Episode Title: What to Expect in Chemicals Policy and Regulation in 2023 -- A Conversation with Richard E. Engler, 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, Dr. Richard Engler, Director of Chemistry for Bergeson & Campbell and The Acta Group, our consulting affiliate, returned to the studio to discuss what to expect in the Toxic Substances Control Act (TSCA) regulation in the new year. While we cannot predict with precision, what we do know is 2023 will be a consequential year for several reasons. The first final risk management rule will be issued. The final per- and polyfluoroalkyl substance (PFAS) reporting rule will be issued, and the final confidential business information (CBI) rule will be issued. And this is all in the first quarter of the year.

In addition to these new and consequential final rules, we know the new Republican-led House is expected to schedule oversight hearings on a variety of U.S. Environmental Protection Agency (EPA) topics, including TSCA implementation. Litigation is also likely to darken our doorway quite a lot in the new year, so we discussed what issues are likely to be litigated and who might bring the lawsuits. Now here is my conversation with Dr. Rich Engler.

Rich, it's such a delight to be here in the studio with you in the new year.

Richard E. Engler (REE): It's always a pleasure to be here with you, Lynn.

LLB: Well, our 2023 Forecast is literally hot off the press. And in that document, which I hope all of our listeners review because it's now posted on our web page, we devote almost 30 pages to TSCA. Maybe you can help us identify the top U.S. industrial chemical trends that you expect in 2023. Greater regulation, emphasis on environmental justice (EJ), PFAS looms large on the horizon. What else?

REE: I think 2023 is going to be a really big year for TSCA. There's a lot of stuff coming, a lot of firsts. Probably one of the things we'll see very soon -- we don't know exactly when, but very soon -- we'll see the first risk management rule under new TSCA for asbestos.

LLB: That's exciting.

REE: That's been -- we understand that's been negotiated, or I don't know if it's still being negotiated or if that's close to nailed down. We expect the final CBI rule fairly early in the year.

LLB: CBI being confidential business information.

REE: Right. EPA's rules for handling CBI, TSCA CBI.

Probably in March, we'll see the TSCA Section 8(a)(7) PFAS reporting rule.

LLB: The dreaded PFAS reporting rule.

REE: What exemptions will EPA provide in that? That'll be quite substantial.

Plus we have the fees rule. Comments are due January 17. EPA wants that in place so that they can start charging the new fees in the new fiscal year, which starts October 1.

LLB: There's been a lot of consternation over that proposal.

REE: We can talk about that more. Along with all those final rules, there's a lot of proposed rules coming. We've got the other nine of the "First 10." EPA's now completed all of -- its re-review of all of the risk determinations, and EPA will start proposing the risk management rules for those. I expect they'll be staggered. EPA is going to be under the extraordinary weight of getting these things out, and, of course, TSCA practitioners like us are going to be very busy helping clients respond, review. It's going to be important for stakeholders to pay attention.

We've got the draft risk evaluations for the "Next 20." EPA has been working through those, and they're hoping to start getting those draft risk evaluations out, maybe late in the summer, probably more likely in the fall. EPA has also stated that it plans on proposing significant new use rules (SNUR) for uses that are not ongoing for phthalates, for flame retardants, for its prioritized solvents, and for inactive PFAS, so PFAS substances that are listed on the Inventory that are not active. For those, I expect EPA to issue dead chemical SNURs, where they simply state that *any* use is a significant new use.

Back in -- I believe it was 2018 -- EPA was really taken to task by career staff, by the press, and by non-governmental organizations (NGO) for issuing SNURs for non-ongoing uses of asbestos. I really wonder if we'll see that same criticism. I never really understood that criticism. I thought it was an effective way to prevent reintroduction of those uses of asbestos. I've always thought SNURs are a significant barrier to commercialization because they are --

LLB: Let's talk a little more about that because there is a fundamental misapprehension of the utility of a SNUR under those circumstances.

REE: Yes. I went back and looked, and the Asbestos Disease Awareness Organization stated that -- I have the quote here -- quote, "EPA can decide to take no action after a company has provided notice of its plans to introduce one of the listed products. If EPA takes no action, the manufacture and sale of the discontinued product could resume without restriction," end quote. And I don't understand that at all, because one of the major changes in new TSCA is that if EPA does not take affirmative action on the notice, the PMN, the premanufacture notice for a new chemical or a significant new use notice, then that commercialization cannot proceed.

LLB: In other words, it's an eventuality that can never happen.

REE: Right. If EPA takes no action, the submitter still has to wait. And that's what new chemical submitters have been struggling with, with the backlog of PMNs, I've never understood that, and I wonder if it was just throwing criticisms at EPA and see what sticks. Will we see that same behavior this time around? I don't know.

EPA will continue to issue test orders. There have been a handful of test orders. There was just a new one issued last week, I believe, for PFAS. There are more coming, so we'll see those. And then we also expect EPA to start issuing test orders for potentially the next -- some of the Next 20, and other substances that EPA is considering for prioritization. Because once EPA finishes one of the Next 20 risk evaluations, it is required to prioritize another substance. If EPA does wrap up a risk evaluation for one of the Next 20, it will have to immediately prioritize something else. EPA is going to be trying to look ahead to gather information about those prioritized substances.

In the Reg Agenda, EPA is proposing to update the new chemicals regulations: what's required to go into a PMN -- 40 C.F.R. Sections 720, 723, 725 -- and update the risk evaluation framework under TSCA Section 6. These are significant rulemaking. Given everything else that's going on, I don't know that EPA will get to that this year, but that would be a place where EPA would pull EJ considerations in. If EPA starts to try to incorporate EJ into the rules, those are the two rulemaking opportunities for that.

What else? The systematic review. EPA has proposed an update to its systematic review policy after it was criticized by the National Academies [of Sciences, Engineering, and Medicine]. The first systematic review was criticized by the National Academies. EPA has proposed an updated systematic review policy, but it hasn't taken that final, and this is critically important because it underlies so much of what EPA does under TSCA. And then to top it all off, we have the [persistent, bioaccumulative, and toxic] PBT regulation that EPA -- that after all of the mishegoss in 2021 --

LLB: That's one word for it.

REE: -- EPA stated that it would reopen the PBT rules. We thought it would be early, but in the Reg Agenda, it looks like it's going to be in the fall of this year that EPA will reopen the PBT rules. That is a lot.

LLB: Yes, that's just the intro here, Rich.

REE: I know. Are we done? Has it been an hour?

LLB: That was like nine minutes. It's just -- what I hear in terms of trends is relentless pace continues.

REE: Absolutely. It's going to be a huge burden on EPA. I feel for them, and it's going to be tough on all stakeholders to pay attention and really stay on top of things.

LLB: And PFAS, PFAS, PFAS. It's not going away.

REE: Oh, no.

LLB: It's terrible.

REE: All the PFAS activity is going to expand. There will be more test rules. And then, what else is EPA going to do? The SNURs at PFAS, the chemical SNURs, by taking their PFAS strategy forward. It's going to be a significant burden.

LLB: And next generation chemicals, the Next 20. I think -- that's kind of huge in and of itself, coming up with some of those --

REE: -- risk evaluations.

LLB: Risk evaluations, super big deal. And those are just kind of our shot at big trends. Yes. Any one of these. I mean, the last thing you mentioned, the PBT, that's *huge*! It was just huge.

Well, in our Forecast, we outline a lot of the significant initiatives in 2023 with regard to the TSCA piece. We also do FIFRA, and chemical regulation in Europe, and around the world. But for present purposes, maybe you can share your ranking, beginning with the most significant in descending order, what some of those initiatives are.

REE: Yes, I think the risk management rules, especially the asbestos rule and the other risk management rules, those are precedent setting. This is EPA trying to figure out how is it going to do these -- what's going to be the rules for risk management rules? How is it going to implement the whole chemical approach? These are going to be extraordinarily consequential and, as I said, precedent setting for risk management rules going forward. This is critically important for people to pay attention to, even if these chemicals are not in your supply chain, even if you do not use any of the First 10 chemicals, you need to be paying attention to what EPA is proposing to do, because this is how EPA is going to do existing chemicals going forward. So that's probably the most consequential.

And then the risk evaluations for the Next 20. As those start to come out, is EPA doing a credible, transparent job? Have they incorporated the criticisms from the First 10? And how has EPA addressed the weaknesses of the systematic review criticism? Has EPA taken the lessons learned from the First 10, and now is EPA applying those to the Next 20?

LLB: Well, in -- at a very general level and in a least favorable to EPA, the bottom line is no. I mean, the whole chemical approach, EPA went back and revised eight of the ten First 10 chemicals to reflect that fundamental paradigm shift, which many people continue to disagree with, find it has no basis in the statute, was proposed in a way that was in violation of the [Administrative Procedure Act] APA and TSCA rules. To some extent, has EPA learned its lesson? No.

REE: Will the first risk management rule that goes final be an opportunity to challenge the whole chemical approach? Because it -- I'm not the lawyer in the room, but it seems to me that the first opportunity, the first final agency action --

LLB: -- under the law is at that juncture.

REE: -- Is the final risk management rule. Asbestos, I suspect a lot of people do not view the asbestos rule as necessarily meeting the whole chemical approach. But maybe the first of the next nine, maybe methylene chloride, I think, is probably top of the list. If the methylene chloride rule goes final under the whole chemical approach, then that would be an opportunity to challenge the whole chemical approach.

LLB: Well, in that regard, some people regard the asbestos rule as a little bit different. I mean, it's -- is it a good illustrative example of risk management for EPA?

REE: You're talking about the proposed rule or the final rule?

LLB: What we regard -- or what we will *see* -- as the first final risk management rule in the not-too-distant future.

REE: I think it depends on what's in there, what are the final parameters of the rule. There were certainly some disconnects in the proposed rule. EPA proposed two years and then a full ban, and then as an alternative, proposed an existing chemical exposure limit, an ECEL, for five years and then a ban after five years. That struck me as internally inconsistent. The statute says that EPA must regulate "to the extent necessary." If an ECEL meets the extent necessary, then EPA doesn't have the predicate to impose a ban. Is the ECEL protective or not? Is a ban really justified by the underlying science? These are questions in my mind. I don't know what's in the final rule, how that's going to turn out. We've heard some rumblings about what's going on, but I don't know, so until it comes out --

LLB: -- Stay tuned.

REE: Yes.

LLB: Let's talk a little bit about CBI. I think CBI tends to be underrated in terms of its impact on business. Real TSCA mavens are focused on it in a big way. But what do you think we can expect? We've had a number of CBI challenges with EPA over the past year, in particular. When the final rule does come out, what do you expect to see?

REE: I'm very interested to see what comes out because CBI got a lot of comments. There's a lot of tension between the legitimate need to protect and the legitimate need to be transparent to the public. And where will that line fall? I don't know where EPA is going to end up.

The proposed rule was not outrageous. I thought a lot of what was in the proposed rule was really EPA codifying the practices that it had set up over the previous five and a half years as a rule. A lot of those struck me as practical balancing of those competing interests. The one that we particularly objected to was EPA's practice of, if anybody submits something with an accession number and does not seek to claim the identity as CBI, then EPA automatically discloses the substance, even if that submitter does not know the specific identity that underlies that accession number.

I've never understood EPA's view on that -- well, I *do* understand EPA's view on this. It's easy, right?

LLB: Right. That doesn't make it right.

REE: This person submitted -- they assume that if you have the accession number, you know what the underlying identity is, and that's just not the case.

LLB: Right. What about fees, Rich? Many of us spent the holidays preparing comments on EPA's retake on fees, recognizing that the last fee approach fell well under the 25 percent of the portion that EPA is authorized to collect. Where do you see EPA ending up? Because I think, as you suggested earlier, there's quite a lot of consternation with the proposal.

REE: Dr. Freedhoff warned us of sticker shock. And essentially, all the fees doubled. That was roughly -- from a rule-of-thumb standpoint, EPA is doubling all the fees. It's very difficult to know if EPA's fee increase is justified because EPA provided no basis for its [full-time equivalent] FTE or cost estimates. It simply asserts that, for example, it needs 185 FTEs to review new chemicals. That was an eye-popping number to me.

LLB: How many FTEs does it have now?

REE: 72, I believe. I mean, it's -- they're more than doubling the FTE ceiling, which would then lead to more than doubling the fee, which is basically what they proposed. When you do the math on FTEs and the number of cases, I think EPA's number of cases, 500 [low volume exemptions] (LVE), PMNs, [significant new use notices] (SNUN), and [microbial commercial activity notices] (MCAN) together, they came up with the number 500. That strikes me as probably right. That's about the number -- when you look across all those submission categories -- I think that's -- the numbers have been down lately, but that's probably fairly accurate. I think the number of cases is right, but that works out to about 600 hours of FTE time per submission, which just boggles my mind.

LLB: And that's EPA FTE.

REE: That's EPA FTE effort, per case.

LLB: Not contractors?

REE: Contractor is a separate category. They also asked for $21 million for contractors. There was an extraordinary number of hours for that, for contractor time. But this is time for EPA to review contractor reports. EPA doesn't generate these reports internally. Contractors generate reports. EPA reviews them and pulls them together in a final determination. I just -- it boggles my mind that it requires that much effort to review a single PMN, LVE --

LLB: -- and you would know. I mean you've reviewed maybe 10,000.

REE: Yes. I mean, I didn't do that much work on all of them.

LLB: No, but you know the drill.

REE: Yes. Various parts take -- some cases take more effort than others, but it's 50 to 100 hours. Maybe it's more, but let's be generous. 200 hours. I still can't get to 600 hours.

LLB: 600, yes.

REE: It just -- it boggles my mind. And EPA doesn't give a basis for --

LLB: Well, that's the real problem, the lack of transparency here. Again, we're not trying to pile on, but if you're coming up with these eye-popping increases, you need a really compelling basis to justify it. And many people believe it's just not there.

REE: I didn't see it. All I see is the number. They somehow come up with a number, and then the number is the basis for the justification for that fee increase.

LLB: Right. Let's pivot to test rules. We spent a whole lot of time in 2022 dealing with test rules. We appreciate and support the Agency's issuance of them, because they do help provide for better risk evaluations of chemicals, but we saw an awful lot of goofiness, scientific lapses, inexplicable changes, delays in review of protocols that test consortia were coming up with. And many of those consortia we represent, so we have a *lot* of firsthand experience. Where do you see the problems, and do you expect them to continue, or will EPA learn as we progress with the issuance of test rules?

REE: I think EPA *has* learned, because what we've seen -- late last year, we had a number of clients come, "Oh, I got this letter -- I got this e-mail from EPA saying, 'You may be subject to a test rule.' What should I do?"

This is what we asked EPA to do. We asked EPA to reach out to potential test order recipients, number one, to make sure they're proper recipients of an order, that they're a proper target of the order, because they were -- certainly, EPA was issuing orders to companies that were not involved --

LLB: Mistakenly, right.

REE: -- And that's more work for everybody. It's work for the recipient, it's work for EPA to then back them out. It's better for EPA to get a more accurate picture of who are the appropriate targets of those orders. So that's part of it.

And another part of it that we asked EPA to reach out about is to discuss what the actual data needs are. What does EPA feel it needs to do prioritization, risk evaluation, whatever it's going to do with that information? What data does it need? Does that data already exist? Does one of the stakeholders own it, or is it in a [European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals] (REACH) dossier that a U.S. stakeholder can purchase access to? Or is there a compelling reason that that information is not needed? You know, it's a data gap, but it's not a data need.

These are in-depth scientific discussions that we hope happen before EPA issues the order. And everybody's on a very short timeframe to resolve. So rather than issuing the order and then back-and-forth extensions, it's like, "Let's talk about it; let's figure out what the data needs are, and then, whether it's an order or an enforceable consent agreement." But let the industry stakeholders move forward with the testing, under whatever mechanism, so that EPA gets the data that it needs in an efficient manner.

LLB: Yes. Do you see similar improvement with regard to the TSCA Section 5 new chemical process? I had two bottom-line questions. Will we see improvement in that process this year? And if so, in what key areas, in your view?

REE: Leading up to the holidays, we saw some significant improvement in throughput. EPA did -- Denise Keehner, as she discussed in the middle of 2022 after -- she started, I believe in March of 2022 --

LLB: As Director of [Office of Pollution Prevention and Toxics] (OPPT) --

REE: Director of OPPT. By the middle of the year, it was clear to her -- and management within OPPT -- that they needed to do something extraordinary. And they brought in a bunch of -- they reassigned a number of senior assessors and assigned them to -- health assessors -- and assigned them to fill the substantial gap that they had, the staffing gap they had for health assessments. We saw the fruit of that in October and November; we started to see cases moving again. We got -- a couple of clients got consent order offers. This is what -- that first bid on a consent order, we had -- I think we had one signed. We had some LVEs get resolved. We already saw big progress before the holiday. Then it's the holiday, everything's going to slow down. I fully expect that that's going to continue now in the new year. Everyone's back to work -- that we'll start to see those moving again. Improvement's already there.

EPA had openings -- they'd advertised a number of openings. I assume they're moving forward with hiring folks into those positions. That's another critical piece. Those folks will need to be trained, so the fixes to new chemicals, in terms of staffing, are in the works. That will continue to improve. What I *don't* think is going to change yet is EPA's approach.

LLB: Right.

REE: Yes. In 2022, EPA regulated 95 percent of all the PMNs for which it completed a determination. I think it did 74 determinations, and 70 were consent orders, and four were not likely. We've discussed many times on the podcast, and many other public occasions, that EPA's hazard-based approach is just unsupported.

Now, EPA has been reaching out. They had a webinar in the fall with their engineers trying to talk about how to build a better PMN. What are the facts? Still it's not clear to me, if we do all that work and bring all the facts to bear, will EPA still foresee what might happen if it -- other than what the submitter is representing? We don't -- that's an ongoing discussion that I hope -- that we hope to address with EPA this year.

LLB: We are addressing it in the context of our comments on the proposed fee increase. You can have all the money in the world, you can have all the risk assessors in the world, but if the fundamental risk assessment paradigm that EPA's embracing doesn't fairly reflect what are reasonably foreseen conditions of use, what actual data suggest, what risk mitigation measures ought to be perceived as risk provisions within the context of the risk evaluation, you're going to have overregulation, which is, I think, where we come down. It's great that the throughput is increasing, but we want the result to fairly reflect the risk potential of the chemical being reviewed.

REE: Indeed.

LLB: Maybe we can talk a little bit about litigation because we began our conversation with recognizing that we're going to be seeing a host of final agency actions, perhaps one of the most important of which is the first final risk management rule. But with final agency action and additional measures that we expect to see, in addition to citizen actions under TSCA Section 20, one lawsuit of which was recently filed. We put a blog up on Bob Sussman's challenge to fluorinated plastic containers and that constellation of issues. I would expect litigation to really pick up steam in 2023. Agree?

REE: Yes. The final asbestos rule -- what will be the parameters of that? What will the various stakeholders think of that final agency action? The CBI rule, the PFAS reporting rule -- I think if the PFAS reporting rule comes out largely as proposed, I would expect that there would be an industry lawsuit. But if it comes out, if EPA does offer some exemptions, will the NGOs sue for -- that EPA has failed to meet the statutory requirements under the NDAA, the National Defense Authorization Act? I guess I'll be surprised if -- especially these final agency actions -- if two of the three of them do not invite some litigation.

LLB: That's supposed to be the hallmark of a successful rule: everyone's unhappy, right?

Let's pivot to our flipped House. Given the change in House leadership, we address some of these issues in the Forecast, but we expect additional scrutiny of EPA actions generally. And although the regulation of chemicals is not high on the American consumer's list of things to worry about, we do expect enhanced scrutiny of TSCA implementation by this House. What do you see the content of those reviews focusing on?

REE: A lot of it will focus on new chemicals. There's been a significant frustration with the new chemicals program. I'm not sure that flipping the House leadership is going to make much of a difference. There were hearings, even last year. Dr. Freedhoff was quite capable in deflecting the criticisms, largely pointing to the lack of resources. She got a 20 percent bump in the OPPT budget.

LLB: No small feat.

REE: -- which we supported. Okay, you've got more resources now. Let's see the results, the improved results, the improved throughput. I'm not sure that House oversight will make a -- certainly in those hearings, there were questions from both sides of the aisle. Dr. Freedhoff was fairly capable at dealing with criticisms from both sides of the aisle. I don't know that the hearings will make much of a difference. I think the courts will have a much larger effect, the litigation that we talked about -- I think that will be where we really see some change in direction on EPA's part as a result of court decisions.

LLB: As we are now into 2023, a year before a major general election, do you see any changes in EPA senior leadership in [the Office of Chemical Safety and Pollution Prevention] (OCSPP)?

REE: I do not expect Dr. Freedhoff to leave prior to the election. Maybe if she's going to run for office somewhere else, she'll go, but I think she's happy where she is. This is her -- she worked so hard on TSCA reform, and now she's --

LLB: -- curating the fruits of her labor.

REE: Exactly. I expect to see her there through the year. Dr. Tala Henry, who was the Deputy Office Director of OPPT, retired at the end of the year. That's a major hole to fill.

LLB: Agree. Big loss.

REE: That's going to be tough for EPA to fill her shoes. But now that Denise Keehner has been there for a year, she's really, fully aware of what the issues are. She has brought her significant experience to bear in addressing those issues. I'm hoping that the loss of Tala will not be as significant as if they still were without an office director or had an acting office director.

The other thing is a lot of the folks that were there when I started at EPA in 1997 that are still there, they're aging out. They're going to start to retire. Is EPA in a position where it's going to harvest that institutional knowledge and transfer it to the new folks that are coming in?

LLB: That's always just a huge problem. Same with the FIFRA office. It just walks out the door.

REE: Yes. And that's been a tough challenge for ten years. So that may also have a substantial effect, as we lose some of those senior folks that are just, they're ready to go, they're ready to retire, move on to whatever the next phase is. That will certainly impact EPA's ability to do everything that it does.

LLB: As we gear up for our webinar next week, focusing on the EU Chemicals Strategy for Sustainability, do you expect, Rich, REACH and [Classification, Labeling and Packaging regulations] CLP changes to influence U.S. chemical policy in any meaningful way this year or in the near future? I know *I* do, but maybe for different reasons.

REE: Yes, OCSPP has really gone its own way ever since REACH was -- even back when REACH was first passed, OPPT has operated fairly independently from what ECHA -- the European Chemicals Agency -- has done in the EU. This is certainly a frustration for clients that there are these two utterly independent reviews. And there's no coordination or thought that, "Well, ECHA thought this was okay. Why does OPPT have a problem with it?" Or vice versa.

LLB: Or the reverse.

REE: Yes. I think that the Chemicals Strategy for Sustainability may drive a bunch of new sustainable chemistry technologies, which is great. I'm a big proponent of green chemistry; have been for not a thousand years, but certainly a couple of decades. I'm hoping that that will help continue to enable new green chemistry technologies, but if there are new chemicals, they're going to suffer under TSCA the way everything else is we've seen. We may just see the blossoming of that sustainable chemistry being implemented in Europe and just hampered in the United States for the time being. And that'll be too bad. I guess I don't really see what's going on in Europe making much of a difference in the United States in the short term.

LLB: What about other parts of the world? Our Forecast, of course, all 100-plus pages of it, focuses on chemical regulation globally, with an obvious emphasis on domestic matters. But there's a lot going on in Canada, Pac Rim, Asia. What do you see happening there?

REE: In those regions, the chemical regulations are a little more stable, so I don't know that there are going to be monumental changes. South America will be very interesting. A lot of the countries in South America have been working on standing up their own chemical regulatory schemes, typically REACH-like, but in the end we have to wait and see. Some of those countries, they've been discussing it for years, so those could be an interesting place for change.

The other is the UK. After Brexit, the UK essentially cut and paste REACH under UK REACH. But there's -- how will that depart? How will that diverge from EU REACH? I think the UK is finally getting to a point where they're thinking more seriously about that divergence, trying to put some time and effort into that. So that would be a place to watch in

particular, other than South America. I don't think that Asia-Pacific will be -- we'll see a lot of change.

LLB: Last question, Rich, and one that we hope will linger in our listeners' memories, and that is what are the most important takeaway messages from this podcast you would like our listeners to consider as they confront the new year and the tsunami of TSCA regulations we expect to see?

REE: Unfortunately, you're going to have to pay attention to all of it. The breadth of what's happening, what we expect to happen under TSCA, all the -- final rulemakings, the proposed rulemakings -- there is going to be a lot, and it's going to be consequential across the board. It's not -- just as I mentioned before -- it's not just "Is it about your substance?" This is -- EPA is figuring out and setting up the protocol and the template for how it's going to do risk evaluation going forward. You need to pay attention and be prepared to comment on the substance -- not *chemical* substance, but the meat -- comment on the meat of the proposal and what underlies it.

And pay attention to the litigation. We talked about that there's a decent likelihood of litigation, that there may be some litigation on which folks want to intervene. Again, they may not have direct interest in the substance, but they have an interest in how EPA is doing its job. And they may want to step in and intervene and say, "Yes, we agree that EPA has exceeded its authority" or failed to do whatever the statute required. But those -- I think those in particular, it's being aware and being prepared to step in and speak out, whether it's individually or through a trade association or other consortium. 2023, I think is going to be the biggest year for TSCA since 2016.

LLB: Wow. And I know as we prepare our listeners for all of these rules, final and proposed, that EPA is expected to issue, we also wish our listeners to be mindful of opportunities. We've issued a lot of information on our website and blogs on perhaps the new chemical category, initiating those, working with EPA. It's so hard for EPA, as busy as it is, to get its day-to-day work done because of all of these regulations and all the time limitations imposed by new chemical review, Section 4 test rules, and so on and so forth.

But there are also opportunities to help influence new chemical initiatives. Maybe you can spend just a second on that because we don't always want to be defensive. We also want to be -- not in a bad way, but -- offensive, to help EPA --.

REE: **--** Proactive.

LLB: Be proactive. Exactly right.

REE: Yes, going back to the test rule, those preliminary e-mails that came out about the test rules. I think this is an excellent opportunity for stakeholders, again, to be engaged with EPA. EPA has a job to do. It has all these statutory obligations it has to meet. And in my view, it's not productive to just dig in our heels.

LLB: Right, exactly.

REE: EPA *has* to do this. How do we help EPA do it efficiently in a well-informed -- scientifically well-informed -- and legally supportable manner? Let's come together, figure out how to get this done, figure out a way to do it that's less of a burden on the regulated community and on EPA. If we can do it more efficiently, we can get these things done more

efficiently. EPA will be in a better place. The regulated community will be in a better place. And then the general public, who have the benefit of the regulatory outcomes, will be in a better place.

LLB: Exactly right. Well, we've mentioned before our Forecast. We want to leave our listeners with a suggestion, the recommendation that they go to our web page, www.lawbc.com, and either download a copy or read it. Set aside a few hours because it is about 110 pages, but just chock full of information. It is our informed judgment on what happened last year, what can we expect this year, and why you should care.

Rich, always a pleasure. Thank you so much for being here.

REE: My pleasure, Lynn. It's always a pleasure.

LLB: Thanks again to Dr. Rich Engler for speaking with me today about TSCA regulation and litigation in the new year. It is going to be an eventful year.

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