TSCA Reform: The Standard of Safety

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. On July 21, 2011, ELI convened a panel of experts to examine the central issue of whether and what standard of safety should replace TSCA's current "unreasonable risk" standard for regulating chemicals. Topics addressed included: hazard/exposure/risk criteria; burden of proof; judicial review of Agency decisions; sensitive populations; cost-benefit analysis; and application of the safety standard to new materials/technologies.

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Linda Breggin: I would like to welcome everyone to our panel discussion today on reform of the Toxic Substances Control Act (TSCA).[1] I'm Linda Breggin. I am a senior attorney with the Environmental Law Institute (ELI), and I direct our nanotechnology initiative.

This is the second in ELI's series of webinars on TSCA reform. ELI's overall goal with this series is to provide a forum for examining some of the key issues that are being discussed and will need to be addressed in order for legislative reform to occur. If you missed it, an audio recording of the first panel is available on the ELI website. Today is the first webinar in this series to focus on a specific TSCA reform issue, the standard of safety. We'll have four more webinars on additional TSCA reform topics in the coming months.

TSCA reform has been on the legislative agenda for quite some time now. It is, of course, about the only environmental law that has not been amended since it was enacted in 1976. Over the last couple of years, the consensus seems to have emerged that reform of the law is needed, but despite the fact that a wide range of stakeholders, from the American Chemistry Council to the Environmental Defense Fund, agrees that reform is needed, achieving that reform has been a real challenge.

Today, we'd like to focus on a fundamental reform issue: the standard of safety that should be used in regulating chemicals. The standard of safety is obviously a core component of the TSCA regime, and as a result, it is also a particularly difficult issue to resolve for legislative purposes. Many of the key stakeholders have made public statements about the standard of safety that they think should be employed, and we'll hear about some of those today.

I. Introductions

Linda Breggin: Wendy Cleland-Hamnett, our first speaker, is the director of the Office of Pollution Prevention and Toxics (OPPT) in EPA's Office of Chemical Safety and Pollution Prevention. Ms. Cleland-Hamnett began her career at the U.S. Environmental Protection Agency (EPA) in 1979 and, in addition to a variety of jobs within the OPPT, she served as deputy director of the Office of Information Collection in the Office of Environmental Information. She also held several positions in the Office of Policy, including director of the Center for Environmental Information and Statistics. She received a B.A. in political science from Earlham College in Indiana and a J.D. from George Washington University.

Our second speaker today is James Aidala, a senior government consultant with Bergeson and Campbell. Before joining Bergeson & Campbell, Mr. Aidala gained roughly 30 years of experience in the government as a policy expert, congressional staff member, or senior government official working in areas related to EPA's regulation of pesticides and chemical substances. Jim served as Assistant Administrator for EPA's Office of Prevention, Pesticides, and Toxic Substances, where he managed over 1,500 employees in implementing TSCA and other chemical and pesticide programs. Prior to that, he served in various positions within EPA, as a policy expert for the Congressional Research Service, and as a senior staff member for a subcommittee of the U.S. House of Representatives' Government Affairs Committee. After leaving government in 2001, Mr. Aidala was a consultant for JSC Inc., a private consulting firm, before joining Bergeson & Campbell. He is a graduate of Brown University, where he earned both his Masters and undergraduate degrees.

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

Richard Denison is our third speaker. He is a senior scientist with the Environmental Defense Fund. He has 27 years of experience in the environmental arena, specializing in policy, hazard and risk and management for industrial chemicals, and nanomaterials. Dr. Denison is a member of the National Academy of Sciences' Board on Environmental Studies and Toxicology, and serves on the Green Ribbon Science Panel for California's Green Chemistry Initiative. Dr. Denison has testified before various congressional committees on the need for TSCA reform and on nanomaterial safety research needs. He is the author of numerous reports and studies, including a 2009 article in the *Environmental Law Reporter*, entitled "Ten Essential Elements in TSCA Reform."[2] Dr. Denison has a Ph.D. in molecular biophysics and biochemistry from Yale University.

II. Agency Perspectives

Wendy Cleland-Hamnett: Improving the chemicals management program and reforming TSCA is one of the highest priorities of EPA's Administrator, Lisa Jackson. Her first day after being sworn in as the Administrator of EPA, she stated the importance of "managing the risks of chemicals in consumer products, the workplace and the environment" and called for revising and strengthening EPA's chemicals management and risk assessment programs. She has continued to place a high priority on these programs.

TSCA was enacted in 1976 as the primary means of regulating the production, use, and disposal of industrial chemicals. The only sorts of chemicals that are explicitly excluded from TSCA are those that are regulated as pesticides, those that fall under exclusions for firearms and ammunition, or those regulated under Food and Drug Administration (FDA) authority, such as food, food additives, drugs, and cosmetics. Otherwise, TSCA's scope is broad, including the life cycle of many chemicals. TSCA is the only major environmental statute that has not been reauthorized since the 1970s. TSCA needs to be reformed to address structural flaws and to reflect the evolution of understanding of chemical toxicity and how chemicals move through the environment.

One of the key elements forming the foundation of TSCA was the creation of an inventory of chemicals that were in commerce at the time TSCA was enacted. At that time, there were 60,000 chemicals on the TSCA inventory. This inventory is updated by a program, put into place by TSCA, through which EPA is notified about the intent to manufacture new chemicals—chemicals that are not on that original TSCA inventory—and then EPA has the ability to determine, within 90 days, whether the chemical may present a risk and whether additional action should be taken.

Since the late 1970s, approximately 24,000 chemicals have been added to the TSCA inventory through the new chemical notification process.

We have regulations in place that allow us to periodically collect information on a subset of the chemicals that are in commerce. The type of information collected includes production volumes for listed chemicals and sites where the chemicals are being produced. Amendments in the early 2000s changed the collection period from once every four years to once every five years. Last year, we proposed additional amendments to those reporting requirements, such as changing the reporting period back to four years and amendments that would improve the quality and the amount of information we're receiving on those chemicals.

Information that the Agency collects is publicly available with one big exception, and the exception is that TSCA allows the submitters of that information, chemical manufacturers and importers for the most part, to claim much of the information as confidential business information. This has made it difficult for the Agency to share much of the information collected over the years about chemicals, commerce, health, and safety, and is another important point of discussion in TSCA reform.

The new chemical notification process begins at least 90 days in advance of manufacture of the chemical that's not on the inventory of existing chemicals. Companies are not required to develop any data in order to submit new chemical notification to EPA. They provide us with data that they have in their possession, such as the identity of the chemical, how they believe it will be used to the best of their knowledge at that point, and what they think the production volumes might be, but they're not required to develop any toxicity information on the chemical, for example. Unless EPA takes action, chemicals may enter commerce without further consideration. To date, EPA has reviewed more than 35,000 new chemicals, but not all of those chemicals have actually gone into production, which accounts for the fact that only 24,000 have been added to the inventory.

In the TSCA world, we have those new chemicals that aren't on the inventory and those many tens of thousands of chemicals that are on the inventory. In the current version of TSCA, the 1976 version, there is no general requirement to test or prioritize or address existing chemicals. EPA may issue a rulemaking to require submission of data regarding toxicity and information on production and exposure. The Agency needs to make certain findings, particularly in the area of §4, in order to complete such a rulemaking. This has proven to be a fairly slow and burdensome process. It's not a very efficient way to get data on chemicals so that we can, within a reasonable time frame, prioritize chemicals according to their potential risks.

When we determine that a particular chemical, chemical use, or chemical exposure presents a significant risk, the response called for by TSCA, again, has proven to be fairly burdensome. Section 6 of TSCA gives us authority to make a range of responses, from requiring recordkeeping, report-

2. Richard A. Denison, *Ten Essential Elements in TSCA Reform*, 39 ELR 10020 (Jan. 2009).

ing, or labeling to enacting complete bans on chemicals or uses of chemicals. To trigger §6 authority, EPA must show that a chemical will present an unreasonable risk to human health or the environment and that the action we're taking to reduce that risk is the least burdensome alternative.

The Agency has only successfully invoked §6 five times since 1976. The most ambitious attempt to use §6 was in the 1980s, when there was an attempt to ban most uses of asbestos, a known human carcinogen. That attempt was overturned in litigation that resulted in additional burdens on Agency action under TSCA. Since the early 1990s, the Agency has not used the provision of TSCA that allows us to address unreasonable risks from existing chemicals.

Given the difficulties of using some of TSCA's regulatory tools, the Agency has pursued various voluntary and stewardship approaches to address risks from chemicals. Where very significant risks have been identified for certain chemicals, EPA has encouraged industry to voluntarily phase out those chemicals. One of the more notable voluntary programs is the High Production Volume Challenge Program, where we worked with the chemical industry and with the Environmental Defense Fund to get basic toxicity and other data on chemicals produced at high volumes, those produced at 1 million pounds or more per year. Many companies stepped up to provide this information, but after more than 10 years, we're still working to fill data gaps on chemicals that weren't sponsored by industry as part of this program. We are still finishing up the work to issue §4 test rules to require the remaining information on those chemicals. This gives you an idea of the issues that we face in using the test rule requirements for chemicals.

Since 1998, when that universe of chemicals for the challenge was defined, more than 500 additional chemicals have at some point been produced in high volumes according to the periodic reporting we receive every four or five years for which we do not yet have basic toxicity information. The chemical industry changes significantly between reports, so there are probably even more chemicals that at some point have been high-production volume that we're not aware of.

In summary, there are many challenges with the current 1976 version of TSCA, but I think the most important problems are that we do not have a mandatory program to determine the safety of existing chemicals and that there are legal and procedural hurdles to limit risks from chemicals or to ban chemicals.

The TSCA's current structure presents significant hurdles to requesting generation and submission of information that would allow us to determine whether chemicals present a risk. The burden is on EPA to show that a chemical may, or will, present an unreasonable risk before EPA even begins its rulemaking process. The confidential business information process makes it difficult for the Agency to share information with our partners in state government or who are managing chemical risks in other countries. Clearly, there is a legitimate need for some information to be considered a trade secret or confidential information, but the current process is more restrictive than what we think is necessary.

Some key dates in TSCA reform were in September 2009, when Administrator Jackson announced the Barack Obama Administration's support for TSCA reform and introduced the Administration's principles that I will discuss briefly. In 2010, several bills were introduced in the U.S. Senate and another bill was introduced in the U.S. House of Representatives. In 2011, Sen. Mark Lautenberg (D-N.J.) introduced another version of a TSCA reform bill earlier this year in health hearings. EPA has been involved in all of those discussions and hearings, and we, along with the Obama Administration, continue to express support for TSCA reform.

Given that the focus of this discussion is on safety standards, this is probably the most important principle to focus on, but I'll touch on a couple of our other principles on TSCA reform that are relevant to safety standards. The Administration's principles reflect the fact that we do think that all chemicals should be reviewed against safety standards based on sound science that reflects a risk-based approach protective of human health and the environment.

We aren't looking at a hazard-based approach only, but instead, we are looking at a risk-based approach that looks at both hazard and exposure. That is different than the current TSCA approach. There is no mandatory review of existing chemicals. The current standard for TSCA review is unreasonable risk, which is risk-based, but "unreasonable" is generally interpreted to mean that it should also consider costs and the availability of substitutes in determining whether a chemical is safe.

Principle 2 says that manufacturers should provide EPA with the necessary information to make that safety finding. I would emphasize the fact that currently the burden is on EPA to demonstrate that there is an unreasonable risk from chemicals.

Principle 3 says that issues such as cost and availability of substitutes and other things should be appropriately considered, not in deciding whether a chemical presents significant risks or whether it's safe or not, but in determining what the appropriate risk management approach might be.

Principle 4 says there should be a process to identify priority chemicals, to work through chemicals in a timely manner, and to address the highest priority chemicals first. Clearly, the nature of a safety standard would determine what constitutes a priority chemical, and the application of that standard would help us to assess those chemicals in a timely manner.

Principle 5 is really two-part: we should be identifying chemicals that present risk issues and addres those while providing incentives for developing safer chemicals. We also need to deal with the issues about confidential business information and public access to information.

Finally, Principle 6 calls for adequate funding for EPA to move through chemicals in a timely manner and to assess them in a way that is science-based and credible.

III. Industry Perspectives

James Aidala: I'm going to talk about the industry reaction to some of the things we're talking about today, but I want to emphasize that we certainly don't speak for "the industry." Others who really do represent the trade associations and things may have, shall we say, a sharper view of some of these issues.

There are several risk management options related to the current law. EPA must have a reasonable basis to conclude there's an unreasonable health risk. I think what's especially difficult for the program is the least burdensome requirement of §6. First of all, Wendy described some of the difficulties of determining what is unreasonable risk, coupled with the least burdensome requirement. You wouldn't want to have the most burdensome requirement to control the risk if you have a less burdensome option.

EPA must consider a range of health and environmental effects, the magnitude of exposure, the benefits of the substances, the availability of substitutes, and the reasonably ascertainable economic consequences. And the rulemaking must be supported by substantial evidence in the record.

Every conceivable option is articulated in the statute. EPA can make requirements ranging from recordkeeping to labeling the product about possible risks, to specific user instructions, production limits, and all the way to, literally, a full production ban. It also includes an option for repurchase of a product, which I always thought was a very interesting option for a federal agency to consider in terms of regulating a problem.

Successful rules issued under §6 include halogenated chlorofluoroalkanes, dioxin, hexavalent chromium, nitrosating agents, and asbestos. The first four were successful. The asbestos rule was overturned in the *Corrosion Proof Fittings v. EPA* case in 1991.[3] The *Corrosion Proof Fittings* case is what's been cited as the "proof" that §6 is flawed. If you can't ban asbestos, then what can you ban?

Some of the failures that the court in that case found were failure to provide notice and failure to consider least burdensome alternatives. In that case, the court interpreted that the options were in a specific order of burden, and that order was meaningful. So. EPA was to have evaluated each of those options and then consider, in a cost-benefit way, which one was the least burdensome. Now, that view is not shared by everybody, to say the least, but that was one of the things seen as especially crippling to the ability to use that long list of potential regulatory options under the current law.

That is background to get to the current legislative proposals. The current legislative proposals center on the idea of a "reasonable certainty of no harm" standard, and that is taken directly from the FQPA, the Food Quality Protection Act. I'd note for the record, the FQPA is a bit of a misnomer. The FQPA itself was a set of amendments to both FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act][4] and the FFDCA [Federal Food, Drug, and Cosmetic Act], for regulating the presence of pesticide residues in food. The FQPA is considered a new law, but it really was an amendment to both acts. The key standard that people want to cite here is in the food and drug amendments set up as a "reasonable certainty of no harm" standard. That language also includes considerations for aggregate risk from all routes of exposure and does define special populations, with explicit provisions about children and vulnerable populations.

The proposals that are currently floating around Capitol Hill have basically some kind of cumulative risk discussion. The idea is that those compounds with the same mechanism of action are to be considered together. EPA and the trade associations have not offered any particular legislative alternatives to the standard. The "reasonable certainty of no harm" standard is not a zero-risk standard. The FQPA "reasonable certainty" standard requires an administrative record to support those findings of safety, and EPA's mechanism is to use standard risk assessment policies and techniques.

From 1987 through 2009, the decisions on pesticides, on what's called pesticide "active ingredients," generated anywhere from about three to 59 decisions per year. On average, that was 20 chemicals per year. The FQPA in its heyday basically was peaking at 30 to 60 chemical decisions per year. I use "chemical decisions" as a bucket term referring to a chemical that may have literally hundreds of uses in various contexts in the food supply system. It's a big data set that gets into a lot of different exposure routes. The data evaluation emphasizes food exposure, even though the full registration eligibility decision under FIFRA includes ecological effect considerations too.

Any legislative debate is going to have to consider how EPA should be making decisions on some number of chemicals that are identified through some kind of process to be "of concern." How long will it take EPA, even with additional resources, to move through that universe? At the rate of 60 per year, obviously 1,000 chemicals of high priority at 60 per year would take a little more than 16 years. Obviously, you can do the math and make it sound absurd, but the whole point is that triaging priorities and trying to figure out exactly what those priorities should be and giving EPA that authority are going to be some of the central and particular questions in any legislative proposal.

With the kind of decisions that EPA makes under the FQPA for a widely used chemical, you do have to note that there's a lot of extensive and expensive data requirements. Even with that, there're a number of conservative default assumptions and things that are all part of the risk assessment toolbox that EPA has to go through. From that experience, EPA has created a very significant administrative record behind using those models and applying those models to EPA's decisionmaking for pesticides.

Whether or not those models and those approaches are appropriate is one of the big questions. There's broad

3. 947 F.2d 1201, 22 ELR 20304 (5th Cir. 1991).

4. 7 U.S.C. §§136-136y, ELR Stat. FIFRA §§2-35.

interest in having the FQPA standard be considered for our TSCA standard, but then the question is immediately raised whether or not that's appropriate for an industrial chemical versus a pesticide. Industrial chemicals are not always designed to be toxic, unlike a pesticide, which almost always by definition has some kind of toxic mechanism. Often, industrial chemicals may not have widespread exposure. Any scheme has to be carefully crafted as to what is appropriate, with what exemptions, and what categories of concern.

Exemption doesn't mean no regulation and no testing requirement, but simply, what are the ways to triage. How do we decide what to put into various categories of what's going to be more intensely looked at or tested? Many chemicals are considerably more benign than pesticides. Chemicals may have much more limited exposure, especially in finished products, and there are questions then about what might be an appropriate blanket requirement for "all chemicals." Again, how do we articulate what priorities EPA should have moving through that long list of 84,000 chemicals?

The safety standard will almost inevitably be tied to requirements for aggregate risk, cumulative risk, identified subpopulations of concern, and what other kinds of additional safety factors should be mandatory in any legislative scheme. It's unclear how those assessments will be required to incorporate uncertainty. That is all up to the legislative drafting process.

Exposure is going to be very, very important even though the exposure information that EPA has for pesticides is much more robust; given that it's a focus on food exposures, it makes life a lot easier. It is not clear, at least to me, what that equivalent will be on the industrial-chemical side. It will have to be articulated.

Those factors and the debate around how to use those assumptions—how to triage, what conservative defaults ought to be imposed, are there any safety factors that are appropriate—those are the things that are going to be more impactful on how this program rolls out under TSCA reform than the very specific language about the standard.

The National Academy of Sciences report in 2009, *Science and Decisions*,[5] has a series of recommendations on how to attempt to reduce delays, how to handle uncertainty, and how to incorporate emerging science about risk concerns, whether there is variation in chemical sensitivity or lifetime exposure. It doesn't only mean lifetime cumulative exposure, because individual humans may have different reactions to even the same chemical exposures over time. The report seeks coordinate risk assessment and risk management, so that things don't have to take forever or that risk assessment ends up being useless to the risk manager.

The safety standard language is not going to be viewed in isolation. It's going to be tied to how many of these other elements are articulated in any statutory formulation. Judicial review is protection for some interest, on one hand, and often a cause of delay, for others. Therefore, what is the appropriate place and role for judicial review, what parts of the revised statutory scheme should be subject to judicial review, and are there other ways to just try to both drive agendas and eliminate delays?

The proposals before the U.S. Congress have a lot of action-forcing provisions, and this may, again, end up having much more of an impact. For example, the past proposals have had different discussions about deadlines or some kind of default control actions. For example, if EPA can't decide timely whether production should be continued, should there be some kind of default control action?

Those make some sense. Default control actions do bring religion to the process and reduce some kind of delays on the one hand. On the other hand, when you have deadlines and other automatic defaults, drivers can end up being regulatory outcomes—it can distort the system. Sometimes, for example, deadlines can be drivers. But if there's a numerical quota, EPA will end up doing the easy things. If we've got to do 50 by the first half of the year, well, which 50 are ready to go, as opposed to the most important 50? That's just the nature of bureaucracy.

Wendy has presented the Administration's principles. At a broad level, the NGO [nongovernmental organization] community and the industry trade groups agree on many elements, but there's little specific guidance about the particulars. Again, for example, exposures need to be safe, but there's very little agreement on specifics.

I would leave you with one last rhetorical question: what happens if there's no TSCA reform over, say, a 10-year period? The smart money is always against amendments in general. Amendments are hard to get through. These proposals are 180-plus pages long; that's not exactly a small package of amendments. I truly don't have an answer to this, just leaving the idea out there that EPA may have to live on the current law—and how do we still meet some of these principles that all the various parties can agree to under current law?

IV. The Current Safety Standard

Richard Denison: I want to touch on two major areas. One is to provide a little bit of commentary on the current safety standard under TSCA. I also want to compare that to the European Union's REACH [Registration, Evaluation, Authorization, and Restriction of Chemicals] regulation and the Canadian Environmental Protection Act, because I think those are often reference points for the debate on TSCA reform.

Some of the burdens that the current safety standard under TSCA, which is "unreasonable risk," imposes on EPA are the types of things EPA has to evaluate, the fact that it has to show any restriction it proposes using a §6 action under TSCA is the "least burdensome" requirement it could impose, has to defend its decisions if challenged in

5. Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, National Research Council, Science and Decisions: Advancing Risk Assessment (National Academy of Sciences, 2009), *available at* http://www.nap.edu/catalog.php?record_id=12209.

court on the basis of "substantial evidence" rather than the more customer "arbitrary and capricious" judicial review standard, and, finally, EPA has to be able to demonstrate that no other statute could address the concern that it's trying to address. When you add all those things up, it's pretty clear that it's become very difficult for EPA to operate under those conditions.

The statute itself, and even its regulatory implementation, contains very few specific criteria on what constitutes a chemical warranting a review or warranting particular actions. That means that generally EPA, to the degree it has acted at all, has done so on a case-by-case basis. That has resulted in a very low level of transparency and even certainty to the regulated community about what EPA is doing, the order in which it's doing it, etc.

Let me just draw a couple of comparisons and contrasts to the REACH regulation in the European Union. REACH does have very specific criteria laid out for identifying chemicals warranting action. It should be noted that REACH is actually a regulation, so it's a step closer to implementation than a statute is, like TSCA. But in REACH, there are a variety of criteria that are explicitly laid out. There are classification criteria for a range of health and environmental endpoints. There are very specific criteria to identify what under REACH are known as substances of very high concern: carcinogens, mutagens, reproductive toxicants, PBTs [persistent, bioaccumulative toxicants], and very persistent, very bioaccumulative chemicals. Then, there's a catch-all category that is still in evolution that's intended to capture chemicals of concern that may not be met through the other alphabet soup there that I've laid out.

REACH does an interesting thing with the bifurcation between what roles industry plays and what roles the government plays, and it's quite a different situation from what has transpired under the U.S. system, and even what's really being talked about under TSCA reform.

Industry, under REACH, not only has the responsibility to develop data and to provide that information, but also to assess the significance of that information as it pertains to risk, and to put in place risk management measures that are adequate for it to be able to demonstrate that it has "adequate control" over a chemical. That's kind of the standard, if you will, for safety of a chemical under REACH.

Now, for certain types of substances of very high concern, adequate control is not deemed to be a sufficient basis for having a chemical remain on the market, and that is for chemicals that tend to build up over time, where the concept of a safe level below which there's not a significant impact is perhaps not justified. For these, there are other factors that need to be shown by the industry applicant for authorization to be met in order for a chemical to remain in use. They include an assessment that shows on a socioeconomic basis that the benefits of that chemical or a particular use of that chemical outweighs its risk and that no suitable alternative exists. These factors enter into the authorization process under REACH.

It's important to recognize that all of these same factors are part of the unreasonable risk standard under TSCA, but the key difference, at least on paper, is who carries the burden of demonstrating those various factors. Under TSCA, that burden is squarely on the shoulders of EPA in order to act to control a chemical; under REACH, those burdens are shifted to industry, and there's an expectation, for example, that a chemical subject to authorization will not be able to be used unless those burdens are met.

Very briefly, let's look at the Canadian Environmental Protection Act, CEPA. Its counterpart is something that's usually referred to as a chemical that is "CEPA-toxic." Don't be confused by the term "toxic" there, because it actually is a risk determination for the chemical, not merely a hazard or toxicity indication. That's the statutory definition that I've cited on this slide. There are a couple of words that I want to draw your attention to. Words like "have" or "may have," "constitute" or "may constitute." Those do represent a difference from TSCA that I'll explain. The two core differences from TSCA that I would draw your attention to are that there's a very clear separation under CEPA between the decision about whether a chemical meets the safety level of concern and the decision as to how that risk or that lack of safety ought to be managed. Those are two very separate steps in the CEPA construct that are blurred together in the unreasonable risk standard of TSCA. And secondly, CEPA really does encompass the ability to go after a *potential* risk, not just an actual risk, and it does anticipate that such a potential risk could be a sufficient basis for acting on a chemical.

There are a few key provisions in the Lautenberg Bill, S. 847, regarding the safety standard, that I'd like to highlight. First, that it should be based solely on health and environmental considerations, not on economic factors and the like. Second, that it should include specific protection of vulnerable populations. It uses as a standard this term that's borrowed from FIFRA and the FQPA context: "reasonable certainty of no harm." It invokes as a core element of the standard that the aggregate exposure, exposure to multiple sources of a chemical, needs to be assessed. And then it does raise the issue of cumulative exposure to multiple chemicals or stressors that may exert similar impacts, but it does caveat that to indicate that such a cumulative assessment is to be done to the extent that it's practicable, where the science and the information necessary to do so exists.

When you look at EPA's principles, the American Chemistry Council principles, and the ones that have been articulated by our coalition, there actually is a fair degree of agreement on a number of elements. First, everybody has agreed that the cost-benefit standard under current TSCA needs to be changed, and that a new standard would be health-based and applied via risk assessment. It would account for uses of a chemical, so it would account for the fact that different uses may incur different levels of exposure or types of exposure.

Everybody agrees that we need to be building a standard that can incorporate the newest and best science, that vulnerable populations merit special attention, and that the full life cycle of chemicals and chemical products needs to be assessed. It also reflects an agreement, I think, that this concept of deciding safety needs to be separated conceptually and potentially even temporally from the consideration of risk management. That latter step is where some of the factors that are currently part of the unreasonable risk calculus under the current TSCA would be taken up, things like availability of alternatives, and so forth.

Now, we have by no means reached total agreement on what the standard should look like. I think our coalition view is that aggregate exposure is critical to assess the real-world exposure to a chemical. There are other views that suggest that that may not be needed in a lot of cases, that you might not have to look at all uses, but only the most significant uses. So, that's still an area of considerable debate.

The concept of cumulative exposure is also an area of continuing discussion. How to deal with uses that fall beyond TSCA's current scope is part of the debate as well: on the one hand, there is the need to recognize that exposures do cross those somewhat arbitrary lines between different statutes and different agency jurisdictions; on the other hand, that does get complicated both practically in terms of the assessment and politically in terms of how to deal with excessive exposures. Finally, the question of whether the standard would apply equally or in different ways to new and existing chemicals is an area of considerable debate.

There has been agreement in our coalition that the primary route by which most chemicals would be managed under a reformed TSCA would be a risk assessment-based safety determination, but that that has two important conditions. First, we strongly believe that the recommendations in the National Academy of Sciences' report, *Science and Decisions*, need to inform the methodology that EPA would use in conducting those risk assessments. Second, there needs to be a way to manage and deal expeditiously with the worst of the worst chemicals, chemicals that have very high hazards, are persistent and bioaccumulative, and for which there is already widespread exposure. We think there needs to be a much more expedited way to manage those types of chemicals.

Aggregate exposure is at the core of our view of what a safety standard needs to account for. That just represents the commonsense recognition I think most people have, that you really ought to be looking at the totality of exposure, not breaking it up and saying this exposure is safe and this exposure is safe, but never looking at the whole picture.

Cumulative exposure assessments we acknowledge are more difficult. The science is certainly evolving there. We think that is quite feasible to be done for certain classes of chemicals today, but we also believe we need to be building a safety standard that will stand up over time and will evolve with new science, and that we need a prompt or an incentive to move toward more routine consideration of cumulative exposures over time in the way in which the standard is articulated in the legislation.

On aggregate exposure: I want to emphasize that there are really two steps to this process. The first is having an entity—and we think EPA is logically the one to do it under TSCA—that has the ability and the mandate to look across uses and sources of exposure to a chemical wherever they appear and under whatever statutes may govern them or whatever agency's jurisdictions they fall under. Then, there is a separate decisionmaking process that has to take place, that is really not the subject of today's discussion, as to what to do if a prominent exposure is happening from a use or source falling under another agency's jurisdiction. We recognize that is tricky, but we think it needs to be faced in developing a reformed TSCA. At the very least, the safety standard needs to be applied to these myriad sources of exposure to a chemical.

We are certainly of the view that the conduct of safety assessments is not a one-size-fits-all concept, that you would not do the exact same level of assessment and require the exact same level of data for all chemicals, regardless of how they are used. At the same time, we believe strongly that there is no reason why a chemical used in a consumer product or in industry should be any less safe than a chemical used as a pesticide, for example. It's not the *standard of safety* that ought to be different between those different types of chemicals and uses. Rather, it may be that the level of assessment and the accompanying level of data necessary can be tailored to reflect factors like how a chemical is used, what its particular properties are, what types of exposures we know about, etc. That's a key distinction in our view, the distinction between not lessening the level of safety that we're looking for, but perhaps lessening the amount of data it would take to demonstrate that level is being met.

I want to briefly address a question about how safety determinations are actually done and who does them. I drew this earlier contrast between the REACH regulation that places essentially the safety determination step as a responsibility of industry. Our view is that, in general, EPA should be the entity that conducts safety determinations, and that the information necessary to do that should largely be provided by industry, although other sources of information ought to be considered. Certainly, if there are assessments being done in other jurisdictions, or even by the industry itself, those should be considered, but EPA should not rely exclusively on them or be bound by them.

We think it's equally important that when industry does an assessment and submits that to EPA, EPA's reliance on that, even on an interim basis, means that the assessment should be publicly accessible. We believe that is a critical component for the transparency aspect of safety determination. There should not be reliance on information that is totally hidden from public view.

There is also this issue of burden of proof, and it should come as no surprise to you now that we believe the industry ought to be bearing the legal burden of proof. I want to distinguish that from burden of work, because there's been some confusion about that in some of the legislative debates. We think that EPA should make the safety determination based on information, including potential assessment-type information, that would come from industry, but that the legal burden of proof should squarely rest on the industry.

The question of how decisions made by EPA ought to be reviewed if they are challenged in court is a §19 issue under TSCA. We regard the "substantial evidence" standard there to have been one of the many barriers that has precluded effective EPA action, and that the more conventional APA [Administrative Procedure Act] standard of "arbitrary and capricious" ought to be in fact the standard by which EPA decisions are judged. And that, of course, would affect any stakeholder who ends up bringing legal action, whether that be the industry or the NGO community. There should be considerable deference given to Agency decisions in our view, and that standard would be a much more appropriate one to apply under TSCA.

V. Speaker Responses and Discussion

Wendy Cleland-Hamnett: Jim talked about the importance of triage in a TSCA reform context. I completely agree with that, given the challenges of the numbers of chemicals we're dealing with, and the scope of uses and other issues we need to deal with. The ability of the Agency to do triage or prioritization and the way that we do that will be very important. That links to a very good point that Richard made about the fact that the safety standard is not the same thing necessarily as the depth of assessment and the degree of data required and so forth, and triage connects with that issue. It's important that everything meet a safety standard. It does not have to be assessed in the same way or found to meet the standard in the same way if we're going to have a system that's workable, given the scope of what we're dealing with here.

I also would very much agree with Jim's point that exposure data is going to be key. It's very important to understand the toxicity and the potential toxicity of chemicals, but that doesn't help us if we don't know whether and how people or the environment might be exposed to those chemicals.

Finally, I'll agree with Jim that another interesting question is, if we don't have TSCA reform—or until we get TSCA reform, is the way I'd like to think of it—how do we improve our work under the current system and the current TSCA? That's something that we are working on very hard here at the Agency.

James Aidala: Richard's description of the position of the coalition—not that everyone agrees with all those points—shows a much more specific articulation. Again, the devil's still in the details, but it shows that some of the discussion on many of these controversies, and the embedded controversial element of trying to get to a large reform package, have come a significant way since this all started two-and-one-half years ago.

Richard Denison: Jim pointed out that, while the FQPA reasonable certainty standard sounds like a zero-risk standard or something approaching it, in practice, it actually has not been such a standard. We are not necessarily wed to those words. I think some of the benefit of using a term that already has a legislative precedent is that it has a precedent, and also that EPA has figured out how to apply that standard.

At the same time, I think that standard does make some in industry nervous, because it implies a certain level of data requirements and assessment and time to get approval of the chemical. I just want to return back to my point about data requirements and level of assessment being things we see as needing to be tailored in order to both be practicable and to reflect the fact that certain uses of chemicals are going to pose much less risk than other uses.

Linda Breggin: Some of the chemical action plans for PFC, for example, suggest that EPA is considering bringing some actions under §6. Is EPA still considering that?

Wendy Cleland-Hamnett: Yes, we are, and that's the other prong of our program under TSCA right now. One is pursuing TSCA reform, the other is using the authorities that are given to us under TSCA, to the maximum extent possible, to do what we need to do to have a credible chemical management system. So, we are pursuing §6 actions as mentioned in several of the action plans, as well as in some other areas that were started up prior to our issuing the action plan.

Linda Breggin: How has "reasonable certainty of no harm" been interpreted or applied to pesticides as a factual scientific matter? For example, is it simply a matter of taking a "no observed adverse effects" level from animal studies and applying safety factors, or is that something else?

James Aidala: It's exactly what you described. There is an administrative record about EPA's articulation of what defaults, and how EPA used those risk assessment assumptions put out there for the world to comment on.

So, there's risk assessment considered separate from risk mitigation strategies. How do you do risk assessment under the pesticide evaluation program to determine safety? And as somebody commenting on what Richard said, there are benefits about EPA concluding an "unreasonable certainty of no harm." What it allows you to do in the pesticide arena is to say: "We the government have said it is safe. It's not maybe safe, it's not mostly safe, it is safe. If you have pesticide tolerance and exposure to that pesticide residue in your food, to you, your children, to a special subpopulation

as articulated under the statute, it is safe." And that helps people in various international fora, and it's a decision that's based on procedures, a transparent record, and so on.

Again, it's not to say that everyone loves it, or that everyone agrees with EPA. But that's one huge benefit once you've run that gauntlet. You've got the U.S. government saying it is safe to have this chemical in your food supply.

Linda Breggin: TSCA currently speaks of cumulative and synergistic effects in the statute, suggesting it was written with the understanding that science evolves. Is this insufficient?

Wendy Cleland-Hamnett: I guess that aspect of TSCA isn't—I think the problematic one that we're dealing with. I think it's more the "reasonable certainty of no harm." It's who bears the burden of doing the work and making the legal finding of unreasonable risk, and so forth. I certainly would agree that it makes sense to allow for the evolution of science. I don't think it's useful to have things locked into legislation that 10 or 15 years down the road may no longer be considered an appropriate way to perceive from the scientific perspective.

Richard Denison: I think it speaks to the fact that the lack of attention to cumulative and synergistic types of effects is something that's been around a long time, so those words do in fact appear in TSCA, and it suggests that some 35 years later, we're still not effectively addressing those issues, given that they're still very much part of the debate. But I would say that the way they appear in TSCA is in a very limited context. They only appear in a provision describing what types of tests and standards for testing EPA can promulgate. There is an implication, perhaps, that they could be taken into account in the assessment phase, but the lack of any specificity as to what that standard means and how you assess unreasonable risk goes to the heart of the problem of TSCA implementation.

James Aidala: For example, if cosmetics are exempted under current law, but it turns out that the big dioxin source in a person's lifetime exposure was cosmetic, what would you do under TSCA? By definition that's clear under the current law; you couldn't regulate it. You'd hope it would be regulated under other places and put that aside. But the whole point is that when you're dealing with these concepts of aggregate and especially cumulative, and they're coming in some of these avenues that are outside the scope of the particular authority that you're trying to implement, it just makes it very difficult.

If the big problem is somewhere else, what should you do under this program or this statute? That may come into play especially for industrial chemicals or certain elements on the atomic table in terms of offshore exposure—blown in the wind from China—does that mean you need to change your domestic production or domestically produced exposures when in fact, that may not have a big impact? That's just a tough issue. Again, I don't have a direct answer on that, but those are the kinds of things that you suddenly get into, and they're not just all theoretical, because some of those issues are going to be very real.

Linda Breggin: Do you foresee eventual TSCA legislative reform serving as a driver in the implementation of the NRC's [National Research Council's] vision and strategy for toxicity testing in the 21st century, which recommends a shift over the long term from traditional testing methodologies to more pathways-based testing?

James Aidala: Yes. It's basically ways to do testing and assessment and evaluation more quickly, more efficiently, more lively—and who could be against that; it's mother and apple pie. If you have to test 86,000 chemicals at least in some way, shape, or form, and some reasonably short period, meaning even if you said a 20-year time frame, you're still going to need that. Even if you didn't have that as a driver, just the march of science is going to produce a lot of what the potential is for 21st century toxicology.

When will you have enough data from these kinds of tests, especially if you currently look at the administrative record for doing risk assessments, with sufficient grounds to impose a significant regulatory control on a compound?

Thirty years ago, we were looking at this when the Ames test came out looking at mutagenicity. At the time, there was a hope that we could look at a set of very, very cheap and very, very quick studies and determine whether or not something might be called carcinogenic or likely to be carcinogenic. It turns out that these are very important things to look at, but they're not determinative. When will that, shall we say, be enough of a 21st century toxicology, the next generation of mutagenicity and beyond kinds of tests, or whatever simple set of assays, be sufficient to impose something like a complete product ban for a widely used industrial chemical? That's what's behind some of the 21st century toxicology debate.

Wendy Cleland-Hamnett: I pretty much agree with what you said, Jim, yes.

Richard Denison: Yes, I do too, Jim. I would just add one little caveat. It's not only deciding when a chemical may merit some control, but also the declaration of a particular use of a chemical as being safe. At what point does this kind of information provide a sufficient basis for making that decision? We do need to be concerned about what I've seen in applications of other tools like structure-activity relationship modeling, where many in the regulated community are happy as clams if such a model exonerates a chemical, but if it raises a red flag, then immediately it's described as being an insufficient indicator of hazard. So, we need to get to a point where in both directions, where they're finding something is risky or finding something is safe, we can apply these kinds of methods with confidence and with acceptance.

Linda Breggin: Jim, please explain what you mean by stringency of the standard may be a trade off with the role of any benefits consideration.

James Aidala: Well, again, my professional Wonder Bread years were spent on Capitol Hill, so everything is possible—the art of the deal. If some constituency really wants a very, very stringent standard, well, what are some of the trade offs in terms of how and who decides? If you're going to be able to ban something on the basis of a set of assays, well, what happens in terms of the implications for the stringency of the regulatory control that's going to be imposed? So, it's all trade off.

Linda Breggin: I want to thank everyone for joining us. I particularly want to thank our panelists. They all really provided some excellent insights and informative discussion of the issues associated with the standard of safety under TSCA, and we're certainly looking forward to watching as this plays out on Capitol Hill and elsewhere.