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March 14, 2014

The Honorable John Shimkus
Chairman
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Shimkus:

Attached please find my responses to the written questions for the record I received in follow-up to the November 13, 2013 hearing held by the Subcommittee titled "S. 1009, The Chemical Safety Improvement Act."

I received one set of questions, from Committee Ranking Member Henry A. Waxman. Responses to each question are attached.

I greatly appreciate the opportunity to have testified before the Subcommittee on this very important subject, reform of the Toxic Substances Control Act.

Best regards,

[redacted]

Richard A. Denison, Ph.D.
Senior Scientist

cc: The Honorable Paul Tonko, Ranking Member

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Responses of Dr. Richard A. Denison
Senior Scientist, Environmental Defense Fund
to
Follow-Up Questions from Congressman Henry Waxman
Committee on Energy and Commerce
Subcommittee on Environment and the Economy
for the
Hearing on "S. 1009, The Chemical Safety Improvement Act"
held on November 13, 2013

The Honorable Henry A. Waxman

S. 1009 would not require new chemical applications to be accompanied by data and would not require testing of all existing chemicals. Instead, testing would continue to be required on a chemical specific basis under section 4. In fact, the bill explicitly authorizes EPA to allow new chemicals into commerce after determining that testing is needed and before receiving the results of that testing.

1. Should a reformed TSCA ensure that EPA gets more information about new chemicals at the pre-manufacture notice (PMN) stage?

RESPONSE: A reformed TSCA should ensure that a new chemical (or a significant new use of chemical) can only commence manufacture upon a determination by EPA that the chemical (or significant new use) is likely to meet the safety standard. Where insufficient information is available for EPA to make that determination, two options should apply:

a. Manufacture of the chemical (or of the chemical for the significant new use) cannot commence until the information is provided and EPA's makes the requisite determination.

OR

b. EPA imposes conditions on the chemical (or significant new use) sufficient for EPA to determine, despite the insufficiency of the information available, that the chemical or use is likely to meet the safety standard. An example would be where a company proposes three uses of a chemical and EPA has enough information to find two of the three are likely safe, but not the third. EPA could allow the chemical on the market for the first two uses, but prohibit the third use until sufficient data are received and analyzed to make the determination on the third use. Another example would be where EPA places limits on the chemical, such as a maximum production volume, use restriction, or release limit, that are binding on the company, based on which EPA could make the requisite determination.

In any case where EPA imposes conditions on a new chemical or significant new use (typically done through a consent agreement or order) – whether or not in response to a lack of information – it is essential that those conditions apply to any manufacturer or processor of the chemical. The most straightforward way to ensure this is to mandate that EPA issue a significant new use rule (SNUR) in

conjunction with the consent agreement or order that delineates those conditions and requires notification to EPA by any company proposing to make or use the chemical in a manner that does not comport with the conditions.

S. 1009 would change the determination that EPA must make before requiring testing under section 4, replacing the risk determination with a determination that the new data is needed to perform a safety assessment, to make a safety determination, or to meet information needs under other statutes. The bill does not provide authority to require testing for the review of the chemicals or in order to inform prioritization screening.

2. Should a reformed TSCA provide EPA with authority to require testing of new chemicals?

RESPONSE: My response to question 1 is germane to this question as well. I believe ideally there should be a requirement that new chemical notifications be accompanied by a robust safety information set. But it is most essential that there be: a) a requirement for EPA to make an affirmative safety decision prior to manufacture, and b) EPA authority and a mandate to either: i) withhold such a decision in the absence of sufficient information, or ii) impose conditions necessary for EPA to make an affirmative safety decision even in the absence of the information. If a new chemical with insufficient information is not allowed to commence manufacture except under conditions sufficient for EPA to make the "likely meets the safety standard" determination, companies have an incentive to provide needed information and there is an assurance that information gaps do not jeopardize public and environmental health.

Current TSCA does not restrict EPA's authority to require testing of new chemicals, so in this respect S. 1009 scales back EPA authority. Current TSCA does not, however, have a requirement for an affirmative safety determination to be made for new chemicals.

3. Should a reformed TSCA, if it requires a prioritization screening, provide testing authority to inform that screen?

RESPONSE: The retraction of TSCA's current authority for EPA to require testing for prioritization is a serious flaw in CSIA as introduced and that authority should be restored. (Again, it is important to note, however, that CSIA does address two other key flaws in TSCA's testing authority: it provides for EPA to require testing by issuing an order rather than by rulemaking; and it eliminates the requirement that EPA first show evidence of potential risk, or high production and high release or exposure, in order to require testing.)

The problems arising from the lack of authority under CSIA to require testing to inform prioritization decisions are compounded by other provisions of CSIA as introduced. First, there is no requirement that low-priority designations be based on sufficient information on both hazard and exposure to ensure confidence in an EPA determination that such a chemical is in fact likely to meet the safety standard. Second, under CSIA as introduced, such low-priority designations pre-empt state and local government authority to impose new requirements on such chemicals, and those designations are not judicially reviewable. Third, while lack of sufficient information can be "a factor" in making high-priority designations, such lack of information should be a sufficient basis by itself to designate a chemical high-priority. Fourth, there are no deadlines or data- or action-forcing steps in the provision authorizing EPA

to defer a prioritization decision due to lack of information. Other than a requirement that EPA solicit voluntary submissions of information on such chemicals, nothing precludes such chemicals from entering what could amount to an indefinite limbo. Finally, there is no requirement that EPA publicly identify chemicals for which it has deferred a prioritization decision and the basis for that decision.

Together, these provisions of CSIA as introduced would yield a situation where lack of data would lead to no decision or potentially an erroneous prioritization decision, with little or no transparency or incentive to address data gaps. Because many chemicals in commerce have significant gaps in available information on their hazard, use and/or exposure, lack of authority to ensure adequate information is developed could stymie the entire purpose of the prioritization process.

S. 1009 fails to require protection of vulnerable populations in safety determinations for chemicals and in risk management decisions. This fundamental flaw could put women, children, the elderly, the disabled, workers, and residents of hot spot communities at grave risk.

4. Do you think that a chemical that poses a serious or substantial risk to a vulnerable population should be able to pass a safety standard under a reformed TSCA?

RESPONSE: A safety standard under a reformed TSCA should be a health-based standard, and the standard should assure protection of vulnerable populations, including those subject to higher exposure, higher susceptibility, or both. Chemicals should be found to meet the safety standard only where risks to such populations have been assessed and found not to be significant.

5. Do you think that risk management decisions must ensure that significant or substantial risk to a vulnerable population should be addressed?

RESPONSE: Where a safety determination for a chemical finds that the chemical does not meet such a safety standard, it should be allowed to remain in commerce only where conditions or restrictions are imposed sufficient to ensure the standard is met – which includes protection of any relevant vulnerable populations.

One of the significant obstacles we have seen to implementation of TSCA, like other environmental laws, is the lack of resources afforded to EPA to carry out its essential public health mission. Yet S. 1009 creates significant new procedural requirements and hurdles to agency action without providing additional resources.

6. Should EPA have the resources necessary to effectively administer a reformed TSCA?

It is essential that EPA be afforded sufficient resources to develop and implement new policies and procedures and carry them out in an effective and efficient manner. The sheer magnitude of the problem – tens of thousands of chemicals in commerce the safety of which has never been assessed – poses major challenges and any system will likely take many years to work through this backlog. Nonetheless, while there is no magic number dictating the optimal pace and scope of progress in a new program, to be credible I believe the new program needs to operate on a scale that is significantly expanded over the status quo. All stakeholders should have a shared interest in having an ambitious program that makes decisions expeditiously and provides confidence to the market, consumer and the

general public that the program is working well and making serious and steady progress in tackling the problem. Assuring that outcome will require that sufficient, sustained resources are provided.

7. Should industry contribute a portion of those resources through user fees?

Industry should contribute a significant share of the resources needed to fund the full breadth of EPA activities under a reformed TSCA, which would include data collection and analysis and new and existing chemical evaluations, but also additional activities such as review of industry claims for protection of confidential business information. Some type of user fee is needed that could expand and modernize the fee provisions in current TSCA (Section 26), which apply only to new chemical reviews.

Similar fees are routinely applied to cover EPA substance reviews and related activities under laws regulating drugs and pesticides, where legislation has implemented specific fee systems, e.g., the Prescription Drug User Fee Act (PDUFA) and the Pesticide Registration Improvement Act (PRIA).