Toxic Substances Control Act Reform: Chemical Prioritization

Summary

Several key issues have emerged as pivotal in ongoing efforts to reform TSCA. Progress on these complex issues is central to the success of TSCA reform. As part of its ongoing series on TSCA reform priorities and challenges, on October 4, 2011, ELI convened a panel of experts to discuss reform related to prioritizing chemicals for regulation. The panel reviewed current EPA, state, and international initiatives for purposes of assessing the feasibility of various approaches. Topics addressed included criteria (hazard/exposure/risk), procedures for identification of chemicals, and the scope of regulatory authority to require alternatives and other actions.

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Peter de la Cruz, Partner, Keller and Heckman LLP
Daryl Ditz, Director, Chemicals Program, Center for International Environmental Law
Steve Goldberg, Vice President & Associate General Counsel, Regulatory & Government Affairs, BASF
Carol Kraege, Reducing Toxic Threats Initiative Coordinator, Washington Department of Ecology
Ted Sturdevant, Director, Washington Department of Ecology

Linda Breggin: TSCA [Toxic Substances Control Act][1] reform has been on the legislative agenda for many, many months now. TSCA is about the only major environmental law that has not been amended since it was enacted in 1976. There seems to be a fair amount of agreement among a wide range of stakeholders that TSCA needs to be updated. You'll hear more about the prospects and time line for reform from our panelists today, but I think it's fair to say it's not moving very quickly, although some progress has certainly been made in identifying the most important issues and the positions of the key stakeholders.

The topic we'll examine today is central to both TSCA reform and to the current operation of the program. Our panel is going to discuss TSCA reform issues related to prioritizing chemicals for regulation. Our speakers will examine the approach to prioritization in pending legislation as well as EPA [U.S. Environmental Protection Agency] state and international initiatives and provide their views on the various approaches, including the criteria and procedures for identification of chemicals and the scope of regulatory authority to require alternatives and other actions. I think we have more to cover today than perhaps in some of the other panels because EPA is currently taking steps to prioritize chemicals, as are some states. So, we have both states and federal administrative and legislative initiatives.

Our first panelist is Peter de la Cruz. Peter is a partner with Keller and Heckman. Peter has over 25 years of experience advising clients on antitrust, trade association, and regulatory matters. His focus is on chemical regulations, compliance strategies for environmental regulations, and product stewardship. His areas of emphasis include statutes on air quality and toxic substances and occupational safety and health. Prior to joining Keller and Heckman, Peter was an attorney with the Antitrust Division of the United States, U.S. Department of Justice.

Our second speaker is Daryl Ditz. Daryl is the director of the Chemicals Program for the Center for International Environmental Law. Over the past 25 years, he's worked at the state, federal, and international levels on a range of environmental issues, including chemicals management, pollution prevention, and public right-to-know. He is an active contributor to efforts to reform U.S. federal policy on chemicals and participated in campaigns around passage and implementation of REACH [Registration, Evaluation, Authorization, and Restriction of Chemicals], the European Chemicals Law. In 2007 to 2008, he served on the Science Advisory Panel to California's Green Chemistry Initiative, and from 2004 to 2006, he coordinated the national campaign for U.S. ratification of the Stockholm treaty on persistent organic pollutants.

Our next speaker is Steven Goldberg. Steve is vice president and associate general counsel for regulatory law and government affairs for BASF Corporation. He leads three groups that cover the scope of regulatory and government activities for the North American subsidiary of BASF. His practice is focused in the area of product and trade regulation, and he is responsible for compliance with product regulatory statutes. He also leads the environmental law group responsible for compliance activities under the major environmental statutes; he also oversees BASF Corpora-

1. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.

tion's government affairs function and is responsible for federal and state advocacy.

We also have Ted Sturdevant on the panel today. Ted is the director of the Washington State Department of Ecology. He's been there since November 2009. The Department of Ecology is the state's primary environmental agency with programs addressing water, air, solid hazards, and nuclear wastes, oil spill prevention in shoreline, and wetland protection. Prior to becoming ecology director, Ted spent seven years as the agency's Director of Governmental Relations and leading Ecology's initiatives to reduce toxic threats. Before joining Ecology's senior management team in 2003, he worked under Gov. Gary Locke leading the governor's external affairs team. He's also served in a variety of staff positions in the Oregon Legislature and worked on several state and national political campaigns in Oregon and Washington State.

And last, but certainly not least, is Carol Kraege. Carol has worked for the Washington State Department of Ecology for more than 30 years. She began her career working on non-point source water quality issues, and then spent 15 years working in the Toxics Cleanup Program. She spent another 10 years managing a group of engineers responsible for multimedia regulation of some of the state's largest industries. Currently, Carol is coordinating toxics policy in the agency, including implementing the new Children's Safe Products Act.

I. EPA Approaches

Peter de la Cruz: My comments have four parts: (1) prioritization criteria currently in TSCA; (2) examples of what EPA has done with regard to prioritization; (3) the August 2011 EPA proposal; and (4) some observations.

While we may not think of TSCA as providing prioritization, indeed, the statute does have a number of prioritization factors. My goal is simply to list or highlight the factors that are presented, as opposed to critiquing them.

In the often overlooked congressional findings section of the statute, [the U.S.] Congress directs EPA to focus on exposure, number of chemicals, new chemicals, reasonable risk, and manufacturer responsibility to provide data, but with the caveat not to impede innovation.[2]

Under §4(e) of TSCA, which governs testing, Congress created the Interagency Testing Committee. While mandating the creation of a priority, Congress instructed that the list not exceed 50 chemicals. The prioritization criteria under §4 includes the familiar categories of carcinogens, mutagens, and teratogens, but moves on to behavioral disorders; cumulative or synergistic effects; persistence; acute, subacute, and chronic toxicity; plus any other characteristics that the Interagency Testing Committee wishes to consider.

The premanufacture notification provisions in §5 are not really prioritization terms, but simply remind us of the frequent observation that, as applied, TSCA has a new chemicals bias. The hurdle for marketing a new chemical is comparatively higher.

The last statutory provision I wanted to mention is the chemicals of concern list of §5(b)(4) of TSCA. EPA has proposed to use this provision for the first time since enactment. Again, criteria include "unreasonable risk of injury to the environment," with other listing criteria relevant to prioritization being human health effects, magnitude of human exposure, and environmental effects.

Turning from the statutory provisions to the regulatory tools that EPA has previously used for prioritization, there is a long history, but I will mention just a few. One is the high-production volume (HPV) testing program, with production volume and lack of adequate data as the criteria for prioritization.[3] Production volume is a common prioritization criterion. In theory, EPA could use hazard characterizations based on the new data and apply appropriate risk management criteria to existing chemicals. The HPV data itself would be used to prioritize chemicals.

EPA's Design for Environment (DfE) Program is worthy of mention for its alternatives assessment components.[4] DfE may not be seen as a prioritization tool, but in the broader context of sustainability, we can characterize the essence of sustainability as comparative analysis with the goal of doing better. Alternative assessments increasingly figure in the sustainability programs.

In the last few years, EPA has issued 10 chemical action plans (CAPs) for existing chemicals.[5] Although the Agency has not provided a systemic overview, if these were selected for priority treatment, what criteria might we deduce? Not only all of the following criteria apply to each CAP, but some relevant criteria include:

- Presence
  - Monitoring: found in environment and wildlife
  - Biomonitoring: detected in human breast milk, blood, and urine
  - Presence in consumer products, potential exposure, or uses lead to widespread releases to environmental media
- Hazard
  - Persistent, bioaccumulative, and toxic (PBT)
  - Toxic to laboratory animals and wildlife
  - Children's health: developmental toxicity
  - Significant adverse effects in humans have NOT been observed, but continued exposure could

2. 15 U.S.C. §2601, ELR Stat. TSCA §2.

3. For information on the HPV program, visit http://www.epa.gov/chemrtk/index.htm.

4. For information on the DfE Program, visit http://www.epa.gov/dfe/.

5. For more information on the Existing Chemicals Action Plans, visit http://www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html. The substance-specific plans are: Long-Chain Perfluorinated Chemicals (LCPFCs) (12/30/09); Polybrominated Diphenyl Ethers (PBDEs) (12/30/09); Phthalates (12/30/09); Short-Chain Chlorinated Paraffins (12/30/09); Bisphenol A (BPA) (03/29/10); Benzidine Dyes (08/18/10); Hexabromocyclododecane (HBCD) (08/18/10); Nonylphenol and Nonylphenol Ethoxylates (08/18/10); Methylene Diphenyl Diisocyanate (MDI) Action Plan (04/13/11); Toluene Diisocyanate (TDI) Action Plan (04/13/11).

increase body burdens to adverse levels given long half-life in humans
- Alternatives Assessment under DfE

In contrast to exposure, the presence of a chemical substance in the environment or a product is one step of a two-step prioritization and selection system. While there are some exposure criteria, there is an increasing trend to use presence as a threshold. Presence in consumer products, potential exposures, and, in some cases, uses that led to widespread releases to environmental media are listed in the CAPs.

On the hazard side of the CAPs program, EPA focused on PBTs; toxicity to animals and wildlife; and children's health or developmental toxicity. In one case, EPA commented that it had not observed significant and adverse effect in humans but, because the substance was either persistent or bioaccumulative, the Agency assumed that exposure could increase over time. As with the DfE Program, the agency also looked to alternatives assessments, asking whether there are feasible and less hazardous alternatives that might be used.

EPA's August 2011 prioritization proposal was the subject of an Agency listening session in September 2011. The Agency indicated that it had a two-step process for priority review and possible risk management. The EPA speakers were careful to qualify or clarify that if a substance was selected, it does not mean that the substance poses a risk, but warranted investigation or review by the Agency. And, obviously, with all of these priority programs, EPA has other initiatives under various statutory authorities, and the prioritization criteria would be filtered through the statutory setting. EPA reported it did not tend to screen or prioritize the entire TSCA inventory. It is unclear from my perspective how one would create a priority list without initially screening the inventory.

EPA's discussion guide is not long and worth reading.[6] The listed, high-priority factors generally relate to toxicity: children's health concerns (reproductive and developmental); PBTs; and probable and known carcinogens. Of course, presence does not equal exposure, and is disconnected from traditional risk assessment.

Other factors relate to presence and potential for exposure, production volume, and actual exposure. Production volume is used as a surrogate for exposure, as is presence in consumer products, especially children's products.

While not presented by the Agency as a separate category, it is clear in the discussion guide that the Agency recognizes that the uses of the chemical need to be subject to TSCA. It is reasonable to view this as a third category of overarching factors. For example, there are a number of uses, including pesticide and food additive applications, that are outside the scope of TSCA.

EPA projected moving fairly quickly, with a first batch of several hundred substances on the list by the late fall of 2011. After selecting the candidate chemicals, EPA will identify data and data sources. After the list of candidate chemicals is compiled, the next step is to identify priority chemicals.

Stated more concisely, step one is hazard and presence screening as the basis for a list of candidate chemicals. Step two is identifying priority chemicals for review. Step two, presumably, is a finer screen. The data sources referenced by the Agency are not surprising, and include the inventory update report, now known as the chemical data reporting rule, the TRI [Toxic Release Inventory], children's health studies, work exposure, and environmental exposure. The data sources are presented in a table toward the end of the EPA discussion document.

That concludes a short outline of the relevant statutory terms, past Agency prioritization, and the Agency's recent prioritization proposal. I was asked to make some "normative comments" about what results our clients would like to see, but must start with a caveat. Given the diversity of our clients, there is not a single, collective voice to channel; please accept these as my individual observations. A client survey would likely result in a much longer list of topics.

First, what prioritization factors have not been mentioned by EPA? The two that jump out are the adequacy of existing regulations or the comprehensive nature of existing regulations, as well as the adequacy of existing data on both exposure and hazard.

The EPA staff is competent and well-intentioned. It is hard to imagine an internal Agency prioritization meeting where somebody says: "What about chemical X, a known carcinogen?" without another staff member responding: "We've been regulating chemical X closely for many years. Let's move on to something else." However, in matters of public policy, it is good practice for the Agency to make explicit that it will take into account the scope of existing regulation and the adequacy of data where risk can be more closely defined or defined with less uncertainty.

Another issue is intrinsic chemical properties. For example, there are some polymers that are considered low-risk under TSCA's polymer exemption.[7] Similarly, other low-risk substances should be removed early in the screening process. There are some factors, such as persistence, which sound like such an obvious prioritization factor. But, there are some categories of chemicals that this might be unfairly judged under the persistence banner, most substances on the Periodic Table of Elements. In practice, the second look requirement probably encompasses metals but, the main point is not to blindly apply prioritization factors.

Exposure analysis can also result in bias, or perhaps better characterized as not being misled by focusing on what we know rather than the unknown or unexpected. For example, biomonitoring studies are usually limited to well-tested substances with established analytical methods based on cost and feasibility. If so, biomonitoring does not provide a full or complete view of exposure in terms of substances on screening lists.

6. The discussion guide can be accessed at http://www.epa.gov/oppt/existingchemicals/pubs/chempridiscguide.html.

7. 40 C.F.R. §723.50.

Another consideration is learning from others, such as the information compiled by the European Union under REACH, by Canada, and by a number of U.S. states. Industry has provided a great deal of information, particularly under REACH.[8] Rather than duplicating that effort, we ought to take advantage of it directly.

Lastly, there is a generic concern with prioritization and that a list of priority substances will prompt deselection of the listed substance and derivative products. Agency communication and terminology is an important factor in shaping perception. Among the terms that have been used here—candidate chemicals, priority chemicals, and chemicals of concern—chemicals of concern is most easily marketed as a deselection list.

II. Lessons From Canada and Europe

Daryl Ditz: Prioritization is something that just about everybody seems to like for good reason, because the task before us requires lots of information and lots of decisions on the part of companies and agencies. If we don't prioritize in some way or another, the whole thing will just grind to a halt or maybe never get off the launch pad.

It's helpful to think about prioritization for what purpose or to what end, and not just to think about it as a kind of an abstract ranking exercise. When I go through these examples drawn from Canada, from the international persistent organic pollutants (POPs) treaty[9] and from REACH, I'm going to try to hit on some of the different ways that prioritization has been and can be applied.

One very common use of prioritiziation is to try to identify the "worst first." Pick out the bad apples, and let's start with those. It's also possible to use prioritization to take a whole cluster of chemicals or a whole universe of chemicals and try to shake them out into different categories and, perhaps, to treat those categories differently. Prioritization can also be helpful in terms of deciding the timing or the sequence: which things happen first, which chemicals are subject to the information requirements upfront, which ones can stand the weeds for some number of years.

There are other consequences of prioritization, including the signaling function. Peter just referred to this under the phrase "deselection." To be called a chemical of concern is going to have repercussions in the marketplace, maybe with consumers and maybe many other consequences.

So, with that as a starting point, I'm about to jump into three short samplers from outside the United States. I just wanted to say at the outset that the Safe Chemicals Act of 2011, that's the Lautenberg Bill in the [U.S.] Senate, if you haven't paid attention to it since it was introduced last spring, you'll know that there are some interesting prioritization features in it that I'm sure Steve Goldberg will treat in much greater detail.

Let's take a fairly simple example of prioritization. The POPs treaty has at its heart a prioritization scheme. How on earth can we identify those chemicals that have these properties that countries of the world had decided are worthy of global action? The treaty itself lays down quite clear criteria concerning the scope of chemicals concerned, the persistence, the bioaccumulation, and the adverse effects. Those criteria are spelled out in the treaty. There is an established process by which countries, in this case, have the burden of identifying chemicals that may be POPs. That is, make sure that the chemical meets those criteria, goes through a risk profile, and then eventually suggest that the countries of the world agree to take action to eliminate those chemicals.

It's not trying to look at all chemicals in the universe; it's not trying to separate the good ones from the medium ones, from the bad ones, so to speak. It's specifically to find certain kinds of chemicals. Interestingly, the Lautenberg Bill of this year has such a feature for chemicals that are persistent, bioaccumulative toxic chemicals.

If we look to our north, to the Canadian Environmental Protection Act and the work that's happened there since the Act was amended in 1999, we see kind of a different style of prioritization. In that case, the twin agencies, Environment Canada and Health Canada, reviewed essentially their entire list of existing chemicals and tried to identify those that met certain criteria.

Now, in this case, the criteria were either high exposure to the population *or* inherent hazards, which Canada defined as a combination of persistent and toxic or persistent and bioaccumulative interesting criteria. In the span of seven years, they worked their way through all 23,000 chemicals, which is something no other country has done. It's a commendable act, especially when you consider the resources Canada has and their relatively small share of the global chemicals market. They've continued the process after identifying those 4,000 that met the criteria and are narrowing it further to several hundred that are subject to a new chemical management plan or chemical management program.

What can we draw from this? First of all, it's possible to do what they did. So, that's a kind of a reality check that is helpful to us. One reason that they could do it, and also a weakness of how they went about it, is that their prioritization was based on whatever information was already in hand. The Canadians quite quickly found serious gaps on the properties side. That would be the hazardous properties like persistence and bioaccumulation and toxicity. And they found even larger gaps on the exposure side.

It didn't slow them down. They had the task, and they did it. But it means that the sifting that they went through to pull out the first 4,000 and then to center on the several hundred could well have missed chemicals that deserved to be in that group, but the data didn't exist to allow them to be caught. The other thing I'd say about this is that the

8. Regulation No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 Concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH). *See* http://echa.europa.eu/web/guest/regulations/reach/legislation.
9. United Nations Environment Programme, Stockholm Convention on Persistent Organic Pollutants (2001).

burden was heavily on the regulatory agencies or the government agencies here. The chemical industry in Canada, in this process, did not have to cough up new data, or do new testing, or do much of anything really, except to let the wheels turn inside the Canadian agency. This idea of taking an entire population and shaking it into different baskets or sorting it into different bins is the concept also found in the new Safe Chemicals Act.

REACH stands for Registration, Evaluation, Authorization and Restriction of Chemicals. In the registration portion, which is the data foreseen or information foreseen aspect of REACH, there are a few different kinds of prioritization. For example, the data is due at different times depending upon the volume produced, or in some cases, the properties of the chemicals. Last December, when the very first of the three deadlines was crossed for submitting registration dossiers to the European Union, those chemicals produced above 1,000 tons per year or imported about 1,000 tons per year, and also chemicals that met certain hazard criteria that would be known under the law as Substances of Very High Concern (SVHC). For mid-sized chemicals, the ones of 100 tons and above, their registration data will be due in 2013, and the remainder of the existing chemicals would be due in 2018. So, there is a simple idea of sequencing on the basis, in this case, of properties and production points.

Many companies thought that was a bad prioritization system. To go on volume alone is not to go by risk. That's a very crude metric, you could say, and it's true. But REACH is trying to establish the safety of chemicals or the risk of chemicals, you could say. So, you can't prioritize by risk because the whole point here is to generate the data needed to establish risk. So, it would be a Catch-22 to say let's regulate the risky ones first and the medium-risky ones later before these determinations are made.

REACH also identifies chemicals, those substances of very high concern, for special treatment. They're not merely first in line, but there are also additional obligations and requirements attached. For example, chemicals that are nominated and accepted as substances of very high concern wind up on the candidate list, which is a waiting room on the way to authorization. Authorization is the sharp edge of the REACH machinery, the place where users could be restricted or production and use can be entirely eliminated.

But to be in that candidate list, there is a stigma, or those companies could be subject to deselection. There are even additional obligations that follow from that, such as a duty on retailers to tell customers whether their products contain SVHCs.

REACH, unlike the Canadian system, is really information-rich and information-generating. That new information also allows other parties to make their own priorities. That means buyers, maybe investors, maybe workers, maybe other parties, would take that information and use it to assign their own priorities to different chemicals. No doubt that's already happening. In fact, if you follow the candidate list process, we're up to 53 or so chemicals out of the estimated 1,500 that might meet that criterion.

So, those 50-some chemicals are already in the bright lights of the candidate list. Nongovernmental organizations (NGOs) have attempted to accelerate that process by naming close to 400 chemicals that meet the official criteria. They've developed a database, and they've actively marketed that list. To the surprise of the NGOs behind that, that list has attracted quite a lot of attention and earned quite a lot of praise by companies who are chemical consumers that will be downstream users, by institutional buyers, by investors, by foreign countries, etc. Maybe it's the worst nightmare of companies who fear deselection. I suppose to be in this list is to have your customers really scrutinizing you. But that's the way it is.

The last thing I want to say about the burden of this particular priority decision scheme is that, unlike the Canadian scheme and unlike the POPs treaty, the burden is primarily on the chemical makers and, in the case of the European Union, also importers of chemicals, as opposed to the authorities. Companies have to cough up the information and declare if they are SVHCs, if they have those properties. This is quite a reversal from how the other two processes work, depending eventually on government action.

Prioritization is necessary. There's just no way around it. We have to do some things before we do other things. It's true for EPA, and it's true for the companies. However, it's very important not to fall into the temptation of a kind of tunnel vision, which is to say we're going to look at only these priority chemicals and kind of put the other ones out of our mind. That would be the wrong way forward.

I would also say it makes sense, as the Canadians did, to start with whatever information is already in hand. That's natural. But I would also like to see a system that's continually learning. As new information rolls in, either because of EPA authorities, or perhaps because of reporting on the very same chemicals under other jurisdictions such as Europe, I would want to see the U.S. prioritization scheme learn from and adjust to that new information.

Personally, I think one legitimate use of prioritization is to target certain chemicals that are really deserving of expedited action. That's a part of the Lautenberg Bill, and it's also been a demand from the civil society for POPs ratification for years and years. We'd like to see the United States tackling POPs before 170 countries get around to it.

The flipside of that is I think it's possible for EPA to also identify chemicals that do not need regulatory action, kind of like a green list as opposed to a red list. That would be credible if there is sufficient information and EPA could make those judgment calls. I think that's a very positive feature, so that TSCA reform is not only about, let's say, catching the bad ones, but also elevating those that are deserving, are cleaner, are greener, and worthy of being in the marketplace.

Then, the last thing to say is that TSCA reform has the ability to inform markets and to serve various public uses.

In fact, I think it might end up in the long run being one of the most important functions of TSCA reform.

III. Legislative and Industry Proposals

Steven Goldberg: I've been asked to cover two topics today. One is the current legislative reform proposal and how it deals with prioritization. Daryl mentioned some of that, the Safe Chemicals Act. The second is sort of industry proposals for prioritization, especially the American Chemistry Council Prioritization tool, which is actually applicable either to current TSCA or to a reformed TSCA.

I have a couple of comments to begin with. I'll second what Daryl said with perhaps not agreeing entirely, and that is that it really is somewhat impossible to separate out the issue of prioritization, which I agree. In fact, as we'll see in the Lautenberg Bill, those two things are actually in the same section. So, understanding what various stakeholders mean or want with the output of prioritization is key to understanding how that prioritization might or might not work and with respect to a couple of the pieces that Daryl has talked about. The issue of prioritization for immediate action, and prioritization to inform the public, those, I think, as we'll talk about and certainly take questions on, tend to be the most controversial.

That being said, I think there are certain principles involved in looking toward a prioritization process that most people would agree with. First, and you see this in a number of the prioritization schemes that already exist, they should be science-based. You can agree or disagree with particular factors, but I think everybody is trying to do something that is science-based.

Second, it needs to be transparent. I think people need to understand what the bases of EPA's decisions on prioritization are or any other agency in order to assess whether we're spending our resources in the right way.

A third, and something that we haven't really talked about, is the fact that, ultimately, it needs to be, I will say, relatively nonbureaucratic. That is, this is a complicated process whether you're dealing with a limited number of chemicals or in the Canadian case 10 or 20 or 30, whatever the right number is. Ultimately, there are other goals to the regulatory process whether they are ultimately risk-assessment measures or risk-management measures. I think there is broad agreement that you don't want to make the process so procedurally heavy that EPA has to spend, for example, five years on prioritization before they can do anything.

Lastly, I think it needs to be communicated in a way that it is clear. Now, Daryl and I, probably, have different beliefs in what that means. Going back to what Peter said, I think if what you're communicating is a list of priorities, what EPA is going to look at then you don't want to communicate that in a way that it says we've reached conclusions about those. If on the other hand, the Agency has reached conclusion about that, that's a different matter.

So, you want to, yes, to some extent, have the market be transparent to all stakeholders, but you don't want necessarily erroneous conclusions that aren't necessarily informed by the full panoply of risk-assessment measures, including assessment of alternatives. So, it does ultimately need to be basically clear communication. EPA did a fairly decent job, in my own view, and these are all my own views, on the Endocrine Disruptor Screening Program, where it did put out notices that said things we list on this list for endocrine testing we have not concluded are endocrine disruptors. We are just doing it for testing purpose.

So, with those preliminaries, let me talk first about [Sen. Frank] Lautenberg's [D-N.J.] bill, Senate 847. Daryl sort of set the stage for this. If you haven't read the bill, this is §7 of the bill, it is actually a rewrite of §6 of TSCA. As Daryl alluded to, it does to some degree blend the concepts of what you're doing with the priority list with the prioritization process itself and puts the onus on EPA, fundamentally, to divide chemicals on an ongoing basis into three buckets, which the bill calls priority classes.

Priority class one is defined as those chemicals that are determined to require immediate risk management. As Daryl indicated, bypassing the risk-assessment process going directly into risk management. The section doesn't have a limitation on what goes into priority class one, other than the following: the Administrator shall put a chemical into class one if it is or biodegrades into a chemical that is persistent, bioaccumulative, and toxic with the potential for widespread exposure to humans or other organisms. In short, sort of a POPs list—probably plus—in some respects.

There is an initial limitation in the legislation that the Agency assigned not less than 20 or more than 30 chemical substances to the initial list. That has to be done within one year. The bill is set up to request prioritization to be an initial step for the Agency. I think, as we said, we all agree it is necessary for them to get it moving with TSCA assessments, safety assessments.

As I noted, these are chemicals for which EPA is directed to oppose risk-management measures without any risk assessment. The standard of that risk management, somewhat separate from prioritization, is to achieve that management necessary to achieve the greatest practicable reductions in human or environmental exposure and to impose such measures within 18 months of listing. Of course, the problem is, in the absence of risk assessment, that's somewhat difficult to determine whether, in fact, you've reached that point. But the Agency is thereafter required to do a safety assessment.

Most likely, the vast majority of chemicals fall into Priority Class 2. Priority Class 2 is simply defined as those chemical substances that the Administrator determines require safety standard determinations. That safety standard, as written in the Lautenberg Bill, is the Food Quality Protection Act, a standard of reasonable certainty of no harm. The statute directs them to put things in Class 2 where there is more than a theoretical concern, whether something would meet the safety standard.

Again, without any further direction of the specific criteria, it simply says that the Administrator should add substances at an expeditious rate, but not greater than they can reasonably anticipate it completing safety determinations for and directed to assign first those that "pose the greatest risk to human health or the environment." Again, it's a bit tautological because you're reaching some conclusions first. Priority Class 3 is the class I think Daryl mentioned last, which was substances that are sort of a green list, and those are defined as those things that have intrinsic properties such that at no stage of its life cycle would such chemicals pose any risk of adverse effect to human health and to environment. The sort of big question is to how much actually falls into that bucket. But I think everybody can see that the vast majority of things fall into Class 2. As a result, the Lautenberg Bill is, I think, less than entirely helpful in specifying how EPA is to prioritize, because it's that vast bulk of chemicals that it's going to have to come to a conclusion, which does it want to review in what form?

I won't get into detail of this, but the bill sets up an interagency committee to make recommendations to the Agency. It's not required to accept them. The decisions of the Agency and the committee are not subject to judicial review. That probably speaks to the nonbureaucratic point.

But the Agency—well, the committee needs to publish its recommendations in the *Federal Register*. The Agency only needs to publish its recommendations. It doesn't need to publish them in the *Federal Register*. Again, whereas the committee recommendations are open to comment, the Agency determinations are not required to be open for comment. Thus, at the end of the day, the Lautenberg Bill really does give virtually unfettered discretion to the Agency regarding the priority process. Again, to give my own opinion, especially in light of the significant impacts on products placed in Class 1 under the bill, to me, at least, raises some serious concerns about both transparency and to some degree due process.

Finally, just to note again a lack of specific criteria and thought in Class 2 are really questions in my mind. How valuable that is as a tool for EPA to make determinations? Ultimately, the bill just says EPA, go do it.

So, it's in that context, but also in the context of current TSCA reform proposals, that the American Chemistry Council has put out a proposal for its prioritization tool. I won't go into the numeric criteria. It's quite specific as to how it judges things.

But the purpose of it is really to provide some greater clarity and transparency to the process of evaluating chemicals for priority treatment by really taking into account a variety of factors, providing numeric weighting to those factors, and then basically providing a sieve by which those are relatively ranked. So, the key criteria in making the ranking include: human health hazards; potential environmental effects; chemicals, industrial, commercial, and consumer uses; whether it persists or accumulates in the body of the environment; the volume of that chemical in commerce; other factors, such as whether it's formulated in children's products or detected in environmental monitoring; and the robustness of the data.

Ultimately, you do get a score. But EPA, under the proposal, retains the discretion to move things up based on a variety of factors, including, for example, is it used in children's products; is the data robust? People shouldn't benefit by the fact that they've never done data. Rather, that should, it seems to me, put things higher on the priority. I think this does in fact meet—but I'm speaking for myself—the principles of transparency, clearness, and based on science. Ultimately, unlike the Lautenberg Bill, I think, it does provide some more specific guidelines for EPA to deal with the vast majority of chemicals.

I will say the proposal also posits putting things in tiers but also allows five I believe—but also allows movement and assessment within tiers. Therefore, it provides a better roadmap for the Agency, again, either in the context of TSCA reform or current TSCA prioritization activities to look at things that require most immediate consideration and timely consideration, and to sort of Daryl's point, sometimes it's the worst first. Sometimes, it's things that people are more exposed or concerned about whether they're worst or not is a judgment to be made. I think there will be a lot of discussion on that proposal, as I said, in both the context of current TSCA and TSCA reform discussions.

IV. State Involvement

Ted Sturdevant: I'm going to speak very briefly on how states came to this point of being quite involved in things like the prioritization process. Then, I'm going to turn it over to Carol Kraege, who has actually overseen that work for us in Washington State. It's fairly similar to work that's happening on prioritization in several other states.

So, quickly, in terms of the evolution over the last decade or so, we, here in Washington, have a robust toxic cleanup program but, over time, came to realize that we weren't doing much to prevent toxic contamination.

About 11 years ago, we formed a PBT Program that led to an approach where we would do chemical action plans on specific PBTs. Those were years-long efforts that took a lot of resources. We started with mercury, then flame retardants. Then, as concern mounted over the last several years, both about environmental exposures as well as consumer products from things like Chinese toys, jewelry from Mexico, flame retardants, bisphenol-A coming out of consumer products, there was a growing sense here that the net just wasn't catching these chemicals. At the same time, there was broader and broader agreement that TSCA wasn't up to the task. So, states that have environmental and human health responsibilities were left holding the bag and with a very clear sense that we have inadequate tools to respond to those challenges.

So, you had this evolution of legislative action here in Washington State and around the country. I've seen it go from the idea of a state taking action on a chemical being a revolutionary and very difficult thing to the point now

where states are getting a lot more comfortable doing it, and it's a lot easier to happen. I think 30 states have taken some chemical policy actions through legislation.

The Children's Safe Product Act that was passed in 2008 in Washington State is really what we're going to talk about today. That represents a shift from the chemical-by-chemical conversations and efforts to—I think there's a dawning realization that that's very resource-intensive. It feels like we're chasing our tails. You're going after chemicals that have been out there and causing problems for a while. Again, it's not really very effective when it comes to preventing both human health and environmental exposures. So, there's a shift from that to more of a systemic effort.

That systemic effort, I think, starts with an understanding of where are the problems, and that really leads to this prioritization work. From there, you have to ask: are there alternatives and/or is the use of this particular chemical in this product necessary? Then from there, making decisions about some sort of action. That certainly has been, in very brief, the evolution here in Washington State, and I think in a lot of states around the country over the last several years. Now, we're at this point where we're very supportive and appreciative of EPA stepping up, as it is doing.

But given the sense that TSCA, again, is not up to the task, I think states are going to continue to move forward. There's more and more support. There's more and more momentum at the state level. Just speaking for myself, we're certainly hopeful that TSCA reform happens soon. I think there's broad agreement that this happening at the state level is not the ideal place. But until that happens, it's the only place.

Carol Kraege: Washington, Maine, Minnesota, and Connecticut all have laws that are working out or focused on children's products. California's law is much broader and looks at consumer products. Washington, Maine, and Minnesota have completed their processes to prioritize. We ended up with different lists.

Maine was required to come up with at least two chemicals. They have done that. Minnesota ended up with nine. We have 66. It just really depends on what your resources are. In our case, our governor said you need to end up with about 50. So, with the thousands that are out there to look at, we decided 66 was about 50.

California is not done yet. They are looking at a different process than what the other states have looked at. I am no expert in what they're doing, but I do understand that they're looking at both prioritization of chemicals but also prioritization of products.

The states all have very similar definitions of what makes a chemical of concern on the toxicity side. The state laws all kind of have similar language with little differences here and there about what makes a source of information that you can go to and depend on. And then, the list of characteristics that we would consider in terms of what is a chemical of concern, what kind of toxicity does it have, it's developmental, it's carcinogenic, etc.

Most of these state laws also have identified how we are going to look at exposure and the potential for exposure. We worked pretty closely with the states that are interested in this topic. A lot of states don't have laws on the books just yet, specifically around identifying chemicals of concern, but they're interested in what is happening and where things are going. So, we've spoken with 13 to 15 states on these issues extensively.

Everybody is struggling with how to assess exposure. As several of the other speakers have pointed out, there's limited toxicity data, but there's even less on exposure. So, how can we create some indicators of potential exposure or surrogates for exposure? The burden is too great for states to do exposure or risk assessment for every chemical, for every product. So, we're looking for ways to get to appropriate decisions without having to do these very burdensome assessments. So, we're looking at presence. I think Peter mentioned this earlier, presence in people and presence in the environment in which people live, household dust, indoor air. That's language that comes in the statutory language that's provided.

I'm going to focus on what we did under the Children's Safe Products Act. We did this in a four-phase way where we identified potential chemicals of high concern for children. Then, we had to prioritize that down, and then we did some final review, and finally we did some rulemaking. In order to identify chemicals of high concern for children, which is the term of work from our statute, the Children's Safe Products Act, the first thing we had to do was find those chemicals that met the definition of a high-priority chemical. Then, we had to identify those chemicals that we could show met the criteria for potential exposure. We chose the ones that met both criteria.

We used a variety of sources to figure out if something was carcinogenic or was an endocrine disruptor, etc. We identified about 2,000 chemicals that met this definition. Then, we applied a standard that nobody else asked for except the companies we were working with. We decided not to carry forward with any chemical that did not have a chemical abstract services number.

We ended up with about 2,000 chemicals that met the toxicity standard, so then we looked at exposure potential. Again, this is about if it's in people or in the environment in which they live, present in consumer products commonly used in the home. We created a separate list. Again, we ended up with about 2,000 chemicals that met this definition for potential for exposure. We had two separate lists and only 476 chemicals were found on both lists. So, we started there.

But our governor had told us that she wanted us to end up with about 50 chemicals on our list, so we still had quite a bit of sorting to do. We consulted with the University of Washington and our Department of Health and some pediatric health specialists and came up with three criteria that are important for children when present in children's

products. We focused on if there was carcinogenicity, reproductive toxicity, and endocrine disruption. And then we ended up in a weight-of-evidence approach for how could we really look at these things.

We did some sort of crude removal of things from further consideration based on these criteria. We looked at the existing regulatory frameworks. For example, we did not include things like PBDEs [polybrominated diphenyl ethers], which in our state have been banned. We didn't include combustion byproducts, because we just thought that's not something that will have been added to children's products. Emerging chemicals, we left those off, because the data was not as robust as we might have liked. And we left off chemicals where the primary toxicity information we had was really centered on ecological toxicity, as opposed to human health. Through that sort, we got down to 185 chemicals. Then we sorted based on toxicity endpoints. Based on that, we ended up with 66 chemicals.

We made a couple of other tweaks to our list. We stopped looking at information on toxicity and exposure in the fall or winter of 2009. Right before we published our rule last summer in 2011, we went back and made sure that there was no new information that we needed to consider, so we just tweaked it again. We also looked at and made sure there was an analytical method for each of the chemicals that we were including, and we figured out what our reporting level would be. Then, we published our rule.

As I said before, we've shared this information extensively with other states, and a number of folks are using similar processes to come up with at least the starting point for what a high priority chemical is.

V. Discussion

Peter de la Cruz: Carol, could you describe the size of the Washington State staff and about how long it took to complete this process, to help frame it against what we might be looking at EPA at a federal level?

Carol Kraege: We had a group of four people and one person who can't be cloned. I hesitate to tell you his name lest you steal him away. But Alex Stone did an awful lot of the work. He's just a really very dedicated and fast worker, so he did a huge portion of gathering up the information available. Of course, we're using existing data. So, we really had about four people working on it. He worked on it full-time, a couple of other people, part-time. It took about 18 months to create that list, and it's very well-documented.

Daryl Ditz: The question, at least under the current bill, is how to prioritize this large bucket in the middle where most of the chemicals are. Do we seek to spell that out in the words of Congress that is in the statute, keeping in mind that some members of Congress are not experts on this? Or do we prefer to have it happen in the hands of EPA in the guise of rules or guidance?

I'm feeling really impatient, because TSCA turns 35 this month. So, there's a part of me that wishes we could get some of it into the statute, maybe basic building blocks of prioritization, rather than waiting three or four or five years for EPA to work out the details.

Steven Goldberg: Sure. I would tend to agree with Daryl. I mean I think it is a balance between what you put in the statute and what flexibility with EPA versus how much direction you give them. I will just say my own opinion that the more flexibility you give probably in either rules or regulations actually to some degree, the longer it takes. I think it's probably a happy medium between some more precise direction without being so prescriptive that it ties the hand or, for example, doesn't allow the Agency to take in proper factors. I think it's a balance there. My own view of the bill right now is that it's just so bare in there that I think you're almost asking for more gridlock as EPA tries to work that out.

Steven Goldberg: On the issue of how you denominate particular lists of chemicals and different priorities, it does from industry's standpoint matter. Again, you're trying to be transparent, and you're trying to inform the public. But at the end of the day, the public is really informed by good risk assessment, and not by a name you put on a bucket.

Linda Breggin: With that, we'll turn to some questions from the audience. The first question is, what will the emergence of commercially viable nanomaterials do to the volume of chemicals subject to prioritization?

Daryl Ditz: It's a good question that I can't answer. But I would say I think it said the volume of chemicals. Unless things are changing a lot faster than I realize, the volume of nanomaterials, I think, is still small, if you were to weigh them, let's say. On the other hand, the count of nanomaterials could be a very large number. So, if we're looking at lists, it's possible that nano could suddenly occupy a lot of spaces on that list, even though they may add up to grams or even smaller quantities. I guess the other thing I'd say is if we can't get our regulatory system to deal with things like formaldehyde, lead, and asbestos, then God help us with nanomaterials.

Peter de la Cruz: In general, I agree with Daryl on prioritization. But I think that the emphasis here needs to be that prioritization should be an Agency management tool. As Steve was saying, that's one of the reasons that you need some flexibility. You don't want to hem the Agency in. The Agency needs to have the flexibility to react to new information and developments. I can think of a great historical example of a substance that was regulated for its explosion hazard. It was used in consumer products as an aerosol. It was used in medical applications and anesthesia for some years. Subsequently, the Agency and the public learned that this was a human carcinogen. Obviously, the

Agency had to jump in and regulate this in coordination with other agencies. The question impliedly assumes that nanomaterials are going to be a problem. I would not make that generic assumption. But, obviously, a need for flexibility in approach is warranted.

Linda Breggin: Since EPA does not intend initially to evaluate the entire inventory, any idea how EPA intends to prioritize their prioritization process, i.e., select the initial group of chemicals for prioritization?

Peter de la Cruz: I do not know, and that was one of the criticisms. At least from transparency and policy perspectives, it assumes that the Agency has some candidates in mind. That might contrast to Carol's presentation for the state of Washington and their screening program, which should be more a transparent process.

Linda Breggin: Has EPA identified the criteria that it will use to determine whether there is a "concern" for children's health?

Peter de la Cruz: I think the toxicity criteria, at least as I recall, the developmental toxicity and reproductive toxicity, perhaps neurotoxin. There are some folks from EPA on the line, if anybody wants to e-mail in a correction to that response, it would be appreciated.

Daryl Ditz: I don't have it on my fingertips, but I recall from the stakeholder meeting on EPA's prioritization system that some people were calling for neuro and maybe other developmental toxicity. So, it's possible those aren't yet in EPA's thinking.

Steven Goldberg: I was just looking at EPA's document. I don't see neuro in their discussion guide, repro definitely, and carcinogenicity. Well, I take that back, the high-risk program based on repro, yeah, repro, but I do not see neuro.

Linda Breggin: What are the key points of contention with respect to prioritization in the legislative discussions? What issues need to be resolved?

Daryl Ditz: In the conversations, say in hearings and the [U.S. House of Representatives] dialogues last year, I think when people get down into the details like we have today, some of this clears up. I think a lot of members of Congress are paying little attention to these details. They're inclined to say like, gee, let's not do REACH, because they didn't prioritize anything. I really wish we could have more hearings in the House and Senate side for the sake of educating the members and their staff.

Steven Goldberg: I absolutely agree with Daryl, but I think there's a lack at times of attention to detail. I think the tool that I've highlighted, and I think came up in Daryl's comment, is prioritization for what? That informs how you do prioritization. Then, purely from the legislative context, what is the process? How much detail do you put in? Right now, as I said, there's really just a very general point. I think, again, probably stakeholders have not sat down enough and informed Congress that these are areas where we think it's the right thing to do.

Again, I think the prioritization process looks very different, depending on what you are coming out of it. So, it's almost unfair to say what are the key points of prioritization because, really, the biggest point is why are you prioritizing and then working that too? If you agree on that result, what is the prioritization going to look like? I think some of the principles I talked about are ones that broadly people agree on. It's putting that in language that is legislatively cognizable. That's the key.

Linda Breggin: I want to thank everyone for joining us today. I particularly want to thank our panelists for a thoughtful and informative discussion on prioritization. It's really one of the more important issues for TSCA reform—both legislative and administrative reforms.