Episode Title: What do "reasonably foreseen" and "unreasonable risk" really mean? — A Conversation with Richard Engler, Ph.D. and Todd Stedeford, Ph.D.

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Lynn L. Bergeson (LLB): Hello and welcome to All Things Chemical, a podcast produced by Bergeson & Campbell, P.C. (B&C®), a Washington, D.C., law firm focusing on chemical law, litigation, and business matters. I'm Lynn Bergeson.

This week, I sat down with Dr. Rich Engler, B&C and The Acta Group's [Acta®], our consulting affiliate, Director of Chemistry, and Dr. Todd Stedeford, B&C's Of Counsel, to discuss a range of issues regarding EPA's [the U.S. Environmental Protection Agency] all-important implementation of the 2016 amendments to the Toxic Substances Control Act [TSCA]. Rich, as you know, is a 17-year veteran of EPA who is a frequent guest of the podcast. Todd is a more recent addition to the B&C and Acta team, is a lawyer and a toxicologist who recently completed a 20-year career with EPA, where he served most recently as Senior Science Advisor in EPA's Office of Pollution Prevention and Toxics [OPPT], among many other prominent leadership positions within the Agency. Rich and Todd discuss a range of issues I know our listeners will find timely and fascinating, including new chemical review, when is something reasonably foreseen, what is unreasonable risk, among other topics. Now, here is my conversation with Dr. Rich Engler and Dr. Todd Stedeford.

Well, good morning, gentlemen. It is a true pleasure to be with you both to talk about a topic near and dear to all of us, which is EPA's implementation of the 2016 amendments to TSCA. There are so many issues to talk about, and we have so little time within which to do this. But let's begin by talking about some key terms in TSCA Section 5. Now for background for our listeners, Lautenberg [the Frank R. Lautenberg Chemical Safety for the 21st Century Act] really changed an awful lot with respect to TSCA new chemical review. Under TSCA Section 5(a)(3), EPA is required to make certain determinations with regard to new chemicals. There are at least four key terms in TSCA Section 5. They are "not likely," "reasonably foreseen," "unreasonable risk" -- these all appear in the determination language -- and finally, "extent necessary." It appears in the language related to EPA issuing orders

following the Agency's review of new chemicals. Let's start with "unreasonable risk." Rich, maybe start with you. Has EPA defined this term, and how is EPA implementing this term, whether or not it is clearly defined?

Richard E. Engler (REE): EPA has never formally defined it, and it is not defined in the statutory language, nor is it defined in the regulatory language. But EPA does effectively have an operating definition. And what EPA does is they establish an effect level -- a point of departure [POD] is the term of art -- where EPA looks for data on the substance or on analogs, and they look for that minimum effect level, whatever that endpoint might be, the most sensitive endpoint. And then EPA uses a benchmark margin of exposure [MOE] somewhere between 1 and 1,000, depending on uncertainty, and they apply that benchmark MOE to establish what is effectively a safe dose. I mean, it's not the way it's implemented, but this is effectively how it works out. You take the POD, you have this MOE for a safety factor. And then EPA compares the exposures that it predicts, or measured exposures, if there's data, against that level, that POD divided by that MOE, and if the exposure is below that, then there's not an unreasonable risk. If the exposure is above that, there is an unreasonable risk.

LLB: It sounds very logical, the way you've just expressed it, Rich, but Todd, is that the way it is playing out in practice? Is that how it's being implemented?

Todd J. Stedeford (TJS): That is how it's being implemented. I'd just add on to that that EPA will also do qualitative assessments for endpoints like irritation, corrosion, where they don't necessarily have a method for quantifying those risks the way Rich had described. And I'd also say that when EPA is looking at unreasonable risk, they do weigh a variety of factors, including health effects, human exposure for cancer and noncancer, effects on the environment and environmental exposures, which include susceptible subpopulations and aquatic organisms. They also look at severity of hazards, so the nature of the hazard, the irreversibility of the hazard, and any associated uncertainties.

LLB: Okay, great. So far, so good. Maybe let's now turn to "reasonably foreseen." Just by very virtue of these words, it suggests there might be something that is unreasonably foreseen. Has this term been defined by EPA, either in the regs or in some guidance document? And how is EPA implementing this term in the context of new chemical review?

TJS: Well, "condition of use," it's not just what you use a chemical substance for. It also takes into account the exposures, releases associated with manufacturing, processing, and so on. EPA has stated numerous times that "reasonably foreseen" is based on information, knowledge, and experience, and it's not merely hypothetical or conjecture. And this approach is consistent with the legislative history of TSCA and the Lautenberg amendments. The term "conditions of use," it was not intended to include intentional misuse of chemicals.

REE: Unfortunately, that's not how -- at least from where I sit assisting clients with, especially with premanufacture notices [PMN] -- that's not how I view this being implemented. And one of the problems is it depends on the assessor. So depending on the review group that's looking at a particular PMN, there are varying degrees of hypotheticals and conjecture that -- frequently, we'll hear an assessor say, "We have this concern, and we did not find unreasonable risk for what was described in the PMN." And there's no connection between information, knowledge, and experience, and that hypothetical of "somebody might do something." So I think this is one of the places that we see a disconnect between EPA's stated policy and how it's being implemented in a day-to-day sense during PMN review.

LLB: Those three terms that both of you have used -- information, knowledge, and experience -- are, by their very definition, very subjective, right? Are they bound in any way? I recall reading those terms in various preamble discussions. EPA leaders have announced these terms in various public settings and in conferences, but are they bound in any particular way? Like whose experience? The Agency's experience, the chemical innovator's experience, *any* experience on record? An experience that is real or one that is reasonably foreseen -- not to be defining a term by using the term -- but those terms are very difficult to quantify and bound in any particular way. Any thoughts, Todd or Rich?

REE: I think you're getting at the fundamental problem here, which is I don't think there is a consensus about what those terms mean and how they should be implemented. And I remember back when Lautenberg first passed, and we had the first ELI [Environmental Law Institute], GW [George Washington], B&C panel. You asked all the members of the panel -- they were congressional staff and political appointees from EPA. And you just asked everyone who was up there, "Should there be an advisory committee, a federal advisory committee, that wrestles with some of these terms?" And nobody was interested in discussing that. But I think we really need to grapple with this term and what it means and how it should be implemented.

LLB: I do recall asking that question, and I think part of the pushback was not so much opposition to trying to define these terms better, but the context in which stakeholders could sit around and kick the tires on how best to move forward in defining and implementing these terms. And a Federal Advisory Committee Act [FACA] is about as appealing as a root canal for most people. So the pushback was on the FACA. I think there was consensus on the need, but here we are five years later! And what is a reasonably foreseen event? Being a philosophy major, something that I think many of us could talk about for days, if not longer: what is reasonably foreseen? So I'll park that thought there, and we'll move on to another very open-ended term: "not likely." Has EPA defined how likely "not likely" might be? And how is EPA implementing this term?

REE: EPA hasn't defined "not likely" yet, either in a quantitative or a qualitative term. But I think the place that we've really seen it be used is in the non-order [significant new use rule] SNUR context. Todd, do you want to talk about the based-on SNUR? And then I'll talk about the follow-on SNURs?

TJS: Sure. In 2017, EPA brought back the non-order SNUR construct, and the idea behind that is that the conditions of use as intended do not present an unreasonable risk. But EPA would issue a SNUR to prohibit conditions of use that were not intended but were known or reasonably foreseen and that might present an unreasonable risk.

REE: And the idea there is that with that SNUR in place, those were because intentional misuse is not part of what is reasonably foreseeable. Then what would be reasonably foreseeable -- conditions of use that would be reasonably foreseeable are now prohibited by the SNUR, that EPA could confidently then conclude that the PMN was not likely to present an unreasonable risk basically as intended. And those unintended things were prohibited, which I thought was a creative way to meet the statutory requirement. I know a lot of people have been very critical of EPA of the non-order SNUR, but it struck me as a way to efficiently get to the protective measure, which is the [SNUR], without having to go through the negotiation, the paperwork, the burden of the order, right? You have the protective measures. You've skipped the step that's just between EPA and the submitter.

The follow-on SNURs, I never really understood the logic behind, so the follow-on SNURs -- these were where EPA does not find reasonably foreseen conditions of use or does not find any intended, known, or reasonably foreseen conditions of use to be an unreasonable risk. But there's this more hypothetical possibility that there might be an exceedance of EPA's concern level in the future, and EPA needs to prohibit exceedance of that level or whatever the activity is, unless and until EPA has a chance to review. And so this is where I think EPA really departed from the statutory language and EPA's view of what is reasonably foreseen, and I never understood the justification. But these follow-on SNURs were basically, "Well, it might happen," and I just never got it.

LLB: If it's something might happen, does that capture -- is that eventuality or potential eventuality captured in the term "reasonably foreseen"? Because it really isn't foreseen. The follow-on SNUR seems to be kind of a prophylactic, like there might be a condition or an exceedance that we're not now anticipating, but it could happen. And the follow-on SNUR is intended to capture that.

REE: I think that's exactly right. So it's a combination of the reasonably foreseen and the likelihood. Is it likely or not? And here EPA concludes that the substance under the intended, known, or reasonably foreseen conditions of use do not present an unreasonable risk. And yet, some vague thing in the future might happen, that would, right? But how likely is it, and is it reasonably foreseeable? EPA never explained that. They simply just say, "We have this concern, and so we have to prohibit whatever it is until we can review it." That was the leap to me, the conceptual leap that really departs from the statutory language.

LLB: And some might argue that that construct is no more or less reasonable, logical, or grounded in Lautenberg than the non-[Section] 5(e) order SNUR, right?

REE: Well, to differentiate, the based-on SNUR, where EPA makes a determination contemporaneous with the issue of the SNUR, the idea there is the SNUR is specifically designed to prohibit those known or reasonably foreseen conditions of use that EPA predicted an unreasonable risk. So EPA does its evaluation and predicts an unreasonable risk under the, whatever those reasonably foreseen conditions are, and says, "Okay, we're going to prohibit those and let what was intended to go forward." So that the decision, the not likely decision, is predicated on the SNUR where the SNUR -- where EPA's prediction was that those problematic conditions of use were reasonably foreseen. So there it does make -- there is the connection between the SNUR decision and the statutory language.

LLB: I'm with you, Rich. That seemed like a useful and efficient expedient under the circumstances, but I know the current EPA Administration, Dr. Freedhoff in particular, under her leadership, has eliminated that. It was early on, I think, in March where EPA eliminated that expedient and made some other changes with respect to the new chemical review program, which we'll talk about later.

But let's move on to the next term and the last term. And that's "extent necessary." If EPA concludes that a chemical substance may or will present an unreasonable risk, how does EPA conclude that protective measures identified in an order meet the quote, "extent necessary," close quote, criterion?

REE: Part of this goes to the evaluation. If we go back to the unreasonable risk calculation, if EPA finds that there's, say, for an inhalation exposure, there's a certain level of exceedance, EPA can require personal protective equipment [PPE], a respirator with a particular protection factor to make sure that the exposures are driven below that problematic exposure level.

They can specify the type of respirator and the rated assigned protection factor [APF] for that particular respirator to protect workers from those sorts of exposures. So that's one of the ways that EPA uses "extent necessary" is in this numeric calculation, which is related to their calculation of unreasonable risk.

LLB: Makes sense. Todd, anything to add?

TJS: I would just add that for inhalation, since we were just talking about that, EPA can also establish what's known as a new chemical exposure limit or a NCEL, and that's basically an exposure concentration that a company can meet through monitoring to demonstrate the concentrations are below that concentration limit or through a combination of engineering controls and PPE. So the NCEL is essentially equivalent to an OSHA [Occupational Safety and Health Administration] PEL [permissible exposure limit], so it is legally enforceable.

LLB: Is it fair to say, gentlemen, that the "extent necessary" concept is perhaps less controversial, and the controversy might be grounded, not in what is the extent necessary to abate a particular risk that has been identified, but rather is the risk that has been identified either reasonably foreseen or derivative of one of the other terms that are embedded in the [Section] 5(a)(3) language? Is that a fair statement?

REE: I think to a large extent that's true. Some of the places where EPA might exceed what I would consider the extent necessary, like if the concern is corrosion -- which I know Todd and I have been debating whether corrosion is an unreasonable risk or not -- but if corrosion is EPA's concern, if that's the hazard that's driving, is it sufficient to warn somebody, to warn a worker -- presumably, it would be a worker if it's a corrosive substance -- that the substance is corrosive? Or do you have to require a certain level of PPE so that the worker is properly protected? To me, that sort of relates to a hot surface. Is it enough to warn somebody that the surface is hot? Or do you have to require that they wear an oven mitt to take the cookie sheet out of the oven? If you have that sort of immediate feedback, if I grant Todd's point that corrosion is an unreasonable risk, if you warn people, "This is corrosive; make sure you don't get it on your skin," is that enough, or do you have to say, "Oh, this is corrosive. You must do these things to protect yourself."

LLB: It's a good point, that's a good point. On the continuum of warning and enforceable measures to protect against the hazard that you are warning, that continuum can go down to some very, very granular regulatory provisions. And I can appreciate, given that context, Rich, which was very helpful, that "extent necessary" could be very controversial in the context of working out orders that are derivative of new chemical review. Does that happen a lot? Is that ongoing as we speak at the Agency, or --

REE: We do have some discussions. Generally, it's more about are there creative ways to get to the protective measure that changes where -- that give some more commercial flexibility but is still sufficiently protective? That might be a negotiation over do you specify [an NCEL] or do you specify a degree of respiratory protection? Do you specify, do you have use limitations versus some other performance metric, like [an NCEL]? There are a lot of different ways to skin the cat, so there is some discussion there with EPA about these are what EPA's concerns are, and these are different ways to address those concerns. So that's to me as a practical sense, that's where I've seen the most application of the extent necessary.

LLB: We've just talked through four terms that are embedded in the revised provisions of TSCA Section 5 coming out of the 2016 amendments. Given the open-ended nature of these terms

and the ambiguity that surrounds their interpretation in the context of a particular new chemical, I guess it's no wonder that there are a lot of issues that EPA is wrestling with now, and we are, too, as counselors and representatives of chemical innovators in getting these chemicals through the New Chemical Review Program. Because there has been quite a lot of discussion about the pace with which the new chemical review process is proceeding, the absence of clarity on these terms. I know EPA is working hard with stakeholders to resolve some of these issues. But I think this discussion illustrates just the inherent ambiguity of key terms in a new law that, despite the passage of time, has brought not a lot of clarity on each of these terms.

Now you both worked at EPA in the New Chemicals Division before Lautenberg was enacted. When you first looked at new Section 5, back in 2016, what were your first impressions when you read it? I know many of us going into TSCA reform, TSCA modernization -- call it what you will -- really didn't anticipate that TSCA Section 5 was going to be the subject of considerable review because we didn't appreciate that TSCA Section 5 was a chemical program that was thought to be in need of significant revision, but that obviously didn't happen. In your view, were you surprised when you read it? And then the second question: Did Lautenberg address whatever weaknesses you observed in the New Chemical Review Program when you were working with it back in the pre-2016 era? Rich, you want to go first?

REE: Yes, I was, in fact, kind of relieved at the language in Section 5 because it looked to me like it was codifying EPA's practice at the time. It was like, this is what EPA does. And so we're going to write this down because the biggest -- to me, the biggest departure was whereas before, although EPA did review all PMNs, it was not *required* to review all PMNs. With the change, EPA is now required to review all PMNs, and commercialization cannot proceed until EPA's determination is complete. So to me, that was the biggest departure, but that really wasn't -- I didn't expect it to change the practice, the function of the New Chemicals Program as much as it did. I just thought EPA would go through the same process as it did before, and it would write down whatever the decision was and put that in the record and do the determination and move on, whether that was a SNUR or an order or whatever that outcome was. So I didn't expect that. Certainly my personal expectation was not -- the departure from before and after Lautenberg was a big surprise to me.

LLB: Todd, what do you think?

TJS: I agree. I think that the decision to publish the basis for EPA's determination, and that's regardless of what it was, provided the public with a better understanding of EPA's decision-making, which I think up until the amendments, it was largely viewed as a black box. It probably is still some today, but that's more of a function of the confidential business information [CBI].

REE: Yes, that's an excellent point, Todd. There was criticism about the secretive nature, and there still is that same criticism. So the part of the point was yes, EPA -- regardless of the decision -- EPA does have to publish the basis for its determination. And that is an important change.

LLB: But what I'm picking up in your comments in particular, Rich, is that the new law requires a greater degree of transparency with regard to the decisions that are made. But it sounds like you thought that the new provisions in TSCA reflected the then state of affairs with regard to how EPA was reviewing new chemicals. But in fact, that has proven not to be the case. And how the sausage is made, as it were, the actual review of new chemicals has in fact

changed not just the transparency with which the Agency issues its decision. So there's a difference between when the decision comes out and how the decision is made. And it sounds like what you were suggesting, Rich, is that that process, in fact, has changed and doesn't reflect what EPA had been doing prior to Lautenberg.

REE: Yes, I think that change is entirely derivative of the interpretation of those terms we talked about: what is reasonably foreseeable, and what is likely or not, and extent necessary. Are those -- all of those things have been interpreted in a way that, in my view, are much more precautionary now than they were in 2015. Despite the -- there's been some change with the, now two changes in administration -- but even if you look in 2018 in the middle of the Trump Administration, EPA was still regulating many, many more, a much higher percentage of PMNs than EPA was regulating prior to the passage of Lautenberg. To me, that's a change in interpretation, not just writing a decision down.

LLB: Yes, I agree, and we're in our third administration. The Obama Administration was pretty instrumental in issuing the foundational rules when Lautenberg was issued in mid-2016. The passage of time has not clarified these terms. There's more of a patina on each of them, but they still defy consistent interpretation, which, in my view -- this is purely a personal view -- has made some degree of predictability as to outcome a more challenging goal.

REE: Yes, absolutely.

LLB: Why don't we pivot now and move on to TSCA Section 6? You know, that is the section of TSCA that addresses existing chemicals. What should listeners expect from EPA's revisions to the first ten risk evaluations? Because I think Assistant Administrator Freedhoff indicated earlier this year that although the risk evaluations were complete, there were going to be a number of them kind of pulled back and tinkered with again. Do either of you wish to speculate on what some of those changes might include?

REE: I think the biggest change is going to be EPA's view about exposures that are managed by other statutes. In the first ten risk evaluations, EPA assumed that risks from water and air would be managed by the Water Office and the Air Office, whether it's drinking water or clean water in terms of, for purposes of environmental or aquatic species. This Administration, I think -- and partly based on the legal challenges that were brought -- this Administration is going back and reconsidering that decision. I think it makes a lot of sense to use exposures. If there's a maximum contaminant limit or some air limit, using that as basically a baseline exposure, so you assume that somebody just in the ambient conditions is exposed at those levels through drinking water, through breathing the air. Then you add on top of that any exposure from the workplace, so if somebody is living near a facility and working in that facility, they're plausibly exposed by all these mechanisms. It does make sense to do an aggregate exposure in that sense. That's something I think is probably the correct change for EPA's approach here is to be looking at those potential aggregate exposures.

LLB: Got it. Anything to add, Todd?

TJS: Just to build on what Rich was saying, I think that by considering the air and water pathways, it's also going to help with addressing the environmental justice issues, which has been Dr. Freedhoff's, one of her areas of interest. I would also say that listeners can probably expect the fenceline assessments that we talked about, those will be added in to the risk evaluations. Also, the evaluation of [PPE] where EPA will actually remove that from the risk evaluation and consider [PPE] when they're doing risk management. And then the

final thing would be the whole-chemical approach, whereby the determination of unreasonable risk, it's made just once for the whole chemical and not for each individual condition of use. Presumably, it was a little unclear when that was announced.

LLB: That's a great segue, Todd, to my next question, because I am totally fascinated by this quote, unquote "whole-substance" approach. And to your point, Todd, Assistant Administrator Freedhoff announced on June 30 what I thought -- and many have characterized as a change in course with respect to conditions of use in these first ten risk evaluations -- for which no unreasonable risk was found. EPA made this announcement on June 30 in Dr. Freedhoff's remarks to the fifth TSCA program that GW, [ELI], and [B&C] sponsors each year.

It kind of threw many of us off because of how significant this announcement was. But EPA announced then that it intends to issue revised risk determinations, or unreasonable risk determinations, for these substances as a quote, unquote "whole substance" and to seek public comment, of course, on its approach. It remains a little unclear, though, what "whole substance" means in the context of risk assessment under TSCA. What do you think EPA will do as a result of this whole-substance approach? And some have speculated in some of the trade press and literature that's cropping up around this concept now that it sounds a whole lot more like a hazard-based approach as opposed to a risk-based approach, which of course is very central to TSCA. Rich, what do you think?

REE: I think saying that this is unclear is a bit of an understatement. I think it's really hard to know how this is going to work out. Is EPA going to -- if EPA finds *any* condition of use as an unreasonable risk, is the entire chemical an unreasonable risk? Or does EPA need to find a certain percentage an unreasonable risk to conclude that the whole substance is an unreasonable risk? I've no idea what's going to come out of this. Then how is EPA going to implement that for the risk evaluation, as opposed to risk management? If EPA finds it's unreasonable risk for the entire chemical, does that mean EPA has to ban the entire chemical? Or can EPA take a more measured approach in the risk management phase? I have no idea. Todd, I don't know if you have any insight on how this might get implemented and how this might work when the rubber meets the road.

TJS: Yes, I wasn't sure because it's interesting the language that was used when this was communicated, that they planned to assess and analyze each condition of use. But the language in the [40 C.F.R. Part] 702 regulations requires EPA to make risk determination for each condition of use, so I think it's unclear whether this whole-substance approach would actually meet the regulatory requirement.

LLB: Well, it will be interesting. And I know when Dr. Freedhoff made that announcement, public comment will of course be requested, and there will be lots of opportunity to understand better what is meant by this approach, whether it aligns with TSCA and Lautenberg revisions to TSCA, and how to square it with regard to the question you just asked, Rich, if you're talking about a whole substance or whole chemical approach, is this an indictment of the chemical in all conditions of use? So really, there's an awful lot here that is not clear, and we are very solicitous of understanding more about this approach. Any sense, gentlemen, of when this will be further identified in the context of which of the risk evaluations that were pulled back?

REE: I think the first new risk evaluation that comes out will give us some insight because that will be EPA's first opportunity to really show its cards, like, "Oh, here. We used the whole-

chemical approach, and here's our conclusion." Other than that, I'm not sure that we're going to get real clarity.

LLB: I know, Rich, you talked a little bit about this just recently. What do you think will be the result of EPA's intention to reevaluate 1,4-dioxane? And consider exactly those other exposures that are regulated by other environmental statutes: air, water, soil contamination, occupational exposure, specifically with respect to 1,4-dioxane generated as a byproduct. Now, these exposures were not considered in EPA's first risk evaluation, so I suspect it generally won't bode well for the molecule because additional exposures that were either intentionally not considered or will be intentionally considered in this go-round will ultimately have a bearing on the risk evaluation. But how do you see that playing out? Because this is a really important aspect of EPA's approach to risk evaluation under TSCA Section 6.

REE: Yes, I think that's going to depend on their particular [MOE] calculations. So if you think about when EPA found no unreasonable risk, if the fold factor below, you know, how much below that safe level EPA identified, if that's orders of magnitude, I doubt that these small exposures are going to lead to unreasonable risk. You might lower that protected [MOE] a little bit, but you're not going to cross over to unreasonable risk. And if you were already at unreasonable risk, then that had to be regulated anyway for risk management. But the things that were marginal right in the middle, where you were close to the line, those will probably pop up over the line, to lean into the unreasonable risk. But that's assuming that there's no change in the rest of the assessment. I mean, is EPA only looking at the exposures or is EPA readdressing the hazard? I don't know, Todd, if you want to chime in on the hazard assessment.

TJS: I don't think the hazard assessment is going to change much, but I think the point that you raised that was really important for this is that, what are the benchmark [MOEs] that EPA used for the non-cancer effects? It was typically 300, but the [MOEs] that they calculated for the environment, for the general population, for consumers, they were all orders of magnitude higher than that. So I guess the question comes down to whether or not the exposures, the additional exposures that they factor in for byproducts would actually bring those up to a level where you would identify risks. I doubt that that's going to happen, at least for the environment, consumers, bystanders, and general population. Occupational, it may be a different story, because they had identified so many conditions of use that had unreasonable risk. It was something like 13 of the uses, and most of those were also for the occupational non-users as well.

LLB: I hope this very brief discussion on Section 6, with these shifting or refined standards against which unreasonable risk is measured, what is the role of other environmental statutes in regulating substances, whether they are sufficiently protective or not, gives some insight into the difficulty in implementing TSCA Section 6, as amended by Lautenberg. EPA has had considerable difficulty in assessing these risks, and I'm imagining that this process, as bumpy as it is, is perhaps necessary to get to the right place. But I want to emphasize again that EPA works very hard at implementing this very challenging law, and it will take stakeholder engagement to ensure that we get it right. And it has been just a very confounding situation, to have three separate administrations taking a whack at a very challenging law to implement and define. But I don't know if you gentlemen have any thoughts on that. The perception is, gee, you know, we're five years into this, and we really don't even have the first ten done, and there are some 44,000 existing chemicals. Not all of them, of course, priority, high priority. But this is going to take a while.

REE: Yes, the challenges are -- there've been a number of challenges. The first challenge, and we certainly saw this in 2016 with new chemicals, and EPA made this point. They're to be credited with the fact of they're trying to do a difficult job -- is they had to make up the program while they were implementing a program. There was no phase-in time. The provisions were immediately effective on June 22, and especially for new chemicals, EPA had to figure out "What does this mean? How are we going to do this?" And meanwhile, the clock is ticking. And the same is true for existing chemicals as well. They had a little bit more time because they had to go through -- they had to select the first ten, so they had some time to figure out, how are we going to select those ten? And then what criteria are we going to use to judge them? But they published the framework rules, and they got to work. But all of that has been, again, being done -- they're doing the rulemaking, they're doing these risk evaluations while they're making this stuff up. And then of course, you've had the court challenges and you've had the administration changes. So that certainly makes life more difficult for EPA. They have to go back and start again. So those are part of the reasons that EPA has struggled.

LLB: Yes, I agree, and we emphasize that in several of our TSCA at One, Two, Three, Four, and Five, that there was no phase-in period. And so burdening -- and it is a burden -- EPA's staff with managing an existing program, a new chemical program, and then implementing a brand new law is a Herculean task. And again, I know there's frustration out there, but EPA works very, very, very hard to get it right, and it's incumbent upon all stakeholders to work to get it right. And in that regard, I know Dr. Freedhoff in some comments before a House Subcommittee hearing, very recently, on October 27, stated that EPA staff, or EPA institutionally is in need of additional resources, particularly with respect to the New Chemicals Division. I think she indicated that they were like 50 percent of what they should be, which is a pretty stark statistic. I guess my question to you, gentlemen, is will resources alone address the concerns that we have identified here in our brief discussion with respect to TSCA implementation? Rich, what are your thoughts?

REE: Resources are necessary. EPA definitely needs more bodies working on new chemicals. They need more assessors, health and eco assessors. They need more industrial hygienists. They need more, they just need more people working the pipeline, more risk managers as well, the program managers that actually communicate with the submitters. Across the board, the New Chemicals Program needs help. But getting new people in isn't enough because those new people need to be trained. They need to understand. They need to understand the law, how the law works. They need to understand the regulatory science, because there are actually differences between the chemistry that I learned when I was in graduate school and the chemistry that I learned when I was at EPA in implementing TSCA. Those two things are distinct. So you need to not just have that degree or that technical know-how, but you need to then learn how to apply that in a regulatory context. And that's a real challenge because of the brain drain at EPA. They've been losing folks -- and not just in the last few years, the last Administration. It's been like a decade in the making where EPA's been retiring two or three to hire one. And so you let 30, you let 120 years of experience out the door. And now you have someone coming in with six months experience. You cannot fill those shoes, or those three chairs, with one person with no experience. This isn't a new phenomenon. I think Lautenberg has made it much more challenging for EPA to address its significantly expanded obligations with a significantly reduced workforce. So step one is get the workforce back up to where it needs to be. But then you need to train and educate the folks on how TSCA works.

LLB: I agree, and I guess one of the reasons I'm so proud of our team is we collectively have -- I don't even want to think about how many hundreds of years of TSCA experience we have,

with your 17 and counting, Rich. Todd, you had just a stellar, storied career at EPA as Senior Science Advisor and Senior Leader in OPPT, and all of our other TSCA assets here at [B&C] and [Acta]. We have just a lot of depth in the bench. And to your point, Rich, there isn't necessarily a linear relationship between somebody retiring from EPA OPPT or the Office of Chemical Safety and Pollution Prevention and a new person brought on. The core skill set might be there, but the rich, textured, and exceedingly nuanced interpretation of the law is an acquired skill. And so just a postdoc or recent grad can be very, very gifted at what they do, but interpreting the law and applying it to a set of facts and circumstances is a very different expectation. It will take some time. Todd, from your perch, what do you see?

TJS: I'd agree with Rich. I think the brain drain has been really an issue there, and I think that as far as the human health assessments go, one of the issues that EPA is facing is that you hire somebody and most people, if they're new, fresh out of postdoc, they're in that research toxicologist mindset. To what you just mentioned, there's really a big gap between research toxicologists, for example, and then going to regulatory toxicologist, where you have to take into account the law, the regulations, the science, any policies, and it just takes time to learn those things.

REE: Yes, I learned it on the job. I had read TSCA before I was hired, but I didn't have any experience implementing TSCA, so I picked that up while I was there.

TJS: Right. And I think one of the problems with losing all the subject matter experts is that you don't have that mentoring that can go on to help people learn faster and know that they've got an expert to go to if they've got questions on something.

LLB: It's definitely a work in progress, and I hope EPA gets the resources that it has requested in the budget and organizes an internal system to bring people up to speed on not just the hard sciences, but the regulatory context in which all of these very, very new and evolving terms are applied. Final question, gentlemen, and that is: It's now late in 2021. A year from now, what do you expect to be different, if anything, with regard to EPA's implementation of TSCA?

TJS: I'll say for existing chemicals. A year from now, I think probably the first ten will have been reissued, and EPA will probably have proposed some initial risk management rules, as they had stated in the June announcement. They're probably going to have PV 29 [C.I. Pigment Violet 29], HBCD [cyclic aliphatic bromide cluster], and asbestos that actually go through that process first. And I think that they will be implementing revised approaches to the next 20 risk evaluations.

LLB: Anything on new chemicals?

REE: New chemicals, hopefully things will be moving again. There've really not been many determinations lately. Very few, even in this calendar year, there haven't been that many. A lot of the fiscal year 2021 PMNs are still awaiting EPA's initial determinations. EPA has to get that back up and running. I'm not sure when that's going to happen. Hopefully that will happen soon. And EPA can start churning through this second backlog.

Yes, the total number of cases under review is similar to when EPA declared the backlog clear, but the total number of cases that have been submitted is way down. So basically, EPA has more years of cases pending right now, or a similar number of years pending, as they did when they cleared the backlog in 2017, early 2018. So EPA has to start turning the

crank again on PMNs. I dearly hope that they're getting back up to a decent pace of turning those out, but I'm not sure when that's going to happen.

LLB: Well, I didn't hear a Lautenberg FACA from either of you, so I'm going to assume that that's just not going to happen.

REE: I think you made a convincing argument that it shouldn't, but I still think we need to wrestle with these terms.

LLB: True that.

REE: I think CBI determinations will probably be pretty stable. I think that's sort of shaken out pretty well. Fees Rule will presumably be updated by then, so that should settle down as well. I think some of the day-to-day working stuff will be more -- getting 6 and 5, those risk evaluation work -- getting all that stuff back on track. We should see at least a clear signal at that point.

LLB: Yes, so there is light at the end of this tunnel. That's all good. Well, gentlemen, I want to thank you for a very engaging discussion. We could talk about these concepts all day because we'd love to nerd out on TSCA and new chemicals and TSCA Section 6, but we'll leave it at that for now. I want to thank you both for coming into the studio today, and I really appreciate your thoughts.

REE: It was a pleasure. Thank you.

TJS: Thank you.

LLB: My thanks again to Dr. Engler and Dr. Stedeford for speaking with me today about TSCA implementation and key terms and developments in the review of new and existing chemicals.

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