Testimony of Mark N. Duvall

Before the Subcommittee on Environment and the Economy

Committee on Energy and Commerce

United States House of Representatives

"The Chemicals in Commerce Act"

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Summary of Key Points

The draft Chemicals in Commerce Act (CICA) would strengthen the core provisions of the Toxic Substances Control Act (TSCA), sections 4, 5, and 6.

The changes to the testing provision, section 4 of an amended TSCA, would bolster EPA's ability to require testing by (a) lowering the threshold findings necessary for EPA to require testing; (b) authorizing EPA to require testing by order in appropriate cases; (c) providing a statutory basis for testing consent orders; and (d) facilitating the transition to the toxicology testing of the future.

The changes to the new chemicals and significant new use provisions, section 5 of an amended TSCA, would codify and strengthen EPA's current practices. They would also require for the first time that EPA make a determination about the safety of chemical substances reviewed under these provisions. EPA could require testing where necessary.

The draft bill would give EPA new tools to evaluate chemical safety by requiring it to prioritize chemical substances, make a safety determination for high-priority substances, and regulate those substances found to result in an unreasonable risk of harm to human health or the environment under the intended conditions of use. These provisions would appear in section 6 of an amended TSCA.

Prioritization would be a risk-based process for identifying chemical substances for further review. A safety determination would be a risk-based analysis of whether a chemical substance will result in an unreasonable risk; it would not involve consideration of costs and benefits. The risk management provision would delete the "least burdensome alternative" requirement in current TSCA and require findings that would help with good governmental decisionmaking.

Testimony

Thank you for inviting me to testify at this hearing. My name is Mark N. Duvall, and I am a principal at the law firm of Beveridge & Diamond, P.C. Although I represent a variety of clients on TSCA issues, I am appearing here today solely in my personal capacity. The views I express today are my own. I am not representing my law firm or any client of my law firm.

I have extensive experience with the Toxic Substances Control Act (TSCA). I have been advising clients on TSCA for some 30 years.

I have reviewed the Discussion Draft of TSCA legislation entitled the "Chemicals in Commerce Act." My comments today focus on the core provisions of the Discussion Draft, which would amend sections 4, 5, and 6 of TSCA, relating to testing, new chemical substances, and existing chemicals. These provisions would strengthen TSCA.

1. Testing Requirements

The draft CICA would bolster EPA's ability to require manufacturers and processors to conduct testing.

First, the draft would lower the threshold findings that EPA must make before requiring testing. Today, in order to require testing, EPA must find that testing is needed and that a chemical substance "may present an unreasonable risk" or that a chemical substance is produced in substantial quantities and may have significant or substantial human or environmental exposure. EPA has found these additional threshold findings to be obstacles to its ability to require testing. The draft would delete those additional threshold findings. It would only require EPA to conclude that testing is needed.

Second, where appropriate, EPA would be able to impose testing requirements by order rather than by rulemaking. This should streamline its ability to require testing, since EPA has found the rulemaking process for test rules to be resource-intensive and time-consuming.

Third, the draft CICA would provide a statutory basis for testing consent orders. While EPA has been entering into testing consent orders for several years, its authority to do so is at best implied in the current statute. The draft CICA would establish clear authority for testing consent orders.

Fourth, the draft would facilitate the transition to the toxicology testing of the future. Under current TSCA, EPA has required the testing of chemical substances one at a time, often in expensive tests that require the use of a large number of vertebrate animals. The draft would require EPA to take concrete steps to minimize the use of vertebrate animals in testing. It would encourage the use of innovative technologies that allow for the possibility of testing a large number of chemical substances for a wide variety of endpoints with the use of technology. This vision is far more sustainable than the approach EPA has taken in its testing requirements to date. At the same time, it would leave EPA the discretion to require animal testing where alternatives are not yet available or sufficiently reliable.

2. New Chemical Substances and Significant New Uses

The draft CICA would codify much of EPA's current practices in addressing new chemical substances and significant new use rules (SNURs). For example, EPA has regulated a large number of chemical substances through consent orders under section 5(e) of TSCA. The draft bill would clarify and strengthen EPA's ability where appropriate to restrict new chemical substances as they enter the market or as a manufacturer or processor commences a significant new use of an existing chemical substance.

The draft bill would make a significant change in how EPA reviews new chemical substances and existing chemical substances subject to SNURs. For the first time, EPA would be required to make a determination about the safety of such chemical substances. Today, EPA may simply allow the notice period to expire without taking regulatory action. Under the Discussion Draft, EPA would have to decide whether a chemical substance, or engaging in a significant new use, would or would not be likely to result in an unreasonable risk of harm to human health or the environment under the intended conditions of use. Jim Jones, Assistant EPA Administrator, told this Subcommittee recently that the corresponding provision in the Senate bill, S. 1009, is one of the best features of that bill.

EPA may find that it lacks sufficient information to make a determination that a chemical substance or significant new use is or is not likely to result in an unreasonable risk under the intended conditions of use. In that case, the draft bill would authorize EPA to require testing to develop the information it needs in order to make that determination. This approach would be a compromise between the concept of minimum data sets, which may result in large amounts of data not necessary for regulatory determinations, and the current situation where many notices are submitted without data. Where appropriate, EPA may allow a new chemical substance to enter the market while the testing is being conducted. Otherwise, EPA may require the testing to be completed before commercialization.

The standard of "likely" or "unlikely" to result in an unreasonable risk under the intended conditions of use is appropriate where available data may be limited. A new chemical substance has not yet entered the market, so it has not produced the revenue necessary to generate the kind of data EPA might need to make a more definitive determination. Once a new chemical substance does enter the market, it would become subject to the provisions relating to existing

chemical substances. At any time after commercialization, EPA could review a former new chemical substance and make a safety determination that the chemical substance will or will not pose an unreasonable risk. If EPA then needed additional data in order to make that determination, it could require testing.

3. Prioritization

One of the most important changes to TSCA in the draft CICA is the prioritization provision. Prioritization would lead to safety determinations, which would lead to risk management in appropriate cases.

Today's TSCA does not direct EPA to review chemical substances systematically for the risks that they may pose to health or the environment. EPA has tried to do so, most recently with its list of Work Plan chemicals. However, we have seen over the years that it has struggled to sustain a focused, reasoned approach to reviewing chemical safety. Without a driver that requires it to prioritize chemical substances for review, and then review them, EPA has faced challenges in obtaining necessary funding from Congress or clearances from the Office of Management and Budget.

The prioritization provision of the draft CICA would direct EPA to establish a risk-based process for designating chemical substances as either a high priority or a low priority for a safety determination. EPA would have no more than 1 year to establish that process. The draft would identify the basis for making prioritization decisions. It would allow for public comment on proposed designations, but EPA would maintain considerable discretion in setting its own priorities for reviewing chemical substances.

Prioritization would be intended primarily as a process for selecting chemical substances for further review. Chemical substances designated as high priority would proceed to a safety

determination. Those designated as low priority would not. At any time, EPA could revisit a designation and change it if the available information supported a change.

EPA would be charged with making a prioritization decision for all chemical substances that are active (as determined under section 8). The draft bill would not mandate a timetable for completing prioritization all active substances, however. A timetable might create a large and growing backlog of uncompleted safety determinations. Instead, the draft bill would allow EPA to make prioritization decisions in part by taking into account its ability to schedule and complete safety determinations.

4. Safety Determinations

The draft CICA would require EPA to make safety determinations for high-priority substances. This would be the second step in addressing chemical safety systematically. The safety determination would conclude that a chemical substance will or will not result in an unreasonable risk to human health or the environment under the intended conditions of use.

Unlike the Senate bill, S. 1009, the Discussion Draft would not have a safety assessment followed by a safety determination. Instead, it would combine both activities into one safety determination step, to be followed by a separate risk management step if appropriate.

EPA would make a safety determination based on existing information unless it determined that additional information was needed. In that case, it would be able to require testing and defer the safety determination until after the test data became available.

The "unreasonable risk" standard in the draft CICA would be very different from the similarly-worded "unreasonable risk" standard of current TSCA, and of some other statutes such as the Consumer Product Safety Act. Those statutes combine a finding of risk with a decision about risk management into a single determination. They require the agency to weigh the costs

and benefits of the chemical and the regulatory action before making an "unreasonable risk" determination. Unlike those statutes, the draft CICA would separate out the determination of risk, which is essentially a scientific conclusion, from decisions about risk management. A safety determination about "unreasonable risk" would be risk-based. The draft provides that the determination would be based on the weight of the scientific evidence after considering the best available science related to health and environmental concerns. It would consider information on potentially exposed subpopulations. There is no provision for the weighing of costs and benefits in making a safety determination. Any consideration of costs and benefits would be postponed until the risk management stage.

Nevertheless, courts might be inclined to find that the CICA's "unreasonable risk" standard requires consideration of costs and benefits simply based on other statutes. To mitigate this possibility, it may be advisable to explain this provision in legislative history to emphasize that the weighing of costs and benefits would not be part of a safety determination.

The draft bill does not include deadlines for EPA to complete a safety determination or a certain number of safety determinations. EPA is likely to need varying amounts of time to complete safety determinations, in light of variables such as the number of uses to be considered and whether or not testing would be needed. If deadlines are added to the bill, they should be flexible enough to address this variability in timing needed to complete any individual safety determination.

5. Risk Management

The draft bill's risk management provisions would significantly strengthen EPA's ability to require appropriate controls. It would delete the "least burdensome alternative" requirement

of TSCA that featured prominently in the court decision invalidating EPA's ban on asbestos.[1] It would also delete many of the procedural requirements that EPA found to make rulemaking difficult.

Instead, the draft would require EPA to make certain findings before imposing risk management controls, all of which relate to good governmental decisionmaking. For example:

- EPA would have to determine that the controls will result in net benefits and would be cost-effective. These requirements are already applicable to EPA decisionmaking through Executive Orders issued by President Clinton and President Obama.[2]
- Where the risk management measures would amount to a ban, EPA would have to ensure that feasible alternatives are available that would materially reduce the risk posed by the chemical substance. This provision would address the concern reflected in California's Green Chemistry regulations about "regrettable substitution," although far less would be required of EPA than the Green Chemistry regulations would require of responsible entities.[3]

Any risk management measure would have to exempt replacement parts for articles manufactured prior to the applicable compliance deadline. It would also have to provide for a reasonable transition period. Both of these measures are important for manufacturers of complex durable goods such as automobiles and airplanes.

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[1] *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

[2] Executive Order 12866, 58 Fed. Reg. 51735 (Oct. 4, 1993) ("Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach …. When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective."); Executive Order 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011) (similar language).

[3] Compare 22 Cal. Code Regs. § 69501 et seq. (Safer Consumer Products regulations).

The bottom line is that EPA would be better equipped than under current TSCA to regulate chemical substances found to result in an unreasonable risk.

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In conclusion, the draft CICA would strengthen TSCA's core provisions. It would delete requirements that have hampered EPA's ability to regulate chemical risks; it would provide EPA with new flexibility in exercising its authority; and it would require EPA to act in ways that promote good governmental decisionmaking.

Thank you for considering this testimony.