Testimony
of
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On

"Title I of the Toxic Substances Control Act: Understanding its History and Reviewing its Impact"

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Good morning, Chairman Shimkus, Ranking Member Tonko, and members of the Subcommittee. My name is Beth Bosley, and I am the President of Boron Specialties in Pittsburgh, Pennsylvania. Boron Specialties is a specialty chemical manufacturer and a small business. I am passionate about making our products in the United States, and about job creation. We currently reinvest every dollar we make (and more) in accelerating growth. We are also committed to responsible operation of our business, including environmental stewardship and regulatory compliance. It is in the spirit of running a globally competitive business while protecting the health and safety of our employees and the public that I speak to you today about the Toxic Substances Control Act (TSCA).

At the outset, I'd like to make three general points that the subcommittee should bear in mind as it thinks about whether and how to update TSCA.

First, TSCA is a law about products, not pollution. And it covers almost all products -- it gives the EPA authority to regulate "unreasonable risk" to humans and the environment from all chemicals and uses that aren't covered by some other more targeted statute. Contrast this approach with the laws that regulate those more narrow universes of products -- pesticides, drugs and food additives. The chemicals used in these specialized products have specific characteristics and exposure pathways. Pesticides are designed to kills pests, drugs are intended to be bioactive, and food additives are intended to be eaten. Congress created exclusions from TSCA for these separately-regulated chemicals and certain others, making it the default statute for everything else -- an enormous variety of chemicals and uses.

Over the years, TSCA has been criticized on many fronts, largely due to the emergence of international chemical control regulations, a growing patchwork of state and local laws, and de facto "retail regulation." Advances in the ability to detect chemicals at extremely low concentrations have also helped raise awareness of the pervasiveness of chemicals in the environment, although it is important to understand that a detectable presence of a chemical does not equate to harm, as the Centers for Disease Control (CDC) has regularly noted. The EPA has had trouble implementing some parts of the statute, and some have attributed this to shortcomings in TSCA (excessively so, in my view).

The second overarching point to bear in mind is the concept of risk. By definition, risk is a function of two things: (1) a chemical's intrinsic properties and (2) the degree to which anyone is exposed to the chemical through the ways it is used. Risk, in other words, requires both hazard and exposure. EPA's job under TSCA is to assess both of these and make a judgment about whether the reasonably anticipated uses of a chemical would present a sufficient probability of harm to people or the environment that we should limit those uses.

Last – but perhaps most important – smart regulation can and should achieve its objectives without inhibiting innovation. This isn't an abstract issue - American companies like mine are on the cutting edge of chemical innovation, regularly developing new chemicals for themselves or on a contract basis for other companies. TSCA has allowed us to lead the world in chemical innovation, and has done so without jeopardizing our nation's health or the environment. Any

amendments to TSCA must preserve the timeframes and flexibility that allow this innovation to continue. They must also protect the confidential business information that is at the heart of innovation. The specific chemical identities of new molecules, and the details of the processes by which we make them, are our competitive advantages and the way we support innovation across the economy.

On balance, much of TSCA has worked, some areas have not worked as intended, and some areas fall in between.

It is easiest to look at TSCA in terms of new chemicals and existing chemicals. The new chemicals program I believe has done its job admirably. The existing chemicals program, on the other hand, has not worked quite as intended and could be improved. Reporting requirements and the treatment of US intellectual property, or Confidential Business Information (CBI), are areas that fall in between.

As a general matter section 5 of TSCA and the EPA's new chemicals program have been a success.

New chemicals are any that are not on the TSCA inventory of chemicals "in commerce." Prior to manufacturing or importing a new chemical substance, a company must submit to EPA a pre-manufacture notice or PMN. PMN submitters must provide all information on that substance that is known or reasonably ascertainable. While upfront testing is not required, EPA is able to employ predictive technology or models – which it interprets quite conservatively – to help decide if a new chemical raises a concern. It can also use available data, and look to similar substances for comparison. EPA has 90 days to review a PMN, but it can and frequently does request an extension pending regulation or collection of more information. Most chemical reviews are completed by EPA within three weeks and conclude that the chemical will not present an unreasonable risk.

The new chemicals program also offers exemptions to full PMN requirements that can allow for reduced reporting and shorter review. Among others, several important examples are the polymer exemption and low volume exemption. The polymer exemption requires an annual report to EPA and the low volume exemption allows manufacturers to get "low volume" (production at less than 10MT annually) chemicals to market within 30 days.

Another important exemption is the R&D exemption. Under the R&D exemption, companies are able to perform research on the production of the chemical and, in fact, may produce it at a small quantity to assess the hazards, the market, and the economics of commercial manufacture. However, no production for any commercial purpose is permitted until a PMN is submitted and approved. Defined recordkeeping and notification requirements are in place to ensure control of R&D chemicals.

Through the new chemicals program, EPA reviews roughly 2,000 chemicals every year. This reflects the rate of chemistry innovation in the U.S., and it is a prevailing view in our industry

that the regulatory process must continue to support this level of throughput in any future program to avoid a serious economic impact and competitive disadvantage for U.S. business. To date, EPA has reviewed about 52,700 new chemical PMNs and exemption notifications, dwarfing other industrial nations. EPA has a lot of experience here.

Only about half of the new chemical notifications reviewed are ever marketed commercially. Since not all of the R&D needed has been completed before a PMN must be filed, there can be any number of reasons a company chooses not to move forward with commercial production – the market may not develop as estimated, technical problems may be encountered with the downstream process, or pending regulation may make the product economically unfeasible.

At the early stage of product development, it is not surprising that detailed studies have not been conducted. Companies often test the market at small scale to determine if a substance is commercially viable and has the potential to recoup investment. I believe the EPA understands this and, as such, developed these state of the art tools and put programs in place that facilitate innovation, while protecting human health and the environment based on the relative scale of risk as commercialization proceeds. Conversely, the cost of blanket testing requirements without consideration of scale would discourage many new chemicals from ever being developed.

It's also worth considering that new chemicals are often "greener" than those they would replace, since minimizing a company's eco or health footprint is a powerful driver for innovation. The new chemicals program and exemptions are critical to American competitiveness and to my ability to stay in business. They have also helped EPA manage its workload successfully.

Information on the universe of chemicals known as existing chemicals is misleading.

Existing chemicals are those that are on EPA's TSCA inventory. The inventory consists of chemicals that were in commerce in the late 1970s when TSCA was first implemented, plus chemicals that have since been reviewed by EPA's new chemicals program and subsequently manufactured. The inventory currently has about 84,000 chemicals. The TSCA inventory is not, however, an accurate reflection of chemicals in commerce. In fact, it is highly misleading – EPA's 2012 survey concluded that fewer than 8,000 chemicals are actively in commerce, defined as being manufactured at the rate of 12.5 tons/year at a single site somewhere in the U.S. (This does not include exempted substances.) The inventory could be improved by dividing it into an "active" and "inactive" list, where EPA could focus its resources on active chemicals in commerce. This would also improve transparency and the public's understanding of the list.

EPA's efforts to evaluate chemicals in commerce have been inconsistent and time-consuming.

Another shortcoming with TSCA is the lack of a mandate for EPA to screen chemicals in commerce for potential data needs, and to do so in a timely manner (though the current TSCA

does give EPA this authority). Most stakeholders agree that EPA should be required to prioritize chemicals in commerce in a comprehensive, transparent and risk-based fashion, but EPA has not been required to do this by law. As a consequence, various administrations have put different programs in place over the years, all of which have tended to lose out in the competition for budget resources to programs that have mandates. This has hampered progress on the review of existing chemicals. A prioritization scheme for existing chemicals is particularly important to optimize federal resources during a time of budget challenges such as sequestration.

Furthermore, when EPA does identify existing chemicals on which it needs more data, it has had to go through time-consuming rulemaking via section 4 of TSCA to request testing even when companies might be in agreement. EPA has developed work-around mechanisms to collect the information it needs, such as voluntary programs and consent agreements, but procedurally, EPA's regulatory efforts for testing have been unnecessarily slow and could be improved.

EPA's ability to restrict existing chemicals that present an "unreasonable risk" has also faced procedural burdens.

Section 6 of TSCA authorizes EPA to restrict chemicals that present an "unreasonable risk." This authority has been seldom used and is at the center of debate over TSCA's effectiveness. EPA and critics of TSCA have pointed to the infamous *Corrosion Proof Fittings* case (*Corrosion Proof Fittings v. EPA,* 947 F.2d 1201 (5th Cir. 1991)), which EPA lost when trying to ban asbestos. Despite previously successful use of this authority on other substances, EPA has been reluctant to use it since. Regarding the asbestos case, it may have been a better approach if EPA had considered regulation of critical, very low exposure uses, rather than an outright ban. It is also essential that EPA fairly consider the substance of all comments before proceeding with a ban.

Nevertheless, EPA's ability to restrict existing chemicals that do not meet a safety standard could be improved by eliminating significant procedural burdens. I suggest that EPA should be permitted to:

- Act through conventional informal rulemaking; and
- Limit its obligation to consider the burdens of alternative approaches to those approaches that are identified by commenters on the proposed rule.

If EPA has to evaluate alternatives identified by commenters on a proposed rule and choose between the least burdensome of those, instead of it having to identify them, much of the burden on EPA in the future could be alleviated.

While this section could certainly be improved, and it is true that few chemicals have been restricted under it, be mindful that many chemicals may be regulated under other sections of TSCA. As a matter of fact, most chemicals can be and are used safely. This is why, rather than banning substances outright, EPA has opted to restrict their uses instead.

EPA continues to improve its ability to collect information on chemicals, but more could be done.

Generally speaking, section 8 of TSCA, the record keeping and reporting provision, meets EPA's need to collect information on chemical substances. EPA continues to enhance, through existing authority, its ability to gather basic information on chemicals in commerce. It gathers information such as production and import volumes and industrial worker exposures, through its periodic chemical data reporting requirements, which apply to manufacturers and processors. The primary remaining problem is EPA's inability to collect use and exposure information from downstream entities. Oftentimes, manufacturers and processors are not privy to information on exposures and uses downstream of them. In many cases, their customers are also their competitors and want to keep this information confidential. TSCA could thus be improved by authorizing EPA to require reporting from distributors and nonconsumer end users of chemicals. These entities are likely to have much more accurate information about use and exposure scenarios than upstream manufacturers like myself.

TSCA section 8(e) requires companies to submit data they receive on any substance when the data supports a conclusion that it presents a substantial risk of harm to human health or the environment. There are no exemptions from 8(e) reporting – it is considered an early warning mechanism for adverse effects. Most companies err on the side of caution and submit data that suggests *any* risk. Through June 2012, EPA had received about 19,000 8(e) submissions. EPA can leverage this data to guide its regulatory decision-making when evaluating other chemicals that may be similar. The problem now is that this section is biased – it only calls for submission of adverse data. Many companies have test data demonstrating a lack of adverse effects. EPA's understanding of chemical hazards could be substantially improved by authorizing submission of non-adverse data and requiring EPA to consider such data during risk assessment efforts.

Protection of confidential business information is crucial to small businesses' and America's competitiveness, but over-claiming and lack of EPA oversight have created problems.

The ability to innovate is what enables my company to remain competitive and protection of trade secrets is essential to guard companies' valuable innovations from unfair competition.

The provision on confidential business information, section 14, has historically worked well to protect trade secrets and promote innovation. However, over many years claims have gone unchecked, creating a negative stigma around the concept of CBI. Furthermore, the statute is less clear than it could be about when the specific identity of a chemical should be protected as a trade secret. EPA's current interpretation creates uncertainty about whether chemical names are confidential when they are contained in health and safety studies

Bear in mind that EPA staff sees all the data that are submitted to them – CBI restrictions do not bar them from access to data. As for publically available information, health and safety studies are not allowed to be claimed CBI, and that is as it should be. But, strictly speaking, detailed

chemical identity is not an essential element of health and safety studies. That is, you do not need to know the precise name of a molecule to understand a study of that chemical and whether, based on that study, a chemical should be restricted. This should be clarified in the law and robust generic names guidance should be developed.

Consideration should also be given to requiring for up-front substantiation, and periodic re-substantiation, of CBI to avoid claims that remain in place longer than necessary. EPA should be permitted to share CBI with other Federal agencies and with state and foreign governments that, in practice, provide protections equivalent to those provided by EPA.

As a specialty chemical manufacturer and small business, I can say unequivocally that the protection of chemical identity can be critical. Given the narrow applications for which specialty chemicals are used and the niche markets they serve, disclosure of chemical identity may be all it takes to give away a competitive advantage to an offshore manufacturer. Simply stated, the incentive to develop greener chemicals largely disappears if prospective manufacturers know the risk is high of having their good idea being revealed. The majority of Freedom of Information Act requests to EPA come from companies, many of which are overseas, not curious members of the public. This fact underscores the real threat of losing a trade secret. The subcommittee must consider the issue of CBI in this context.

A federal effort to improve TSCA's shortcomings is appropriate, but the approach should not overlook or undermine the many ways in which TSCA has worked effectively for over three decades.

This subcommittee's review of TSCA should consider potential impacts on small businesses and the unique nature of the U.S. specialty chemical industry. Decisions must always be driven by sound science. Congress should also look at other statutes that regulate chemicals, and international efforts, as it assesses what might be improved. Regular oversight by Congress will help assess where TSCA currently demonstrates effectiveness, where it could be implemented better, and where revision is necessary.

Thank you for this opportunity to share my perspective on TSCA, and I look forward to your questions.