

Written Statement of
The Honorable Cal Dooley
President and CEO
American Chemistry Council

Before the
House Energy and Commerce Committee
Subcommittee on Environment and the Economy

*Legislative Hearing on the April 22, 2014 Discussion Draft
Cited as the Chemicals in Commerce Act*

April 29, 2014

American Chemistry Council
700 Second St. NE
Washington, DC 20002

Summary of Major Points
In Testimony of the Honorable Cal Dooley, President and CEO
American Chemistry Council
Submitted for the Legislative Hearing on the April 22, 2014 Discussion Draft
Cited as the Chemicals in Commerce Act

The American Chemistry Council (ACC) supports efforts to reform TSCA's federal chemical regulatory system to give Americans greater confidence in the safety of chemicals. The April 22 discussion draft of the Chemicals in Commerce Act (CICA) would modernize TSCA in a sensible way that focuses on those elements of TSCA most in need of improvement. Overall, the CICA discussion draft is an appropriate step forward in TSCA reform.

The CICA discussion draft takes a creative approach to address the TSCA safety standard issue. It makes clear that EPA's risk evaluations of high priority chemicals will be based strictly on a science based finding of significant risk of harm to human health or the environment. Economic cost and benefit would be considered only in EPA's determination of what regulation is needed to manage that risk.

The changes to the TSCA new chemicals and SNUR programs will contribute to greater efficiencies and protections in the chemical regulatory framework, while still allowing industry the opportunity to bring new innovations to market quickly and efficiently.

The discussion draft's inclusion of appropriate deadlines for EPA decisions will strengthen the public's confidence in EPA's safety assessment and regulatory process.

The discussion draft's requirement for EPA to prioritize existing chemicals for risk evaluations based on consideration of a chemical's hazards, uses and exposures, including to potentially exposed subpopulations, will ensure EPA applies resources to the highest priorities.

The improvements to the testing provisions of TSCA will reduce EPA's current regulatory burdens when new information is needed because available information is insufficient. The expansion of EPA authority to mandate testing for prioritization purposes is a significant change that ACC can support.

The CICA's data protection provisions are balanced and will go a long way to improving the justification for and protection of CBI.

Improvements to TSCA's preemption provisions should foster a robust, national chemical regulatory system.

Introduction

My name is Cal Dooley. I am President and CEO of the American Chemistry Council, the national trade association representing chemical manufacturers in the United States. I am testifying today on behalf of the ACC, and our member companies, who employ nearly 800,000 men and women.

ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The U.S. business of chemistry is a \$770 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for 12 percent of all U.S. exports. Chemistry companies are among the largest investors in research and development, and rely heavily on the Toxic Substances Control Act (TSCA) to help bring their innovations to market.

TSCA Modernization is Required to Protect Health and the Environment and America's Competitive Edge.

The American chemical industry is a major source of innovation and economic growth in the U.S. In fact, over 25% of the US GDP is derived from industries that depend on chemicals. TSCA is the major US law governing the reporting, testing and regulation of chemicals in commerce. It's as much a law governing the commerce of chemicals as it is about protecting health and the environment from exposure to chemicals.

The chemical industry takes very seriously its responsibility to manufacture products that can be used safely. There have been many advances in our understanding about chemicals,

about science and technology, our health and our environment in the 35+ years in which TSCA has been in place. Over time, however, public confidence has eroded in the safety of chemicals and in the federal government's regulation of the production and use of chemicals. As a result, ACC strongly supports efforts to reform TSCA's federal chemical regulatory system to give Americans greater confidence in the safety of chemicals.

Safety has always been a top priority of our member companies, as evidenced by ACC's 25 year old Responsible Care® program - a health, safety and security performance initiative that's a requirement of ACC membership. One of the program's most recent enhancements was the addition of a Product Safety Code, to update the program's Product Stewardship management system. The Product Safety Code is an industry complement to an effective and reliable chemical regulatory system achievable through TSCA Reform.

Five years ago ACC released its Ten Principles for Modernizing TSCA. These principles create a general outline for a modern chemical regulatory system that will protect public health and the environment, while preserving the ability of American chemical companies to continue to drive innovation, grow jobs, and compete in the global marketplace. Since 2009, ACC has engaged in constructive efforts to develop and promote a TSCA reform proposal that would put consumer health and safety first, while ensuring that the U.S. is the best place in the world to innovate.

In May of last year the first ever bipartisan bill on TSCA reform, the Chemical Safety Improvement Act (CSIA, S. 1009) was introduced in the Senate. ACC believes S. 1009 holds great promise for achieving meaningful and balanced TSCA reform. The legislation calls for a rigorous chemical regulatory framework that is consistent with the ACC's Ten Principles of TSCA Modernization.

The April 22 discussion draft before this committee today, the Chemicals in Commerce Act (CICA), holds similar promise. It would modernize TSCA in a sensible way that focuses on those elements of TSCA most in need of improvement. It includes a systematic process by which EPA would prioritize existing chemicals in commerce, conduct risk evaluations of high priority chemicals using science and improved regulatory tools, and impose risk management restrictions as necessary. The CICA will go a long way to making chemical regulation in the US both more effective and efficient. Under the revised discussion draft, EPA, the American public and American manufacturers would have the information they need to make well informed decisions about chemicals in commerce.

Key elements of the April 22 discussion draft would improve TSCA's approach to chemicals management.

TSCA Reform Should Appropriately Expand EPA's Authority to Mandate Testing (Section 4)

Like the Senate bipartisan bill, the CICA April 22 discussion draft fixes the "Catch 22" testing requirements of current TSCA. The CICA replaces TSCA's current findings requirement with provisions allowing EPA to require new testing or exposure information if needed for certain specified purposes (subsections 4(a)(1), (3) and (6)). Testing can be required for

- priority designation purposes
- risk evaluations
- restrictions imposed on new chemicals;
- regulation of exports;
- implementation of other Federal laws. (See subsections 4(a)(1)(A-E)).

The CICA also allows EPA to use rules, consent agreements or orders to require the development of new information. (Section 4(a)(2)).

ACC supports these improvements to the testing provisions of TSCA. They will reduce EPA's current regulatory burdens when new information is needed because available information is insufficient for the specific purposes described in this section.

TSCA Reform Must Include a Workable Safety Standard (Sections 5 and 6)

TSCA chemicals can have hundreds of different industrial, commercial or consumer uses. Unlike pesticides or pharmaceuticals, industrial chemicals are not intended to be biologically active, and the standard by which decisions on safety are made should be appropriately different. The TSCA safety standard must not only be protective of health and the environment, it must also be workable when applied to the multitude of TSCA chemical uses.

ACC believes that TSCA reform must help assure that chemicals are safe for their intended uses. This means safety is not just a matter of a chemical's hazard profile; it is also a question of how a chemical is used and the exposures and risks that result from that use. The safety of TSCA chemicals should be determined by integrating hazard, use and exposure information in the risk evaluations for determining safety.

There is no definition of “safety standard” in the revised discussion draft. Instead, the discussion draft applies slightly different approaches to new chemical and existing chemicals and addresses concerns raised about the “unreasonable risk” safety standard in the Feb. 27 discussion draft. This approach recognizes that EPA's evaluation of new chemicals differs from its review of existing chemicals for important reasons. This approach also addresses one of the major criticisms of TSCA related to cost and benefit considerations in the Agency's review of chemical risk.

For new chemicals, EPA must determine whether the substance “may present an unreasonable risk of harm to human health or the environment,” or that the new chemical does

not warrant regulation before it is introduced into commerce. This approach largely reflects EPA's practice today with respect to new chemicals, a practice which has enabled innovation in chemistry to flourish in the U.S.

The standard for evaluating the risk of existing chemicals is expressed in the subsection 6(b)(1)(A)'s high priority risk evaluation provision. EPA must conduct a risk evaluation to determine whether an existing, high priority chemical "presents or will present, in the absence of regulation under subsection (c), a significant risk of harm to human health or the environment under its intended conditions of use."

Existing chemicals that EPA determines do or will present a significant risk must then be regulated by EPA. These regulatory restrictions must meet a second standard, expressed in subsection 6(c)(1) as "necessary to protect adequately against an unreasonable risk of harm to human health or the environment from the chemical substance under its intended conditions of use."

The CICA's risk evaluation standard differs from TSCA's "unreasonable risk" standard in two very important ways. First, the draft makes clear that cost and benefit considerations would apply only after EPA makes determination of significant risk based strictly on the science. Second, it must be applied under the chemical's intended conditions of use. This statutorily imposed bifurcation of EPA's decision-making is very different from Section 6 of TSCA today. ACC believes this approach is very similar in effect to the bipartisan Senate bill's (S. 1009) articulation of the safety standard.

ACC commends the creative approach taken in the revised discussion draft to address the TSCA safety standard issue in a way that makes clear that economic cost and benefit considerations apply only in EPA's determination of what regulation is needed to manage

that risk. ACC's TSCA reform principles make clear our support for risk determinations based solely on health and environmental considerations. Both the revised discussion draft and S. 1009 achieve that objective.

TSCA Reform should Retain Essential Elements of the Existing New Chemicals Program (Section 5)

TSCA's new chemical program has made a significant contribution to innovation in products and technologies in the US. There is broad agreement among many stakeholders - including former EPA officials - that TSCA's new chemicals program today provides a science-based, tailored, and timely regulatory review of new chemicals before they can be manufactured.

The CICA discussion draft streamlines the regulatory requirements of EPA's current new chemicals program and aligns it effectively with improvements being made to other sections of TSCA. The CICA also codifies the new chemical program's current, effective regulatory practices. Just as EPA does today, under the CICA the Agency may request additional information needed either for its new chemical review or for its determination about the new chemical. The CICA also appropriately recognizes that new chemical reviews are most often conducted on the basis of scientifically robust models, structure activity and read-across information, rather than on actual test data. These tools have proven their value in the 35+ years of TSCA, are scientifically reliable, and protective. Under the CICA, once on the market, new chemicals would still be subject to the prioritization screening process in subsection 6(a), and potentially, to subsection 6(b) risk evaluations and subsection 6(c) regulations.

With respect to EPA's significant new use rule (SNUR) authority, the CICA clarifies the considerations for determining whether a use is a significant new use and further clarifies EPA's authority to regulate use of chemicals as part of an article (Section 5(a)(2) and 5(a)(3)).

Until recently, articles were largely exempt from TSCA regulation. This is an area, however, of increasing EPA interest. Appropriately, the CICA proposes workable criteria for regulation of chemicals in articles.

In ACC's opinion, the changes to the TSCA new chemicals and SNUR programs will contribute to greater efficiencies and protections in the chemical regulatory framework, while still allowing the industry the opportunity to bring new innovations to market quickly and efficiently.

TSCA Reform Should Ensure EPA Applies Resources to the Highest Priorities (Section 6(a))

ACC has long held that EPA should systematically prioritize existing chemicals in commerce for evaluation under TSCA, based on available information about their hazards, uses and exposures, so that resources (both EPA's and industry's) could be focused on chemicals of highest concern. Section 6(a)(1) of the CICA would require EPA to establish a risk-based process for obtaining available information and designating chemicals as high or low priority. EPA must designate all active chemicals in commerce as soon as feasible. Factors for assigning priorities would include consideration of a chemical's uses and exposures to potentially exposed subpopulations, defined as including infants, children, pregnant women, workers and the elderly (Section 6(a)(4)). Chemicals designated as high priorities would be subject to risk evaluations.

The revised discussion draft at Section 6(b)(2) also allows EPA to conduct risk evaluations of chemicals not designated as high priorities and determine at any time that they will not present a significant risk of harm under one or more specific conditions of use. This

provision effectively creates a third category of priorities that should promote efficiencies in the overall chemical management framework of an amended TSCA.

There are several differences in how the discussion draft addresses prioritization as compared to the Senate bill. For the most part, ACC does not think these differences are significant. For example, the House discussion draft does not require EPA to establish a prioritization process by rulemaking because it anticipates that the prioritization process may need to be modified over time. The CICA provision does not speak directly about current EPA priorities under its Work Plan Chemical program, but Section 28 of the discussion draft preserves EPA's authority and continues application of actions taken by the Agency under TSCA before enactment of the CICA. In ACC's view, it is clear that EPA can continue to assess priority chemicals previously identified even as it develops a process for prioritizing additional chemicals.

Unlike the Senate bill, the CICA discussion draft does not specify a particular role for the States in prioritization. The extent of State regulation of a chemical, however, would be a factor in designating a substance as a low priority under the discussion draft. ACC believes that legislative history should make clear that under the prioritization process States are able to engage completely in the prioritization process.

Finally, in response to criticisms of the initial version of the discussion draft, the April 22 revised draft authorizes EPA to require companies to develop new hazard or exposure information under Section 4 for prioritization purposes. (Sections 4(a)(1)(A) and 4(a)(3)).

ACC supports these requirements for prioritization of existing chemicals for risk evaluations. The expansion of EPA authority to mandate testing for prioritization purposes is a significant change that ACC can support as long as it is made clear that the

provision does not confer broad authority to impose minimum data set requirements, and is only applied by EPA on a case by case basis. As a general rule, EPA should be able to identify high and low priorities based on available information on chemicals, as the Agency has demonstrated in its existing Work Plan Chemicals program.

TSCA Reform Should Create Effective, Efficient Processes to Evaluate Risk, including Appropriate Deadlines for Action (Section 6(b) and (c))

Subsection 6(b) of the revised draft requires EPA to determine whether a high priority substance “presents or will present a significant risk of harm to human health or the environment,” no later than 4 years after designation as a high priority. Science-based risk assessment practices are at the heart of this provision. The discussion draft includes four factors that EPA must consider when applying the standard for evaluating risk:

- The nature of the risk
- The likely impact of the risk on potentially exposed subpopulations
- Whether harm has occurred under its intended conditions of use
- The probability that harm will occur (Section 6(b)(3)(A)).

The discussion draft also makes very clear (Section 6(b)(3)(B)) that in the risk evaluation, EPA may **not** consider economic costs and benefits of the intended uses of the chemical or of reducing the exposure by rule under subsection (c).

Under subsection 6(c) of the legislation, no later than 3 years after determining that a substance presents or will present a significant risk, EPA must promulgate a rule with restrictions that EPA determines are “necessary to protect adequately against an unreasonable risk of harm to human health or the environment” from the chemical under its intended conditions of use. The discussion draft lays out the broad range of restrictions EPA may apply in these rules, including warnings, recordkeeping, and monitoring, as well as use specific, quantity specific or broad bans/phase-outs.

The discussion draft also addresses TSCA’s current requirement that EPA choose the “least burdensome” restriction. In its place, the discussion draft requires that EPA determine whether the restrictions are cost effective in ensuring a chemical will not result in an unreasonable risk of harm. The subsection provides for a reasonable transition period to implement restrictions. The revised draft also improves language in the February 27 discussion draft regarding EPA’s consideration of alternatives and addresses concerns raised about the burdens on EPA that the earlier discussion draft language may have imposed. The revised discussion draft makes clear that if prohibitions or substantial restrictions on specific uses are being considered by EPA, EPA must determine whether technically and economically feasible alternatives are “reasonably available” as a substitute. This clarifies that the discussion draft does not require EPA to take an exhaustive look at all possible regulatory options or alternatives.

As noted earlier, the discussion draft’s inclusion of a “significant risk of harm” standard in the subsection 6(b) risk evaluation provision and the factors to be considered make clear that this standard is separate and distinct from both the TSCA “unreasonable risk” standard of today as well as from the “unreasonable risk” standard in the next subsection 6(c). ACC believes that appropriate deadlines for EPA decisions will strengthen the public’s confidence in EPA’s safety assessment and regulatory process.

TSCA Reform Must Protect Confidential Business Information (Section 14)

The CICA discussion draft’s provisions on confidential business information largely mirror those in the Senate bill. Section 14 presumes certain information as confidential but requires upfront substantiation of claims for CBI protection even for the categories presumed to

be entitled to protection. These provisions strike an appropriate balance between the public's right to know health and safety effects information and industry's interest in protecting the confidentiality of competitive information.

ACC supports the CICA data protection provisions because they are balanced and will go a long way to improving the justification for and protection of CBI.

TSCA Reform Should Foster a Robust, National Chemical Regulatory System (Section 17)

The discussion draft contains many of the same preemption provisions that are included in the Senate bill, with certain important exceptions. For example, Section 17 of the CICA discussion draft does **not** include language relating to the use of safety determinations in evidence. The CICA would not preempt common law or statutory causes of action for civil relief or criminal conduct (Section 17(c)). Under the CICA, EPA will be making many more affirmative determinations about both existing and new chemicals than it does today, and it is vital to efficient interstate commerce that EPA's determinations create the basis for a robust, uniform national system of chemical regulation.

The revised discussion draft modifies the Feb. 27 version to reduce the preemptive impact of EPA's low priority designations. The revised draft now clarifies that low priority decisions by EPA do not preempt existing State law, and that future State law is preempted by a low priority decision only to the extent that the State law regulates a chemical for the intended conditions of use. (Section 17(a)(2)). In other words, like the Senate bill, preemption of State regulation only occurs when EPA makes a decision, and even then the preemptive effect is only to the extent of the decision. States can certainly engage EPA to identify high priority chemicals for safety determinations and to provide EPA with State-specific use and exposure information for these safety determinations and for any restrictions they believe are warranted. States can

also petition EPA under the Administrative Procedure Act (APA) to allow the States to take state-specific actions on TSCA chemicals.

ACC believes improvements to TSCA's preemption provisions should appropriately put EPA "in the driver's seat" in the regulation of chemicals that are manufactured, processed, used, and distributed throughout interstate commerce. This in turn will help restore the public's confidence in the federal chemical regulatory regime.

The CICA Discussion Draft is an Appropriate Step Forward in TSCA Reform.

The April 22 revision of the CICA discussion draft addresses many of the criticisms and concerns raised about the initial February 27 discussion draft. It is consistent with ACC's views on the needed reform of the federal chemical regulatory framework under TSCA. ACC urges this Subcommittee's serious consideration of the CICA. ACC remains hopeful that bipartisan TSCA reform will be possible in this Congress. We welcome the Subcommittee's efforts to work cooperatively toward meaningful, balanced reform and we remain ready to assist the committee to that end.