Society of Chemical Manufacturers & Affiliates

Testimony
of
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On behalf of the

Society of Chemical Manufacturers & Affiliates

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On

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Good morning, Chairman Lautenberg, Ranking Member Inhofe, and members of the Subcommittee. My name is Beth Bosley, and I am the Managing Director for my company, Boron Specialties in Pittsburgh, Pennsylvania. I am pleased to testify before you today on behalf of the Society of Chemical Manufacturers and Affiliates (SOCMA) regarding the Toxic Substances Control Act (TSCA).

Since 1921, SOCMA has served as the leading trade association representing the batch and custom chemical industry. SOCMA has roughly 300 member companies, which are typically small to medium-sized businesses, each with up to $100 million in annual sales. Our members make a $60 billion annual impact on the U.S. economy and contribute to the chemical industry's position as one of the nation's largest exporters.

TSCA Should be Modernized in Ways that Do Not Seize Up the Engine of Innovation

As we testified before a House subcommittee twice last year, SOCMA supports EPA's – and Congress's – fundamental goal of protecting human health and the environment from harmful chemical exposure. SOCMA members are prepared to continue doing our part in that effort. We are pleased to have this opportunity to share with you our perspective on reforming US chemical safety laws.

First, let me state that no member of the chemical industry, from the CEO at a Fortune 100 company, to the scientists developing new technologies, to the operations personnel at a start-up company, want to have a chemical they produce cause harm to human health or the environment. Through their proprietary ChemStewards initiative, SOCMA members take great care to ensure that their products are appropriately manufactured, tested, packaged, shipped, and used responsibly. Our results of our commitment to product stewardship and process safety are evidenced by the decreasing trends in releases, process upsets, and transportation incidents.

SOCMA members agree that TSCA can be modernized, and that our chemicals policy goals can be accomplished in a way that doesn't devastate a strategic American industry that is already fighting recession and foreign competition. Chemical science innovation, as an enabling technology, benefits many US industries – aerospace, advanced materials, agriculture, pharmaceuticals, electronics, and telecommunications (among many others) – making these industries better able to compete in the increasingly global marketplace. Without such US-based innovations, advances such as lightweight transportation components (a major factor in increasing fuel economy), low-emission paint (resulting in a safer consumer environment), and detergents that work in cold water (resulting in lower energy usage) would not be available today. Our nation's ability to minimize its carbon footprint will also depend on technological innovation – premised on chemistry. Needless to say, all these advances of chemistry also contribute to Americans leading longer and healthier lives.

The US still leads chemical industry innovation; of the roughly 60,000 patents attributable to chemical sciences issued over the past 5 years, 35,000 of them are authored by US entities. US industry also leads the world in research and development of new chemical substances, better manufacturing techniques, and process safety advances designed to minimize the impact of chemicals on human health and the environment.

However, the US chemical industry's competitiveness has decreased substantially in recent years due to competition from countries with lower resource costs, lower wage standards, and a less burdensome regulatory environment. Shifting production to these developing countries does not make US citizens

safer – we need only read the headlines regarding lead in children's toys and sulfides in foreign manufactured drywall to find examples where offshore manufacturing has increased risk to US individuals and decreased public confidence. Of course we need protective chemical regulation, but it must be well-informed regulation, so that we maximize the improvement in our quality of life and minimize damage to US industry's competitiveness.

Canada's Model Is Worth Emulating; Europe's Is Not

Many TSCA critics point to the REACh legislation as a model for the United States. The REACh system is an overly burdensome regulation that, by most estimations, will cost jobs within the EU. REACh is fundamentally flawed in that there was no risk prioritization prior to commencing the initiative. Therefore, a low risk chemical (one that may exhibit some hazard, but very low probability of exposure, for instance) that is produced or imported at a volume of 25,000 lb/year will be screened with the same priority as a high risk chemical (one that is used in consumer products, for example) that is manufactured or imported at the same, or even a higher, volume threshold. According to the European Chemicals Agency, REACh testing costs for a product manufactured at 25,000 lb/year can be expected to reach $150,000. That cost could represent the entire profit margin for a chemical for 5 or even 10 years. Industry, already operating at reduced margins due to the economic downturn, cannot afford to continue to produce product at a loss for any sustained length of time. Eroding gross margins in the chemical industry contribute to the decline of R&D expenditures, the innovation that comes from robust industrial R&D, and the scientific and engineering jobs that drive R&D. Lower margins will also result in lower capital spending, and the job creation that comes with construction of new or upgrades to existing facilities. This REACh expenditure must be made without any certainty that risks will be reduced. Consequently, the manufacture and use of certain chemicals will move out of Europe, simply because the costs to stay in the European market are too high.

In contrast to the approach adopted by the EU under REACh, Canada, through its use of a "Categorization and Prioritization" process, was able to demonstrate that more than 80% of the chemicals in commerce in Canada did not present an unreasonable risk to human health and the environment. This approach allowed Canada to then systematically assign to the remaining chemical substances a priority for more in-depth review by Environment Canada and Health Canada. At present, Canada is much farther ahead of the EU with respect to evaluation of chemicals that may present a risk to human health and the environment.

TSCA Should Continue to Be Based on Risk Prioritization and Mechanisms that Work

Two principles are essential to a sustainable chemical management law that won't eliminate jobs, economic growth, or products. First, TSCA priorities should be established based on risk. Second, proven regulatory mechanisms should be the basis for modernization.

Prioritization based on risk must remain a fundamental principle of TSCA. Basing priorities and regulatory criteria on the scientific evaluation of toxicological dose/response and exposure factors is critical to a sustainable policy. For instance, if a chemical is highly toxic, but used only in strictly controlled industrial environments, or in small quantities, then the risk to public health is fairly small and readily manageable.

The second important principle for TSCA reform is leveraging regulatory mechanisms that work. We agree with EPA that the existing regulatory framework is better suited to American health, environmental, and economic interests than Europe's monolithic REACh regime. Applying an approach like REACh in the United States could devastate small and medium sized companies, including SOCMA members, and do so unnecessarily since a more practical alternative is available.

This is not to say that industry opposes the value of better regulation. We acknowledge the success of current environmental laws and programs. Moreover, as shown by the Canadian approach, these mechanisms show promise in being able to achieve new policy objectives without sacrificing hundreds of businesses and thousands of jobs.

Another mechanism supported by SOCMA was the "inventory reset", which was part of EPA's recently discontinued Chemical Assessment and Management Program (ChAMP). This would have provided an accurate measure of the chemicals now in commerce, which we believe is the only realistic starting point. Of the more than 80,000 chemicals now listed on the inventory, EPA estimates (based on its collection of data through the Inventory Update Rule) that only about 20,000 of these are presently in commerce. The program also identified categories of well-characterized chemicals, prioritized them, and systematically targeted them for further review. Even TSCA critics did not challenge the groupings identified by EPA and supported the notion of prioritization. The program then went into an evaluation of the risks associated with the exposures to these chemicals. We need to prioritize and categorize the universe of chemicals. While ChAMP may have been abandoned, it will have to be reinstituted under another name.

We should also embrace TSCA mechanisms that have worked well, like the New Chemicals Program, where EPA has successfully reviewed some 35,000 new chemicals since 1979 without impeding the innovation that is crucial to American competitiveness. Through this EPA program, known as the PMN process, over 1,000 chemicals undergo a review every year. This successful model could also be applied to existing chemicals. We should recognize the massive amount of data that was generated by EPA's High Production Volume Program and leverage that data in making initial determinations of risk. With reasonable amendments, TSCA could provide an easier mechanism to poll manufacturers and users for data on:

- volumes manufactured, processed, or used,
- health effects (all data should be collected, not simply adverse data), and,
- exposure characteristics, both environmental and human.

Section 71 of Canada's Environmental Protection Act effectively enables this sort of data collection.

A Safety Standard for a New TSCA

SOCMA members have a deep commitment to the safe use of chemicals, and we are proud of our collective track record in protecting our workers and communities. SOCMA favors a formulation whereby EPA would make a "safety" determination regarding chemicals. But let me make several observations about what this "safety" standard should involve:

- First, it should not overlook the basic principle of **risk**; that is evaluation of hazard and exposure.

- Second, because of the vast number of chemicals and applications, we do not think that EPA should be burdened with a determination that each chemical is safe for its intended use. This approach would almost certainly overwhelm EPA and disadvantage US industry. Specific chemicals and specific uses may be approached this way when dealing with a short list of chemicals with narrow uses, as pesticides are managed, for example, under FIFRA – or as drugs are managed under the Federal Food, Drug & Cosmetic Act. But, EPA probably could not implement such an approach across the universe of all chemicals without creating a bureaucratic nightmare. A requirement that all new uses of any chemical be specifically approved would seize up the engine of innovation that America depends on to revive our economy and transition to a lower-carbon future. Instead, under an improved TSCA, EPA should provide goals, prioritization, and oversight; implementation should be based on proven and practical regulatory mechanisms.

- Finally, and regardless of what approach Congress adopts, EPA will need to be adequately funded. The biggest shortcoming of the TSCA program today is lack of resources, not lack of authority. Companies submitting PMNs currently pay a fee, although that fee goes to the U.S. Treasury, not to EPA. SOCMA supports a reasonable new chemicals fee that would go to EPA. However, the benefits of innovation are shared by the public and submitters should not required to foot the bill for the entire new chemicals program.

The New Chemicals Program Works

The new chemicals program at EPA has come under fire lately, and I'd like to address some of the criticisms. EPA reviews over 1,000 new chemicals per year. Under TSCA Section 5, EPA has authority to compel Pre-manufacture Notice (PMN) submitters to provide additional data, either voluntarily or via administrative order. A PMN must be submitted very early in a product's life cycle (before the first commercial pound is manufactured). At that phase of product development, while the manufacturer hopes the product will be a commercial success, it has not produced material in commercial equipment, it doesn't have an established market, and the predicted total sales volume is only a rough estimate. Success of new products often relies upon the success of our customers' or even their customers' products.

Illustrating this fact, roughly 30% of PMNs submitted for new chemicals are never followed by a Notice of Commencement (NOC), indicating that 30% of the new substances reviewed do not commence commercial production. Industry must be ready for commercial manufacture, but there are a variety of reasons that a product may not make it to market.

The fact that limited data is available during the PMN process does not mean that the manufacturer has stopped testing or that it is selling products with inadequate health and safety data. The only mechanism that industry has to report health and safety findings to EPA is through TSCA section 8(e), where only adverse data is collected. If a manufacturer finds that a substance is less hazardous that it originally estimated, there is no mechanism by which to report this finding to EPA. However, if a substance is subsequently found to create a substantial risk, the manufacturer must report this data to EPA within 30-days of the finding.

EPA recognizes that, at the PMN stage, detailed information may not yet be available and has therefore pioneered efforts using modeling software and Structure Activity Relationships to help inform agency decisions. EPA's EPISuite™ software contains 17 individual models that estimate environmental fate,

aquatic toxicity, biodegradability, and other attributes that predict the effect of chemicals on human health and the environment. One of these tools is ECOSAR™, which is a tool utilizing structure-activity relationships (SARs) to predict the behavior of chemicals with limited test data based on chemicals with structural similarity for which detailed test data is available. The scientists and engineers at EPA are extremely knowledgeable and, in the absence of test data, make decisions on regulation of chemicals based on extremely conservative interpretation of the data from their models. Some of the analyses that commenters have argued that EPA should do for new chemicals, such as evaluating cumulative risks, are extremely complex, time-consuming and costly – and in many cases toxicologists are not in agreement on how such analyses should – or even can – be done.

It is important to emphasize, moreover, that EPA is not limited to existing data and models when reviewing new chemicals. EPA has the ability, directly and indirectly, to require companies submitting PMNs to generate and submit specific health data, and it has done so regularly where, in its judgment, such data were warranted. Finally, EPA has the ability, directly and indirectly, to limit the uses of new chemicals.

EPA has not systematically applied the knowledge developed through PMN's to the universe of related chemical substances that were grandfathered onto the inventory. Use of this sort of read-across data would help to inform EPA action on existing chemicals.

I thank you for this opportunity to describe a pragmatic approach to TSCA reauthorization, and I would be happy to answer your questions.