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On

Testing of Chemicals and Reporting and Retention of Information
under TSCA Sections 4 and 8

Before the Energy and Commerce Committee's
Subcommittee on Environment and the Economy
U.S. House of Representatives

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Chairman Shimkus, Ranking Member Tonko, members of the Committee, thank you for inviting me to testify today. I am Dr. Jennifer Sass, a Senior Scientist at the Natural Resources Defense Council (NRDC), and a Professional Lecturer at George Washington University, Department of Environmental and Occupational Health. NRDC appreciates this subcommittee's continuing series of hearings on the strengths and weaknesses of the current Toxic Substances Control Act (TSCA), and the search for ways to address its serious deficiencies. Today's hearing is on two sections of TSCA that are primarily focused on data and information, Section 4, which addresses the testing of chemical substances and mixtures and Section 8 which addresses the reporting and retention of information.

Testing and data collection are fundamental elements of any meaningful system to protect public health and the environment. To adequately assess the potential effects of a chemical, information is needed about its potential hazards. And to conduct a risk assessment of a particular chemical or mixture, or of class of chemicals, it is also necessary to have information about use and exposure.

More specifically, to ascertain the potential hazards of a chemical requires a basic set of data and information on a number of potential endpoints including:

- Chronic toxicity and disease outcomes
- Acute toxicity
- Environmental fate and effects
- Physical characteristics

And to ascertain the potential for exposure requires basic information and data about the chemical's physical properties and use patterns, including:

- Persistence in the environment
- Bioaccumulation
- Bioavailability

- ADME – once in the body, how the chemical is absorbed, distributed, metabolized, and excreted from the body
- Uses in commercial and consumer products
- Known and potential releases into the environment, including surrogate data like production volume

Current TSCA makes it very difficult for EPA to get such information for most chemicals. Unfortunately, the reform bill in the Senate, the Chemical Safety Improvement Act (S.1009), as introduced, will not solve the problems with current TSCA, and in some respects will make things worse. This Committee can play a critical role in removing the fetters that have prevented EPA and the public from obtaining the information needed to assess the safety of substances used in commerce.

The recent spill in West Virginia highlighted how important it is to ensure that information is available. The leaking of 4-methylcyclohexanemethanol (MCHM) and other chemicals into the Elk River in West Virginia brought home - literally into people's homes - some of the ways that timely access to updated and accurate information is a basic requirement for both informing and protecting the public. The Elk River spill presented an acute situation: the public drinking water supply for thousands of people was suddenly contaminated with a chemical about which virtually nothing was known, other than it smelled and tasted so badly that people found the water undrinkable in many cases. Contamination of a tap water supply – and of course the water was being used for drinking, cooking, bathing, laundry and other uses leading to direct skin contact and consumption – is one of the starkest situations any community may face. It was surprising to many people – and wholly unacceptable – that thousands of gallons of a hazardous chemical could be stored and spill upstream of a drinking water intake – and that there was essentially no useful information available for the public, drinking water system operators, state or

federal public health officials, or medical professionals and first responders, as to the safety or potential health and environmental effects of the substance.

But if we take a step back and consider the broken system of TSCA, the picture is even more disturbing: the truth is that we are routinely exposed to hundreds, even thousands of chemicals in our daily lives – even before we are born – in an infinite number of combinations and mixtures – and for most chemicals we do not have the information necessary to know whether or not those chemicals are safe. The lack of information – and lack of action at the federal level – has prompted numerous states to take the initiative and begin to obtain data on chemical hazards, uses and exposure pathways. Federal inertia is also in contrast to the system adopted in Europe that is now moving into a more mature phase of implementation and is serving as a model for businesses and governments around the world.

Section 4 of TSCA – Testing of Chemical Substances and Mixtures

Section 4 of TSCA is the source of EPA’s authority to require chemical manufacturers and processors to conduct testing on a chemical substance. Unfortunately, in practice, the authority given to EPA has proven to be heavily constrained; the amount of information EPA has been able to obtain under Section 4 has been extremely limited. As with other sections of TSCA, this problem stems from both the substantive and procedural requirements EPA must meet before it can seek information.

For EPA to require testing of a chemical substance or mixture it must find either that A) the chemical “may present an unreasonable risk of injury to health or the environment” *and* there is insufficient data and experience with the chemical to reasonably determine or predict its effects on health or the environment, *and* testing is necessary to develop the needed data; OR B) that the chemical “is or will” be produced in substantial quantities *and* it enters or may reasonable be anticipated to enter the

environment in substantial quantities or there is or may be significant or substantial human exposure to the substance or mixture *and* that there are insufficient data and experience with the chemical to reasonably determine or predict its effects on health or the environment, *and* testing is necessary to develop the needed data.

Thus, TSCA creates multiple significant hurdles for EPA to obtain data on many chemicals. In the first place, EPA must essentially be able to prove that a chemical poses an unreasonable risk to health or the environment – based on either hazard or exposure information -- in order to get the data it needs to determine whether the substance poses that risk. This “Catch-22” construction of the EPA’s testing authority has greatly constrained EPA from being able to require testing more broadly. The second hurdle – the process one - is that EPA must conduct a formal notice and comment rulemaking (as well as an opportunity for a public hearing if requested) to be able to require chemical testing. Such rulemakings are extremely burdensome on agency resources, costing the agency much money and taking considerable time – frequently years -- to prepare, propose and finalize – all just to get the information needed to determine whether regulation is in order. As a result of these hurdles, in the nearly forty years of TSCA, EPA has required a full set of testing on only a few hundred chemicals of the 62,000 grandfathered under the law in 1976.

The good news is that the flaws in section 4 can be resolved relatively easily. By eliminating the “Catch-22” provisions of section 4, and allowing the agency to require testing by order rather than by rule – as is done under the pesticide program – the bottleneck would be largely fixed, and the agency would begin to get more of the information necessary to inform and protect the public. Another step would be to enable EPA to require minimum sets of information for chemicals or classes of chemicals. The agency should retain flexibility to increase or decrease the particular data requirements for a chemical or class,

but could more easily ensure that the basic information needed to do at least a screening-level assessment of chemicals is routinely produced.

These fixes would reduce the prospects for another embarrassment like West Virginia, where nobody has had a useful set of information about the hazard characteristics of the main chemical spilled.

Unfortunately, the Senate bill to reform TSCA, as introduced, leaves EPA without the tools it needs to get information, even though some individual provisions are improved. The Chemical Safety Improvement Act (S.1009) as introduced does amend Section 4 to allow EPA to issue test orders in certain circumstances, and eliminates the general Catch-22 threshold requirements for EPA to show sufficient evidence of hazard or exposure. But the bill then erases the impact of those advances by eliminating EPA's current testing authority for the first, key step it creates in the process – deciding whether a substance is a high or low priority. That's a major problem because that priority designation effectively determines whether a chemical can be regulated at all under the bill.

To be designated a high priority substance under the introduced bill EPA must have evidence of hazard or exposure. (Lack of data can be a factor in designating a chemical high priority, but not the sole factor). But under the introduced bill, EPA has no authority whatsoever to get that information; it must rely on whatever industry submits voluntarily based on what they've already developed. In effect, the bill's provisions eliminate the existing Catch-22 only to replace it with a new one.

The Catch in the bill is especially serious because being designated "low priority" for assessment, would also mean that states would be preempted from taking action on those "low-priority" chemicals – and EPA itself would face new restrictions on obtaining or requiring additional information about the low-priority substances. The introduced bill appears to impose similar new constraints on EPA's ability to

require testing for new chemicals and to prevent new chemicals from entering commerce in the absence of fulfilling the requirements to provide the necessary data. Thus, under the introduced version of the CSIA, EPA would actually *lose* its existing authority to require testing by rule for non-prioritized existing chemicals and by administrative order for new chemicals. While a relatively small number of substances may already have enough hazard and exposure information in their profiles that EPA can begin working in earnest on them – like the eighty-three Workplan chemicals and presumably a larger universe of substances from which the eighty-three chemicals were selected – for a much larger universe of chemicals on the inventory, EPA may never have the authority necessary to obtain the information it needs to assess such chemicals.¹

Any reform legislation, including the CSIA, must ensure that EPA can obtain information without the long-standing barriers of the existing law, or new hoops and hurdles to replace the old ones.

Information needed to assess the potential hazards of chemicals

TSCA also needs to allow EPA to use its scientific expertise in determining the nature of what tests need to be used. While that discretion does not need to be entirely unconstrained, Congress should not try to bias the nature of testing or freeze in place the science of the moment. For example, over time the viability of non-animal test methods may improve. In some cases there are non-animal testing protocols that are already being effectively deployed, and in other cases animal tests are still the most reliable protocols. Lacking adequate chemical hazard information, neither government, industry, nor the public can make informed choices about how to manage potential risks. This is the situation we are in now,

¹ These problematic provisions are in addition to numerous other problems with the introduced version of the CSIA as outlined in testimony before this subcommittee from Andy Igrejas, Director of the Safer Chemicals Healthy Families coalition (<http://docs.house.gov/meetings/IF/IF18/20131113/101468/HHRG-113-IF18-Wstate-IgrejasA-20131113.pdf>) and from my NRDC colleague Daniel Rosenberg before the Senate Environment and Public Works Committee (<http://www.nrdc.org/health/drosenberg-131114.asp>).

where public trust in government is eroded, and its mistrust of the chemical industry is so low that it ranks 15th out of 18 business sectors; only mass media, banks, and financial firms are less trusted than the chemical industry, according to a 2013 survey reported in Chemical Week Magazine titled, "Who do you trust? Chemical makers forming poor bond with public".² The article goes on to note that, "*Stakeholders are placing greater emphasis on engagement and integrity-based attributes, such as ... exhibiting ethical and transparent practices*". A BASF spokesperson emphasized that, "*Ensuring safety, minimizing our environmental impact, and complying with all applicable laws and regulations are the only path[s] to earning and maintaining public trust*". The status quo benefits no one.

The introduced version of the Chemical Safety Improvement Act takes an extreme approach in this area, imposing multiple redundant and confusing requirements on the agency, including several different frameworks, plus a slew of policies, procedures and guidance documents, all of which will slow any progress by EPA to less than a crawl – preventing EPA from getting through even the first step of prioritization for years. In addition, the CSIA imposes numerous requirements of science and methodology that, although supported by the chemical industry, are in conflict with the recommendations of the National Academy of Sciences. We understand efforts are underway to revise the introduced version of the CSIA to address these problems, and we look forward to reviewing those changes to ensure new and unnecessary burdens and approaches are not mandated.

Section 8: Reporting and Retention of Information

Section 8 contains several provisions which provide EPA with the authority to require some information reporting, or require the retention of records by manufacturers and processors.

² Chemical Week Magazine cover story. May 31, 2013. Robert Westervelt.
http://www.chemweek.com/sections/cover_story/Who-do-you-trust-Chemical-makers-forming-poor-bond-with-public_52450.html

Section 8 (a) authorizes EPA to issue rules requiring manufacturers and processors to maintain records and submit required information. It is under the authority of section 8(a) that EPA has periodically promulgated its Inventory Update Rule (IUR), renamed the Chemical Data Reporting rule (CDR) in 2011. EPA can also use its authority under section 8(a) to gather one-time snapshots of basic information regarding production, exposure and release from specific facilities for particular substances. EPA has a template form for these rulemakings, called Preliminary Assessment Information Rules (PAIR). At times, EPA has used section 8(a) rulemaking to obtain data necessary to meet the evidence thresholds for a Section 4 test rule.

Section 8(b) establishes the TSCA Inventory of chemicals that may be used in commerce. It is commonly estimated that there are currently roughly 84,000 chemicals on the TSCA inventory, comprised of the 62,000 substances grandfathered under the law, and the approximately 22,000 substances that have subsequently been added to the inventory through the new chemicals program.

Section 8(c) requires manufacturers and processors to retain records of “significant adverse reactions” to health or the environment that are alleged to be caused by the substance (or mixture) or its manufacturing, distribution or processing. These records are intended as an “early warning system” that a substance may pose an unanticipated health or environmental risk, for example harm to workers using the substance.

Section 8(d) authorizes EPA to require manufacturers, reporters and distributors to provide EPA with copies of health studies that they have conducted, know about or are ascertainable. Section 8(d) has also been used to gather information to support section 4 test rules.

Section 8(e) requires manufacturers, processors and distributors to inform EPA immediately after obtaining information which “reasonably supports” the conclusion that a substance or mixture presents a substantial risk of injury to health or the environment. EPA has received a significant number of 8(e) notices, and it has also taken enforcement action against parties who fail to provide EPA notice of substantial risk information as required. Unfortunately, much of what is provided to EPA under 8(e) is claimed as Confidential Business Information (CBI). As a result, the public can read summaries of studies finding that a particular chemical poses a substantial risk of injury to health or the environment but never find out what chemical poses the risk.

EPA has used these different provisions of Section 8 over the years to varying degrees, and they have varied in the amount of useful data they have yielded the agency. Besides its maintenance of the TSCA inventory and review of Section 8(e) notices, the most active area for the agency in recent years has been its revisions and implementation of the Chemical Data Reporting rule (CDR) under section 8(a). The CDR requires site-specific reporting on manufacturing and uses (at the industrial use category level) above a certain threshold. This birds-eye level snapshot of higher level production and importation of chemicals – which requires reporting electronically once every four years – is an important tool for EPA to prioritize chemicals for assessment purposes. For example, information on chemicals used in commercial and consumer products helped inform EPA’s selection of Work Plan chemicals. The CDR calls for a general level of reporting by manufacturers (and some processors) for chemical manufactured above a certain per site volume threshold. The most recent CDR rule expanded the amount of information to be reported in several important respects, and will ensure additional information is reported in the next reporting period in 2016. However, the reporting thresholds and other constraints limit the number of chemicals for which data is gathered to roughly 7,000 and provide only a general birds-eye view of exposure and use information for those substances. We need more

detailed use and exposure information for many more chemicals than are currently captured by the CDR.

Unfortunately, although the chemical industry insists that exposure data must be factored-in to any assessment or regulation of chemicals, it has also strenuously resisted action and advance on collecting even this general level of production, use and exposure information. And the introduced version of the CSIA appears to narrow the scope of EPA's authority under Section 8(a) in a manner that could fundamentally undercut the CDR. Whereas now the law authorizes requiring reporting of information "that the Administrator may reasonably require" the CSIA would only authorize reporting requirements "to the extent the Administrator determines the submission of reports is necessary for the effective enforcement of the Act." Narrowing the scope of EPA's existing authority under Section 8 is yet another step backward in the introduced bill that needs to be corrected and that any House-generated legislation should avoid.

One area of potential action for TSCA reform is the TSCA Inventory. Some industry representatives bristle at the 84,000 number that is generally used as the figure identifying the number of substances on the TSCA inventory because it is not necessarily reflective of the number of substances actually in use in commerce. The estimates of what the actual number might be vary fairly widely, even among industry representatives. Various proposals have been made to "re-set" the TSCA inventory as part of TSCA Reform, in part to provide a more "realistic" picture of the number of chemicals in commerce. Congress should hold firm to two principles about any "inventory reset" approach. First, such a process should not in any way delay efforts by EPA to take expedited action on substances such as PBTs for which we have sufficient information to know they are unsafe, or to slow the process generally contemplated in TSCA reform –and already underway for the Workplan Chemicals -- of EPA prioritizing,

assessing and (where necessary) regulating substances. Second, if a substance is taken off of the TSCA inventory because it is no longer in use, or has not been in use for a reasonable period of time, it should not be able to reenter the inventory without going through a thorough review process for health and environmental safety, including the development of a minimum set of data and information about the substance. Without such a limitation, previously used chemicals of unknown safety could re-enter the market without ensuring their safety – simply perpetuating the mistakes that have already been made under TSCA.

Generally speaking, any substance on the TSCA inventory can be manufactured or processed for any use, and in any amount, without requiring any reporting to, or registration with, EPA. This is a central reason why EPA and the public have so little idea of what chemicals are used in what amounts, for what purposes, and in what products. It is also a major reason why reporting, testing, assessment and regulation authorities need to be strengthened by Congress to inform and protect the public.

Substances on the inventory – whether grandfathered “existing chemicals” or those approved in the new chemicals program based on particular assumptions about uses and production volumes may subsequently be adopted for other uses and at much higher production levels that greatly expand the potential for environmental or human exposure. One disturbing example that illustrates this fact is the persistent, bioaccumulative and toxic flame retardant Firemaster 550, promoted by its manufacturer as a “safe substitute” for certain PBDE flame retardants that were being phased out after they had been identified in the blood and breast milk of most Americans as well as wildlife at the North Pole. Now Firemaster 550 is being ubiquitously found in house dust and wildlife³. Some of the chemical components of Firemaster 550 had been on the TSCA inventory for decades before showing up in the mix of this particular flame retardant.

³ See http://articles.chicagotribune.com/2012-05-10/business/ct-met-flames-regulators-20120510_1_flame-retardants-ban-chemicals-chemical-safety-law

Finally, the identities of approximately 16,000 of the substances on the inventory have been classified as (CBI and are currently a secret kept from the American public, although a confidential inventory is not authorized under the Act. The TSCA inventory is supposed to inform the public about what chemicals are available for use in commerce. Allowing roughly 25% of the inventory to be kept secret fundamentally undermines the public right to know and needs to be addressed.

The Chemical Safety Improvement Act does contain provisions to “re-set” the TSCA inventory. We have some concerns about elements of the proposal as introduced, including its limitations on EPA’s ability to prioritize “inactive” or phased-out substances for assessment, and its unnecessarily cumbersome process for implementing a “reset” of the inventory.

Conclusion

TSCA has failed to provide the public and its representatives with adequate information about chemicals. Its failings stem from the basic structure of the law, many of them in Sections 4 and Section 8, which contain many of the Act’s testing and information provisions. Implementation issues, such as the unconstrained use of CBI, have made the problem even worse. At least in hindsight, the design of TSCA was almost guaranteed to limit the information and testing available about chemicals. Congress should not make the same mistake again by moving forward with the introduced version of the CSIA, which would leave EPA with even less ability to gain the information it needs and the public expects. It should be possible to come up with an information and testing regime in statute that is balanced and effective at protecting the public, while enabling the chemical industry to dissipate the cloud of suspicion that is growing around many of its products. But that will require learning from past mistakes.