Testimony
of
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On behalf of the

Society of Chemical Manufacturers & Affiliates

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Energy and Commerce Committee
Subcommittee on Environment and the Economy

On the

"TSCA Modernization Act of 2015"

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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 woman-owned small business.

I am pleased to be back in Washington on behalf of the Society of Chemical Manufacturers and Affiliates to share my perspective on the April 7 discussion draft of the TSCA Modernization Act. At the outset, I would like to applaud the great work you and your staff have been doing on advancing TSCA reform – and your bipartisan approach. It has been refreshing to hear such positive statements coming from both Republicans and Democrats in the leadership. We are hopeful this tone can be maintained. We also appreciate your outreach to stakeholders, and your interest in SOCMA's perspectives on TSCA.

After many years of failed attempts, this appears to be an excellent opportunity for TSCA reauthorization. While these past efforts may have been frustrating, they have also been educational. We have identified what parts of TSCA required the most work. We also have a better idea what approaches are realistic and achievable for the universe of chemicals that fall under its scope. TSCA covers a wide variety of chemicals and applications and impacts a huge swath of the economy. Given the wide range of interested parties, it is truly remarkable how much alignment on issues has been achieved this time around. I hope that, working together, we can continue to expand this support.

To borrow an expression from chemistry, the draft TSCA Modernization Act passes the Litmus Test: It maintains the provisions that have worked well, and it fixes provisions that have been blamed for TSCA not working well. This bill has real potential for attracting substantial bipartisan support. In some areas, the bill challenges EPA and stakeholders to make more of existing law than EPA has in the past. We are interested to hear others' views on whether it does enough in that regard. There remain a number of ways that we believe the bill could be improved upon, or clarified, but this is what the legislative process is for.

TSCA is a complicated statute, and you've been careful not to make it more so; not to unfix areas that have worked well, and not to give EPA more authority where it already has enough. This bill really focuses on the essentials. I will now talk about some them.

Safety Standard. The bill retains the language of the current TSCA safety standard, but it corrects its fundamental flaw by preventing cost from playing a role. As a result, the standard is purely based on human health and environmental concerns. The bill also requires specific consideration of vulnerable subpopulations, to protect individuals with greater susceptibility.

There is no question, therefore, that EPA could make very different decisions under Section 6 than it has (or more accurately, has not) in the past. As a practical matter, any differences will be determined in practice as EPA makes policy decisions about specific chemicals informed by evolving science. But we don't think EPA has to be given any new words to interpret in order to make protective decisions. In particular, it simply would not work for EPA to be forced to use a safety standard that is borrowed from laws governing pesticides or food and drugs. Those laws

cover much narrower fields of chemicals that are intended to be bioactive, and that have easily defined and managed applications. Most industrial chemicals have different exposure pathways than pesticides, food or drugs and many of these are used exclusively within industrial settings.

New Chemicals. For many years, SOCMA has advocated for TSCA Section 5 to remain, basically, as it is. We have heard from many other stakeholders that this is the one section of TSCA that has worked very well. It also happens to be the most important part of the statute for the future of our environment and our economy. Experience has taught us that new chemicals tend to be greener. If we want to promote innovation and the development of greener chemistries, Section 5 must remain efficient, predictable and affordable.

Timely access to market is crucially important for innovation. It is especially important to specialty chemical manufacturers, who often have to manufacture custom chemicals on demand, on a batch-to-batch basis. In fact, the one change we would urge to Section 5 would be to eliminate the one source of delay under the new chemicals program. Currently, even if EPA concludes its review of a new chemical in less than 90 days, the statute requires the chemical submitter to wait the full 90 days. EPA should be authorized to allow commencement of manufacture upon EPA's decision to "drop" from further review (which often occurs on or about day 22), indicating that a new chemical will not present an unreasonable risk of injury to human health or the environment.

Testing of Existing Chemicals. While the new chemicals program has worked well, the same cannot be said about reviews of existing chemicals. Two main problems have been identified with Section 4 – and the draft bill fixes both:

- First, currently EPA has to establish that a chemical poses a risk before it can seek the data to enable it to make that determination. The bill adds a new provision stating simply that EPA can seek data under Section 4 whenever that data "is necessary to conduct a risk evaluation," and it *requires* EPA to conduct a risk evaluation whenever it has "a reasonable basis for concluding that the combination of hazard from and exposure to the chemical substance under the intended conditions of use has the potential to be high enough to present an unreasonable risk."
- Second, current TSCA requires EPA to act by rulemaking – a resource intensive and time consuming process. EPA has dealt with this problem quite successfully by utilizing enforceable consent agreements and voluntary efforts. But that is only a partial solution. Under this bill, EPA would be authorized to issue orders and enter into consent decrees, much the same way as it does with new chemicals – in addition to promulgating rules.

The most notable omission from the bill's treatment of Section 4 is a detailed prioritization or screening process for existing chemicals. We support a more comprehensive review of existing chemicals and with the other improvements made by the bill (including access to greater financial resources) there is arguably nothing to prevent EPA from continuing a risk-based prioritization process similar to the current Work Plan chemicals initiative, which has been generally supported. EPA can also review the information it gets from periodic reporting under the Chemical Data Reporting rule. With all the tools at EPA's disposal under the bill to collect

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data and conduct risk evaluations, EPA should be able to establish its own, de facto, high priority chemicals – it should not need a specific legislative direction to do that.

The real issue is whether this and future EPAs can muster the necessary resources (which will require political support from the White House and Congress) to step up the review of existing chemicals. SOCMA supports legislative specification of workload requirements and deadlines, if they turn out to be necessary as a practical matter. Specific review timelines have worked well in the new chemicals program; we believe they could work for existing chemicals as well. What is key, however, is that EPA has adequate resources and sufficient tools to review existing chemicals – and this bill addresses those shortcomings of the current program.

Risk Evaluations and Risk Management. One of the most contentious aspects of TSCA implementation has been EPA's ability under Section 6 to impose restrictions on existing chemicals that "present or will present an unreasonable risk." As noted earlier, the bill changes that standard by excluding cost considerations, making it a purely safety-based exercise. Should EPA make an unreasonable risk finding, it would also be freed from having to choose the "least burdensome" restrictions. The bill also eliminates the requirement that Section 6 rulemakings include public hearings whenever requested. These are all huge improvements. Furthermore, a manufacturer can offer to pay the costs of an evaluation, which should help with EPA resource constraints, provide additional data, and increase the throughput of chemical evaluations. We would support going further and requiring EPA to consider industry drafted risk evaluations, as the Senate bill does. That bill leaves to EPA's discretion how much weight to give such work, which can be guided by objective criteria such as compliance with Good Laboratory Practice standards and use of EPA-approved test methods.

Reporting Requirements. The principal change in Section 8 is to establish an inventory reset. This is an essential improvement since understanding the universe of chemicals in commerce will help to focus EPA's efforts. We ask that you take this a step further and include a list of inactive chemicals in commerce like the Senate does. SOCMA would also like to see additional reporting to enhance the data available to EPA. We acknowledge that EPA already has authority to require reporting from downstream processors, but we also support language requiring processors to report use and exposure data when EPA concludes that such reporting would materially improve their understanding of actual exposures, a necessary part of the risk equation. This would not have to be identical to manufacturer reporting, but it could be helpful in certain cases. We understand that processor reporting is a politically challenging issue (and could be logistically challenging as well). But we believe information from processors (who are in the best position to report on exposure patterns during use) will be crucial to evaluate the need for additional test data and in generating well-informed risk assessments. We urge you to consider this issue.

As I have mentioned in prior testimony, the bill should also authorize submission of non-adverse data under Section 8(e) and to require EPA to take such data into account in evaluating chemicals. Currently EPA accepts what it calls "FYI" submissions, but it is criticized by some for doing so. The bill defines "weight of the scientific evidence" to mean "the results of an approach that gives appropriate weight to all relevant information in an integrative and objective

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manner that takes into account the strengths and limitations associated with each type of information.'' The only way for EPA to do that is to consistently consider all information that bears on the health effects of a chemical, both positive and negative. Such an enhancement would greatly increase the amount of data submitted under Section 8(e), which can only improve EPA's understanding of chemical hazards.

Finally, we would also like to see the bill include a section on statutory mixtures to recognize certain nomenclature for specialty chemicals, including color pigments. Much can be gleaned from the Senate bill in this regard.

Confidential Business Information. As I've stated previously, CBI is essential to US manufacturers, especially small businesses like mine; protection of CBI allows us to pursue research and market development without disclosing details of these activities to the public (and by extension, to our competitors). While we wish to keep certain aspects of our new product development efforts confidential, we appreciate that we must proceed with as much transparency as possible. Section 14 is where these competing values are balanced. The biggest shortcoming with current law is that industry can claim a trade secret and essentially have it stay that way in perpetuity, unchecked. The bill addresses this problem by requiring upfront substantiation and re-substantiation every ten years. The bill also addresses another common criticism of Section 14 by allowing disclosure to states, emergency responders and treating physicians. These are major improvements. Additionally, we would like to see chemical identity explicitly protected as CBI in health and safety studies, when the claim can be adequately substantiated. I would never advocate keeping the hazard or the study confidential, only the specific chemical ID. We believe that robust generic names could give enough information to stakeholders while still maintaining confidentiality for business sensitive chemical IDs. We would also like to see some more specificity about exactly what kinds of trade secrets need to be substantiated and re-substantiated. The Senate bill declares a list of types of information to be presumptively confidential, so that substantiation is focused on chemical identity, which has been the principal source of transparency concerns. There are many types of CBI and having to substantiate obviously sensitive things like manufacturing processes or market information could turn into a highly and unnecessarily burdensome exercise.

Preemption. This topic has become the main source of controversy over the Senate bill. As noted above, the House bill has no mandatory prioritization process, so the issue of whether prioritization decisions should be preempted is avoided. In retaining Section 18 of current law, state co-enforcement would remain unpreempted. The section also clarifies that state tort law is not preempted. However, if EPA determines that a substance presents no unreasonable risk, state laws that are prohibitions would no longer be preserved from preemption. These are fair and reasonable provisions. We are still assessing this section, but it does address the biggest controversies that have emerged in discussions over the years on preemption.

Resources and Fees. Inadequate EPA resources has become another hot-button issue. The bill lifts the $2,500 cap on fees for submissions under Sections 4 and 5 currently imposed by Section 26. As with EPA's workload under Section 4, this simple change would seem to allow EPA to structure a fee program comparable to that contained in the Senate bill. The bill would also require EPA to set lower fees for small businesses, a very good thing from the perspective of

SOCMA's membership, 70% of which are small businesses. Manufacturers can also offer to pay all costs of a risk evaluation, as noted earlier.

We do have some concerns about this part of the bill:

- Because it works with existing law, under the bill, fees associated with certain submissions would go to the Treasury, and would not necessarily alleviate EPA's resource problems. The bill should establish a dedicated fund to which fees would be directed and which could only be used to support the TSCA program.
- The Senate caps fees at $18 million, with a goal of covering 25% of the TSCA program. This bill should include some comparable cap.
- We are concerned about the potential for new chemical fees to be used to subsidize other parts of the program. Pre-manufacture notices (PMNs) are mandatory and are filed with great regularity, thus offering a tempting target for fee increases – whereas EPA has no obligation to impose any Section 4 requirements, so fees from implementation of this section are a less certain funding stream. In our opinion, fees for new chemical submissions should be used for the new chemicals program and should not be prohibitive – PMNs filed represent innovation, usually encompassing chemicals that pose fewer hazards than their existing chemical predecessors. Keeping new chemical fees reasonable ensures that manufacturers are incentivized to develop newer, greener chemistries.
- We also believe there should be no fees for exemption notifications, such as the low volume exemption. We are pleased this bill does not mention this prospect, unlike the Senate bill. Remarkable innovation often occurs with low volume chemicals. Furthermore, these sorts of notices tend to be extremely restrictive in volume, manufacturing methods, and end use applications, and therefore do not raise the same concerns that larger volume chemicals do. Additionally, exemption notices have shorter review times and do not require as many resources from EPA as a PMN review does.
- Finally, the bill should clarify that EPA cannot charge higher fees for submissions that include CBI claims – this would be a deterrent to innovation and to the protection of intellectual property.

Conclusion. To conclude, the bill generally maintains the most effective and politically sensitive parts of current law and fixes the areas that have been most problematic. It takes some notably different approaches than its Senate counterpart. Many of the most controversial parts of the Senate bill are not present in this bill, particularly given the absence of a prioritization scheme. Given my experience, I am sure new controversies will emerge, or take new form. Either way, as an optimist, I see this an improvement over the status quo and a promising vehicle for a bipartisan solution.

We appreciate your intense focus on TSCA reauthorization and remain committed to helping in any way we can.

Thank you again for this opportunity to share SOCMA's perspective. I look forward to your questions.

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