived from its use.¹

While the legislation proposed by the Nixon Administration was modified, in some cases significantly, before the enactment of TSCA in 1976, the perspective reflected in this statement was carried forth as an expectation for how EPA would be using its Section 6 authority to address existing chemicals.

EPA did not, however, move ahead quickly to use Section 6 on specific existing chemicals. Many explanations have been offered for the slow implementation of the TSCA existing chemical program but several factors are particularly worth noting. First, once TSCA was enacted EPA had a pressing responsibility to create the TSCA Inventory and then establish the framework for the new chemical program. Since chemical manufacturers had immediate statutory responsibilities in this area, it was important to give priority to clarifying those responsibilities. Second, the first major existing chemical challenge for the Agency involved creating the regulatory structure for the ban on polychlorinated biphenyls (“PCBs”) that was mandated under Section 6(e) of the statute. This effort required a variety of complicated rulemakings addressing precedential issues for EPA on how it would regulate hazardous substances in commerce and provide for their safe disposal.

Third, EPA was also challenged by the broad mandate, with no specific agenda, that Congress had provided in TSCA. After the statute was passed, there were substantial internal debates within EPA about the relative importance of, and thus resource allocation

¹ U.S. Council on Environmental Quality, “Toxic Substances” (April 1971), p. vi.

for, information collection, chemical testing and risk management activities. Given the thousands of chemicals in commerce, EPA was further challenged to determine which chemicals warranted priority action.

EPA reached a conclusion early in the history of TSCA's implementation, however, that asbestos would be a prime target for regulatory action under Section 6. The rulemaking on asbestos began with the issuance of an Advance Notice of Proposed Rulemaking on October 17, 1979. As time passed into the 1980's without EPA initiating Section 6 actions on other chemicals, the asbestos rulemaking took on an importance larger than the issue of asbestos itself. It became the test case of whether Section 6 (and the promise of TSCA itself) could work. The stakes became particularly high as the Agency's regulatory strategy also began to shift from an array of less stringent approaches, such as labeling or limitations of particular uses, to a comprehensive ban and phase-out of all asbestos uses.

The final asbestos ban and phase-out rule was issued on July 12, 1989. It drew legal challenges from multiple parties in U.S. Court of Appeals, Fifth Circuit. The court issued its decision on the various challenges to the rule on October 18, 1991 in *Corrosion-Proof Fittings, et al. v. Environmental Protection Agency*, 947 F.2d 1201 (5th Cir. 1991). The decision represented a complete loss for the Agency, as the court vacated the primary sections of the rule.

With this decision, some stakeholder groups began to characterize TSCA as a “broken” statute. While this characterization was probably an overstatement, the court’s opinion clearly set forth a more restrictive version of EPA’s authority and flexibility under Section 6 than the Agency had assumed TSCA provided. The decision came at a time when OPPT was being given additional responsibilities in the Agency, including expansion of the Toxic Release Inventory and other “right to know” programs, as well as implementation of the Pollution Prevention Act. As Office Director of OPPT during this time, I worked with my staff to develop and pursue a variety of new approaches, both regulatory (e.g., expanded use of TSCA Significant New Use rules) and collaborative (e.g., Design for Environment program), to recast the TSCA program as an effort to improve the management of existing chemicals using a variety of tools, without being dependent on Section 6 as the primary mode of action.

Over the last several years, legislative efforts aimed at reform of TSCA have once again focused on a rewriting of Section 6 as the centerpiece of revitalizing EPA’s existing chemical program. Thus it is useful for the committee to evaluate the current structure of Section 6 to determine its strengths and weaknesses.

Unreasonable Risk Standard

The threshold finding that EPA must make to justify a rule under TSCA Section 6 is that “there is a reasonable basis to conclude that the manufacture², processing, distribution in commerce, use or disposal of a chemical substance or mixture, or that any combination of

² “Manufacture” also includes import of a substance under TSCA.

such activities, presents or will present an unreasonable risk of injury to health or the environment.” Based on this finding, EPA may take a variety of actions, which may include a ban on manufacturing, production restrictions, limitations on use, labeling, controls on disposal, recordkeeping or product recalls.

The essence of the “unreasonable risk” standard is that it requires a weighing of the factors enumerated in Section 6(c), which include the health and environmental risks associated with the substance, the benefits of the substance for various uses, the availability of substitutes, and the “reasonably ascertainable economic consequences of the rule.” TSCA does not require on its face, and the court in the *Corrosion Proof Fitting* case confirmed, that this standard does not necessarily require cost-benefit analysis. However, it certainly would allow EPA to consider the results of a cost-benefit analysis should one be prepared.

While the general standard for regulation of existing chemicals under TSCA is “unreasonable risk”, Congress has amended TSCA several times to require specific actions on certain chemicals. As part of the original statute, Congress directed EPA to phase out the manufacture and use of PCBs. In 1986, Congress amended TSCA to create an EPA program for inspection and management of asbestos in schools. In 1992, Congress added a program to address lead-based paint in residential housing. In 2008, Congress added restrictions on export of elemental mercury. In 2010, Congress required EPA to issue certain standards for composite wood products. In each case, Congress specified differing approaches unique to the particular risk of concern.

Several other federal statutes that address products in commerce have a similar structure. For example, the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), which is the legal framework for pesticide regulation, sets standards based on an unreasonable risk standard for most forms of pesticide exposure, including those affecting consumers in the home, workers or ecological resources. For purposes of pesticide residues in food, however, EPA is required to use a “reasonable certainty of no harm” standard as described under the Food Quality Protection Act. Similarly, the Consumer Product Safety Act’s general standard –setting authorities apply an “unreasonable risk” standard or mandate consideration of a wide range of factors that include a balancing of the costs and benefits of a regulation. At the same time, the law has been amended several times to ban specific chemicals, such as butyl nitrite or phthalates in children’s toys, and to set standards for specific products such as lead in children’s products.

Thus, the committee should be aware that several federal laws regulating industrial technology and products in commerce tend to share a common pattern characterized by a general standard allowing for the weighing of health and environmental risks, the availability of better alternatives, product benefits and overall cost impact, along with targeted restrictions on risks that warrant specific action.

There are certain aspects of the unreasonable risk standard that draw support from many stakeholders. For example, most stakeholders would agree that when EPA considers restricting the uses of a chemical, the Agency should consider whether there are feasible

and practical alternatives that offer net improvements in protection of health and the environment. To do otherwise would run the risk that regulatory action could be counterproductive for health and the environment.

A more controversial topic concerns the role of cost-benefit analysis under the unreasonable risk standard. In this regard, it is useful to consider long-standing regulatory policies that have been pursued by the Executive Branch. At least since the early 1980's the Executive Branch has required federal agencies to conduct cost-benefit analysis on major regulations, to the extent allowed by statute. This approach to regulation was first formalized in the Reagan Administration with the issuance of Executive Order 12291. This Order remained in place for twelve years, to be replaced in 1983 by Executive Order 12866 issued at the beginning of the Clinton Administration. Executive Order 12866 also embraced the cost-benefit principle, stating that a regulation should be adopted "only upon a reasoned determination that the benefits of the intended regulation justify its costs."³ The subsequent Bush and Obama Administrations have retained this element of Executive Order 12866 as the blueprint for their approach to regulation as well.

Thus, when EPA issued its asbestos ban and phase out rule in 1989, it had prepared a detailed cost-benefit analysis of the rule, which the *Corrosion Proof Fittings* cited in its criticism of EPA's decision. This cost-benefit analysis, however, was prepared by EPA because it was a requirement within the Executive Branch, not due to a specific

³ Executive Order 12866, Section 1(b)(6).

obligation in TSCA. What is important to recognize is that such a cost-benefit analysis would have been prepared by EPA under each of the Presidents of the last three decades and would still be required today under Executive Branch policy.

Thus one of the central questions for Congress as it considers reform of TSCA is its perspective on the proper role of cost-benefit analysis in regulatory decisionmaking. The current unreasonable risk standard in Section 6 allows regulatory decisions to be made based on cost-benefit analysis. One of the most important strategic questions in any reform of TSCA is whether the Section 6 standard should be changed to direct the Executive Branch to suspend its long-standing policies favoring cost-benefit analysis when EPA regulates existing chemicals.

Least Burdensome Alternative

Section 6 provides that the regulatory approach selected by EPA to address an unreasonable risk shall “protect adequately against such risk using the least burdensome requirements.” This provision is not inherently a significant constraint on EPA’s authority as agencies routinely examine options that can achieve health and environmental objectives through measures that minimize social and economic disruption. Such an approach is often described as “smarter” regulation.

As with cost-benefit analysis, this principle has also been enshrined in the Executive Branch policies that have guided regulatory policy for decades. As articulated in Executive Order 12866, agencies are expected to assess the costs and benefits of

“potentially effective and reasonably feasible alternatives” to a proposed regulation.⁴ Executive Order 13563, issued in 2011, further refines this mandate by stating “Where relevant, feasible and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.”⁵

This is an area, however, where the *Corrosion Proof Fitting* decision imposed a significant burden on EPA’s ability to utilize Section 6. The court interpreted the “least burdensome alternative” obligation in Section 6 to require EPA to assess each option potentially available that is less burdensome than the option that the Agency intends to pursue. Specifically, the court stated,

Upon an initial showing of product danger, the proper course for the EPA to follow is to consider each regulatory option, beginning with the least burdensome, and the costs and benefits under each option... Without doing this it is impossible, both for the EPA and for this court on review, to know that none of these alternatives was less burdensome than the ban in fact chosen by the agency.⁶

This obligation sets up a task for EPA that goes well beyond the analytical task typically carried out by regulatory agencies under Executive Branch policies and other federal environmental statutes.

⁴ Executive Order 12866, Section 6(a)(3)(C)(iii).

⁵ Executive Order 13563, Section 4.

⁶ *Corrosion Proof Fitting*, at p. 1217.

The general expectation for options analysis in federal regulatory contexts is that agencies must examine a set of major alternatives that are, as articulated by Executive Order 12866, “potentially effective and reasonably feasible.” Instead, the *Corrosion Proof Fitting* court appears to say that EPA must calculate costs and benefits for each alternative, which would essentially mean all alternatives that are arguably less burdensome than the option EPA intends to pursue under TSCA. Given the broad range of potential actions that EPA could take under Section 6, this suggests that EPA would be compelled to undertake an assessment of costs and benefits for a wide array of alternatives, including variations on those alternatives, proposed by opponents of a Section 6 rule in order for the Agency to have an adequate record for the rule.

In my experience as Director of OPPT, it was this aspect of the *Corrosion Proof Fitting* decision that had the most significant chilling effect on the Agency’s willingness to pursue additional Section 6 rules in the wake of the court’s decision. There was a strong concern among EPA lawyers, managers and staff that this part of the decision was a prescription for regulatory gridlock through so-called “paralysis by analysis” in future Section 6 rulemakings. Ironically, EPA viewed this part of the decision as a distortion of a reasonable regulatory principle – looking for “smart” approaches to achieving regulatory goals – that enjoyed broad support in the Agency.

Accordingly, an important issue for the committee to evaluate in its review of Section 6 is to consider the question of how to set a reasonable expectation that EPA should find effective regulatory strategies that minimize economic and social disruption, while at the

same time not imposing an overwhelming analytical burden that would stall necessary action.

Procedural Aspects of Section 6

One of the reasons that TSCA was considered an innovative statute at the time of its enactment was that it constituted a bit of an experiment in administrative law procedures. In the context of the Administrative Procedure Act, most agencies take action either through “adjudication” procedures, which tend to parallel trial-type proceedings in courts, or through “informal rulemaking” procedures, typically understood as notice and comment opportunities for the public. For the most part, EPA acts through informal rulemaking procedures, with the exception of administrative enforcement proceedings and pesticide cancellation and suspension actions.

The procedures set forth in Section 6 of TSCA create a hybrid process, incorporating elements for both informal rulemaking and adjudication. Section 6(c)(2) requires a notice and comment rulemaking process for all rules under the section but also calls for an “opportunity for a public hearing” subject to the procedural requirements of Section 6(c)(3). At this hearing, parties may present oral and documentary submissions and, where there are material facts at issue, cross-examination of witnesses may occur. A transcript of the hearing is created for the record. EPA is allowed to set ground rules for how various parties may be represented and for conduct of the hearing. Under Section 6(c)(4), EPA is allowed to provide compensation for expert witnesses and attorney fees for parties that do not have adequate resources to participate in the hearing.

These procedures for cross-examination of witnesses were invoked during the course of the 10-year asbestos rulemaking. I was involved in the preparation for, and conduct of, the 1988 hearing on the asbestos rule. It was clearly an adversarial proceeding, in which attorneys for the asbestos industry challenged EPA staff witnesses, while Agency lawyers sought to protect these staff witnesses. While these procedures added time to the rulemaking and generated additional documents, they did not, in my view, add new information or uncover new issues that had not already been raised during the multiple rounds of public comment during the rulemaking.

It is worth contrasting these procedures with the kinds of refinements of rulemaking processes that we see more often in current practice. It is much more common today than it was at the time of the asbestos rulemaking to provide an opportunity for peer review of major scientific and technical questions that are central to policy decisions on a rule. In contrast to the Section 6 process, which adds trial-type procedures onto notice and comment rulemaking on the same issues, peer review processes can provide new and valuable insights from credible experts that might not otherwise be part of typical notice and comment processes.

In evaluating Section 6, the committee may want to consider whether the procedural experiments placed in the statute in 1976 continue to have value today, or whether the experience with rulemaking over the last three decades suggests a different approach.

Conclusion

Chairman Shimkus, Ranking Member Tonko and members of the Committee, I thank you again for the opportunity to testify in this hearing. I applaud your efforts to obtain background information on the strengths and weaknesses of TSCA in its current form as a context for consideration of possible statutory reform.