Episode Title: TSCA Developments in 2024 -- 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, business, and litigation matters. I'm Lynn Bergeson.

This week, I discuss with my colleague, Dr. Richard Engler, Director of Chemistry for B&C and The Acta Group, our consulting affiliate, what to expect in 2024 regarding Toxic Substances Control Act (TSCA) Developments. Rich is a leading voice on all things TSCA, especially new chemicals, and a widely sought after thought leader on the U.S. Environmental Protection Agency's (EPA) implementation of the Lautenberg Act, Congress's 2016 amendments to TSCA. We begin with the most recent Senate hearing on TSCA on January 24, and then discuss Rich's thoughts on key TSCA initiatives the rest of the year. Now, here is my conversation with Rich Engler.

Rich, great to have you back.

Richard E. Engler (REE): It's such a pleasure to be back, Lynn.

LLB: It's early in the year, and we are still breathing a sigh of relief getting our 2024 *Forecast* document out. The document is about 106-107 pages, covering everything from soup to nuts in the United States and globally on chemical, legal, regulatory, and scientific developments.

REE: It's a labor of love.

LLB: It is definitely a labor of love. It's a fantastic piece of work. We're going to talk about some of the highlights on the TSCA chapter in the 2024 *Forecast*. Let's begin by talking about the hearing -- the Senate Environment and Public Works hearing last week featuring Dr. Michal Freedhoff, Assistant Administrator for Toxics. I thought it was a very, very interesting exchange of views, kind of Dickensian with regard to *A Tale of Two Cities*. You had the Republicans and the Democrats having very different views on EPA's implementation of

TSCA. What do you think some of the key takeaway messages are from Dr. Freedhoff's testimony and the hearing in general?

REE: I wasn't surprised by much. As you say, a lot of the messages are the same. Dr. Freedhoff is still strongly of the view that [the Office of Chemical Safety and Pollution Prevention] OCSPP is under-resourced. I agree. I think she and I disagree on how much. I'm not sure what the right number is, but she thinks it needs to be much, much higher. Hopefully, we'll talk about the fees rule in a little bit. Then the Republicans were generally worried about overregulation. Senator Boozman (R-AR) was particularly concerned about formaldehyde and what the formaldehyde level might look like. One of the surprising things that I heard is that Dr. Freedhoff stated that if the [existing chemical exposure limit] ECEL was below background levels of formaldehyde, that that would not be the basis of regulation.

LLB: ECEL meaning --

REE: -- the existing chemical exposure limit. If EPA calculates an ECEL for formaldehyde that is below the background level of formaldehyde, that EPA would not set the ECEL to that very low level. Don't know what they *will* set it to, but at least there was a commitment that they're not going to regulate below what we just --

LLB: -- what people exhale when they breathe.

REE: Yes. That we encounter every day, regardless of industrial -- or exposures. The Democrats were particularly worried about things *not* happening. [Senator Edward] Markey [D-MA] brought up a number of chemicals, trichloroethylene in particular, because there had been a cancer cluster in his district, or in his state. That is -- that's a tragedy, so he was -- he's particularly concerned about that. Then the East Palestine [Ohio] accident came up a couple times, which I thought was interesting -- not really surprising, but it came up a couple times. A lot of the political theater was -- the traditional roles were there. But we'll see. We'll see. I think the -- more interesting to me is the communication that clearly happened prior to the hearing, that Michal had been meeting with staff and members to talk about some of the in-the-weeds issues that we tend to focus on, that make less interesting political theater in a hearing. That, to me, is maybe more productive in terms of advancing the efficient implementation of TSCA.

LLB: I know in reading Dr. Freedhoff's prepared remarks, which were very good as always, but one passage jumped out to me anyway, and I suspect it hit a nerve in you, too. You spent 17 years with EPA working in the New Chemicals office [New Chemical Division, or NCD] of the Office of Pollution Prevention and Toxics (OPPT), and there's always a disconnect between old TSCA and new TSCA with regard to how new chemicals are reviewed. One passage in the testimony reads, "The 2016 amendments to TSCA brought about a dramatic increase in EPA's workload."

REE: Okay.

LLB: Which I think we can all agree. And then, quote, "Previously, EPA only made formal risk determinations for around 20 percent of new chemical submittals. The remaining 80 percent went into commerce automatically." I know we all tend to lapse into TSCA-ese. And there might be some shortcuts to expressing views, but to the lay audience and the viewing public, that might suggest that 80 percent of chemicals, prior to Lautenberg, went into commerce without any type of EPA review by virtue of the term "commerce automatically." I was wondering, Rich, if you could kind of explain what this really means.

REE: I have questioned the basis for that number since I first heard it. I think in 20 -- I think it was during the hearings leading up to Lautenberg. Only 20 percent got reviewed. I don't want to speak for all of my former colleagues, but I remember looking at basically every [premanufacture notice] PMN that came in. There were a number of criteria that we used to more efficiently decide, if there were cases that were found to be low hazard to health and eco. We did not send those forward to engineering review and exposure review and fate review, because it was predictable that the outcome would be that there wouldn't be an unreasonable risk. Now they're reviewing every substance to the bitter end. I'm not sure what the point is. If there are criteria that EPA can -- that NCD can set to say, "If the substance meets these criteria, the rest of the team doesn't need to look at it, because we know what the outcome is going to be." Why not do that? That's a more efficient use of program resources.

There were those drops. There were also the majority of chemicals that we reviewed were in one of the many categories that have been established and are still around. EPA's category document is still there, NCD has created new categories, and they're using those to, again, more efficiently review things in those categories. That's great. That is, again, efficient use of their expertise and their resources to make decisions and get the work done. Not reviewing every case *de novo* to the bitter end, and saying, "Now we have to do that." I don't think it's true that they have to review every case *de novo* to the bitter end because there *are* efficiencies to be had. I still -- I wish -- and I haven't been able to figure out -- I've gone back and looked at the PMN statistics. I do not know the basis of the 20 percent. I would love to hear where that number came from. I imagine it was just -- I used to think it was the total number that received orders and [significant new use rules] (SNUR), but it's not that. I used to think it was standard reviews.

LLB: It's not that.

REE: It's not that. I don't know what that number is, and it *does* bother me, because it does make it sound like those of us that worked there were just like, "Yeah, whatever. Oh, no, I'm not gonna look at that one. It's a Tuesday. I'm not going to look at that one."

LLB: It is a little misleading. And it's taken on a bit of an urban legend, kind of feel to it.

REE: It's got a life of its own. I'm just like, "Help me, help us understand what that is and why the workload truly is five times as significant as it was before." Or is it just you haven't yet taken advantage of the efficiencies that you could?

LLB: Right. Another reference in Ranking Member Capito's prepared testimony also jumped out at me, but perhaps for a different reason. People tend to linger over the 90-day review period. There's been a lot of talk about how the Agency is going far beyond that. We know that "90 days" can be 18 months to 24 months. On average it is, I think, coming down a bit, but it is also a little bit of an urban legend to presume that 90 days was *ever* a meaningful marker in the law and lore of TSCA new chemical review. It's been historically overlooked pre-Lautenberg, and it's definitely overlooked now, post-Lautenberg. Maybe you can just put some markers around that context as well, Rich.

REE: Most reviews -- pre-Lautenberg, most reviews were done within the 90-day review period, even ones that were getting regulatory outcomes. The average -- if I remember correctly -- the average for all cases was 110 or so days, but no PMN could be under 90 days because pre-Lautenberg, you had to --

LLB: We had to wait, right.

REE: You had to wait the 90 days, regardless of what the decision was. Now, if EPA makes a not likely [to present unreasonable risk] determination, the review period ends earlier, so you could have a review period that's less than 90 days. This "90 days" has really become -- I think it's an inappropriate focus, but it *is* a signal. My view is that it is a signal from Congress about the level of effort that EPA should go through. This isn't a dissertation. It's not a five-year project. Right?

LLB: Hope not.

REE: Right, it's -- look at the data that are available, look at analogs, look at the models. Make a decision. Make a determination. Write it down. Move on to the next one. I think there's more -- I don't know if it's more in depth or more -- dithering is not the right word, but a lot of back-and-forth discussion. It's like anticipatory regret.

LLB: Right.

REE: I think that EPA does not want -- I mean, I appreciate you don't want to make a mistake, but they're so concerned about letting something on the market that they later discover that it was a problem, that they don't want to let *anything* go forward. So they're trying to ensure a very high level of certainty, that I think is not -- it goes beyond what Congress intended in its writing of Section 5. But these are legal questions that have yet to be resolved.

LLB: We spend, I think, a good deal of time in the *Forecast* going through the statistics, SNUR development, new chemical review. Dr. Freedhoff made much of the 14 new members of her team in OPPT -- which is good news, two more that are onboarding soon -- so I guess one hopes that the new staff, new resources, and additional revenue will hasten the process. But I think as you and I have spent many months in our advocacy initiatives on matters that are both specific to clients and also our coalition work, that in a perfect world, it's not just the speed of the review, it's the quality of the review and whether --

REE: And the predictability.

LLB: And the predictability. Is EPA adhering to the legal standard under TSCA, which is a risk-based statute, not a hazard-based statute? That tends to confound the analysis, and I think to your point, also adds to the review time.

REE: Yes, and also use of reasonably available information. At what point is EPA going to use the submitted data in preference to its models or analogs? I think that one of the frustrations that I've had and that a lot of our clients have had is that data don't seem to make a difference in the outcome. And that, to me, is a signal that something's wrong. I don't -- I'm not sure what, but if you have data and you end up with a regulation that says, X, Y, and Z, and you don't have data and you end up with essentially the same regulation, then what was the point of developing the data?

That's part of the frustration. But the other frustration is predictability, is that we've seen cases where basically the same fact set goes in, and we get two different answers, depending on who reviews it. That's, I think, also a signal that things are not working well. Hopefully, the new policies and procedures that EPA is now being pressured -- not just by Congress, but by the Office of Inspector General (OIG) -- to develop and begin to use to onboard folks

that training. I think that will help. Getting a standard operating procedure, I think, will help quite a bit in terms of the quality and, frankly, the throughput.

LLB: I know in our Firm Clients and Friends memo on this, we make reference to a document that was circulated after the hearing, or perhaps during the hearing, about commitments to prioritize resource allocation to improve the NCD program. To some extent, there might be some improvements made with regard to the use of actual data, or at least a better, more coherent explanation as to why actual data might be not used, instead of some of EPA's more conservative risk program. Right?

REE: Yes. It's not always the case that data are of sufficient quality that EPA can rely upon them, but when EPA does not rely on those data, it needs to provide that rationale. When EPA does not rely on the analogs provided by the submitter and they rely on some other analog, they need to provide a rationale. We haven't been seeing that. Now that is more work, because now EPA is going to have to explain what it's doing, but honestly, that's Section 26, the best available science, and scientific integrity. You -- as a scientist, you have to provide the basis for your decision. As I've said a number of times before, "Because I said so" is not a compelling scientific argument.

LLB: Yes. Any other comments you wish to make on the hearing or things that leapt out at you, either with regard to the question and answer period following the prepared remarks, or directionally, where EPA may be headed, particularly with regard to new chemicals?

REE: No, the resource document that you referred to, I think -- that to me is where the real meat of where we may see progress. I think that's more promising than the political theater that we -- the *kabuki* dances, as we say, of the actual testimony.

LLB: Stepping back a bit -- the hearing, which was very timely and, to us TSCA aficionados, very, very interesting -- but stepping back a bit and looking at our *Forecast*, maybe you can share with our listeners, what do you think? What are you most excited about this year, if anything, with regard to TSCA developments?

REE: The final risk management rules, I think, are going to be a key milestone. This is -- *the* key driver for TSCA reform was review of existing chemicals. Asbestos is coming out soon, maybe March.

LLB: That's what the Unified Agenda says.

REE: We may get the asbestos rule. I don't expect it to be a full ban, so if asbestos is not fully banned, was Lautenberg a failure? Banning asbestos was *the* goal. "Oh, we couldn't even ban asbestos." Well, asbestos sounds like it's not going to be banned. Does that mean that Lautenberg is a failure?

LLB: Not immediately, right.

REE: There may be some uses that are not banned at all, that are allowed to continue, because there are simply not alternatives. I don't know. We don't know what's in the final rule. Everything is sort of rumor and speculation. But in the final rule, when it comes out, we'll see. It'll also be the first opportunity to litigate some of the key terms, interpretive terms. What does "extent necessary" mean? What is "the best available science"? What is "reasonably available information"? These are all new terms.

LLB: That is to say, you think there will be litigation in our future?

REE: I would be surprised. I would be gobsmacked if there was not --

LLB: Right!

REE: -- if there was not a lawsuit on asbestos. I would not be surprised if EPA got sued by both sides.

LLB: For our listeners' benefit, it's not necessarily chemical-specific; it's because this is the first final risk management rule, which means now parties are able to challenge this final Agency action, the risk management rule, as opposed to the risk evaluation.

REE: Well, or the risk evaluate -- I mean, the only opportunity before this to challenge was -- what the circumstances were -- EPA said there was *not* an unreasonable risk. But for EPA to find that there *is* an unreasonable risk, the basis of the existing chemical exposure limit -- the ECEL -- is EPA banning conditions of use when compliance with an ECEL is sufficient. There are all these implementation issues where -- this will be the first opportunity. And even if potential litigants don't have a specific interest in asbestos, they might sue on EPA's use or interpretation of these terms, because this will be precedent setting. Maybe it won't be asbestos; maybe it'll be trichloroethylene (TCE), which is the one that's scheduled to be out next, or methylene chloride, or one of the other ones that are coming down the pike.

LLB: That should be interesting, particularly given the backdrop of the Supreme Court's oral argument a week or so ago in the relentless case as to whether the *Chevron* deference will survive. And what does that mean for these types of judicial challenges? A lot of speculation out there regarding how these cases will be teed up, whether *Chevron* will exist, and if so, in what form.

REE: Yes, and if the final rule comes in March, and the decision on *Chevron* deference comes in June, the litigation -- the lawsuit gets filed between there -- it's very much going to change the landscape of what happens throughout the suit.

LLB: Exactly. We legal geeks are kind of breathless with anticipation on these issues. What, in your view, Rich, are the top five TSCA initiatives you see coming down the lane here between now and, say, June of this year?

REE: Let's see, it's risk management, risk management, risk management, risk management, and fees. We've got four major risk management rules. We've got asbestos, trichloroethylene, methylene chloride, carbon tet[rachloride], and perc[hloroethylene], actually five. Those are going to be out probably in the first half of the year. They have various issues with them, one degree or another. And then fees. The fees rule is due out. EPA's anxious to charge more fees. I'll be very interested to see what the final fees rule says, but I think those are going to be the drivers. And then we have the framework rule, which probably will bleed over into the summer.

LLB: Okay. I know the fees rule -- just to provide a little background -- we were all a little, I think, taken aback, given some of the hikes in the administrative TSCA fees EPA was proposing. And this is now well over a year ago, when the proposal came out. Cleared OMB [Office of Management and Budget] review last week, so, as luck would have it, we should expect to see something, probably in February?

REE: Maybe February, March. Yes, the timeframe is always fuzzy.

LLB: Is there any scuttlebutt on the street as to whether those high fees have been subdued a little bit, given the significant pushback that --

REE: -- The scuttlebutt is that fees are going to double. Yes, and when the proposed fee rule came out, I was like, "Okay, yes, you need more resources," but I didn't see the factual basis to justify doubling. OIG audited, I think it was [fiscal year] FY 2019, FY 2020, and found that EPA was, in fact, collecting about 25 percent of the costs of implementing Sections 4, 5, 6, and the CBI [confidential business information] provisions of 14. Did the workload truly double between 2020 and 2021, or 2022, when the fee rule was proposed? I don't think so. I mean, EPA got a 20 percent plus up in their budget. That's not doubling. That's a 20 percent increase.

EPA may think that they need a *lot* more to run efficiently, but I don't see the authority for EPA to charge 20 percent of what they think the costs *should* be. What I see is what are the costs to implement the program, which means what is EPA spending? What EPA spends is based on its authority, the budget that Congress passes. I don't see the authority -- again, you're the lawyer here. When you read, it says, EPA may charge fees to 25 percent of the cost. Is EPA allowed to say, "We're just not getting enough money from Congress, so we're going to increase the fees of 25 percent what we think the costs *should* be, even if that's way more than the appropriation that we're getting." But again, we haven't seen the final fees, haven't seen the response to comments. I know there was --

LLB: There's a lot of concern expressed with the lack of granularity in the request for higher fees, so some of these issues were simply very difficult to answer, based on the record evidence, right?

REE: Yes, and this was the criticism the first time around in the -- when, 2018, 2019? -- when the first fee rule came out, and EPA said, "It's going to be this." And the comment was, "No, you're required to provide a basis." Then they re-proposed, providing one additional level of -- they said, "Well, it's this much in FTEs [full-time equivalents] and this much in extramural funding," but still no basis for those estimates. I don't know. I don't know if that will be -- I don't know if we'll get that clarity in the final rule. We'll see what the final rule says.

LLB: I think there was renewed -- Dr. Freedhoff in her testimony last week -- there was renewed emphasis on a lack of resources. As I noted a minute ago, we have new staff, certainly in NCD and OPPT, so one hopes that this issue will be addressed somehow through the additional fees that will be made available to EPA.

The fact that there was the hearing last week at all -- still a lot of discontent, with regard to the administration of the TSCA program, the slowness of the process, the fact that the results have yet to be seen, the extended period of new chemical review and the impact that has on the economy, and the exportation of chemical reviews and jobs, and so on and so forth.

But we're in an election year, and in your view, is there any opportunity for congressional attention to TSCA, even in very limited, surgical measures?

REE: Yes, I think congressional attention. Yes. Legislative changes? It's hard for me to imagine this Congress getting anything done legislatively.

LLB: Yes.

REE: But who knows? I think there are -- from an oversight standpoint, from a congressional oversight standpoint -- it's like, "Okay, yes, you need more resources. But what are you doing with what you have now?"

LLB: -- the money that you have, right.

REE: What progress has been made since -- I mean, it's been three years since Michal came on, and none of the risk management rules is final yet, and none of the additional risk evaluations is final yet -- so there's -- maybe there's been some discussion. It's not apparent to us, from where we sit, what the progress there has been. NCD, I understand they've completed more of the risk assessments because they brought in more assessors, but we're not getting more determinations out. The determinations are still basically flat, so now the bottleneck is somewhere else. I understand they're trying to hire new risk managers. I get that there's this slow progression, but I think if I were an appropriator, I'd want to see more progress with the additional money that they've already had, already been appropriated, before I appropriated more. Maybe there's more transparency between OCSPP and Congress, and it's just not getting out to the public, but those are legitimate questions.

LLB: You mentioned a moment ago -- we don't want regrettable decisions made, and it might be adding to an element of *uber* caution in new chemical review. We've seen a lot of activity with regard to PFAS [per- and polyfluoroalkyl substances] and EPA, particularly new PFAS technologies. We spent a lot of time focusing on PMN development for new PFAS substances. One of the cases that has been, I think, garnering an awful lot of attention relates to the *Inhance Technologies* case. Maybe you can give our listeners some background on what *Inhance* is all about, what it means for PFAS technologies generally, and dispositionally, where do you think the court is likely to go in that challenge?

REE: Let's start with the basic technology. High-density polyethylene (HDPE) is a very useful material for making transportation containers: totes, jugs. It's used for all sizes throughout the economy, not just for transporting chemicals, but like, the gas tank on your lawn equipment, like a handheld trimmer, is probably --

LLB: -- fluorinated.

REE: It's probably HDPE. If you've ever put gasoline in a milk jug, you know that hydrocarbon solvents eat away at HDPE, so to protect the container from that high solvation power material that it's containing, you fluorinate the HTPE. You take the polymer object, whatever the container is, and you put it in a chamber, and you flood it with fluorine gas. What that does is it coats the inside and the outside of the container with a -- you're essentially making Teflon *in situ*, or you're making this fully fluorinated surface. That provides the chemical resistance to maintain the integrity of the container.

During that formation process, a small amount of perfluoroalkyl acids are formed, parts per trillion, if I remember some of the numbers from the experiments that we saw results for. It's a variety of lengths: some short, some medium, some long, but they're there. And they're there at low levels. Then the concern is that those PFAS then contaminate whatever is being contained by the container, and, depending on what happens to the stuff in the container, those may be released to the environment.

Inhance has been doing this for decades. In 2019, EPA proposed the LCPFAC [long-chain perfluoroalkyl carboxylate] SNUR. It would prohibit the use of an LCPFAC in a surface coating, and it applies both to the coating itself and to articles that have that coating. These LCPFACs that are formed during this process appear to be within the scope of that significant new use rule and that prohibition. One of the standard exemptions to a SNUR is when the substance is present as an impurity. EPA has taken the position that in *this* case, these LCPFACs that are formed during the fluorination process are byproducts, which they are, but not impurities. It's this arcane interpretation of can a byproduct -- something that's incidentally formed during the manufacture of an intended substance -- can that also be an impurity or not? For as long as I've -- well, for longer than I've been working on TSCA, a byproduct can also be an impurity, as long as that byproduct is unintentionally present in the final product. Now EPA's taking the position that that's *not* true, that for SNURs, if it's a byproduct, it *cannot* be an impurity, so the SNUR still applies to that byproduct. That is EPA's assertion of Inhance's violation that's the basis for their bringing the legal action against Inhance and EPA forcing Inhance to submit significant new use notices (SNUN) for these uses, and those SNUNs have led EPA to issue unilateral orders banning this process for the longer chains, banning it entirely for the shorter chains, banning it until Inhance develops a set of test data. It basically puts Inhance out of business with these order decisions.

The other interesting issue is this was ongoing when EPA issued the SNUR. Can EPA prohibit a use that's ongoing, that was ongoing at the time that EPA proposed the SNUR? And does EPA need to have record evidence that it's ongoing, literally in the rulemaking record? The only way to defeat it is you have to submit something to the docket to say this is ongoing. And is that sufficient?

LLB: It presumes someone that historically has not been watching this would need to be monitoring the *Federal Register* to understand when --

REE: -- they have to know that it's happening, and they have to be monitoring to say, "This applies to me." Inhance might have seen the SNUR. There is evidence that Inhance knew this was happening in the past; they published a paper. It's in the literature, and people have pointed to that to say, "You should have commented on the SNUR." But if Inhance was like, "Well, but we -- these are impurities, so the impurity doesn't apply -- so we don't need to comment on the SNUR. We're not concerned about what EPA's identifying as a significant new use." But also, EPA should have known. If that's in the literature when EPA is doing the rulemaking, why didn't EPA say, "Hey, this is something that's known to happen"? Write that as an ongoing use and either address it specifically with Inhance in the moment, or say this is allowed to continue, because it is an ongoing use.

There's some real tension there, I think, to what's ongoing or not. That, I think, is going to be an interesting legal question. I don't know how the court's going to come out on that one. The flip side, going back to the byproduct versus impurity, I see this as a potentially very disruptive decision. If this sticks, then any time that you manufacture, anytime that there's a byproduct or you import a substance with a byproduct in it that you have considered in the past to be an impurity, and now EPA says, "Oh, no, for SNURs, if it's a byproduct, it cannot also be an impurity." Then you have to look at every one of the reactions that you run, at every byproduct that's formed, and you have to compare those byproducts to the 2,000-2,500 SNURs, go through every one of them and say, "Is this SNUR plausibly one of my byproduct substances?"

Most SNURs have generic names, not specific names. Then you're like, "That one says it's a nickel oxide. All right. Well, I've got an organic acid here, so that's not it." But there's some where you're like, "That might be it." So now you have to submit a bona fide intent notice (BFI) to say, "This is what I'm doing. Is this subject to the SNUR?" And ask EPA for every one of those byproducts, for every one of your reactions.

LLB: Which is -- none of the sequence of events you just went through, Rich, is a commercially plausible scenario.

REE: No, I totally agree. I don't know. I mean, I've discussed this with some of my former colleagues, and they're like, "No, no, that's not what's going to happen." And I'm like, "I don't see how you --"

LLB: But right, how --

REE: I don't see how we avoid that. Compliance with the SNUR is a primary obligation. It's not whether or not you *know*; it's is it happening or not is the -- when enforcement comes and knocks on the door, if it's happening, even if you didn't know, their position is you're in violation.

LLB: Is there any scientific reason to believe that a byproduct cannot be an impurity? I mean, is that -- that's an interpretation that heretofore has not been articulated by EPA, as best as we can tell, right?

REE: There are -- the two definitions are different.

LLB: Right.

REE: Byproducts are unintentionally formed, or they're formed during the production of another substance.

LLB: Right.

REE: If that byproduct remains with the substance unintentionally, it doesn't add any value to the product. It's still there. It doesn't detract. You're like, "We purified as much as we could out, but there's a little bit that's left. That has historically -- frankly --

LLB: It's an impurity.

REE: For the PMN regulations and for other TSCA regulations, a byproduct *can* be an impurity. But now EPA is saying that's not true for SNURs, so somehow this is different. It's potentially this very disruptive reinterpretation of the regulations. Byproducts that *are* separated and don't -- you do something whether you put them into commerce, or use them, or dispose -- those *are* treated separately. If you do make a byproduct from -- you're making chemical A, and you get byproduct B, and you separate B from A. Now B, you're going to do something with. If B is subject to a SNUR, you are subject to the SNUR, so that would apply. Because it's no longer an impurity. You've separated it from the initial product.

LLB: That makes logical sense.

REE: I agree.

LLB: It's the tiny residual of B that was separated that remains in the product that, I think, historically we have often regarded that as an impurity.

REE: Right, and until this action, EPA viewed it that way as well.

LLB: -- Interpreted it that way. That is an important case. The Sections 5(e) and (f) orders were challenged judicially in the Fifth Circuit Court of Appeals. I think oral argument is early in February, if I recall.

REE: Yes. Pretty soon, I don't remember the dates.

LLB: It's coming up, and I know many of us wish to listen up to that, because it's both a tough issue to argue to the Court of Appeals, because of the nuance and complexity of SNUR impurity byproduct rules. And it's a complicated record here. The administrative record in *Inhance* is complicated, but that is being closely watched. We talk a lot about it in our *Forecast*, and it will have an important outcome when and if the Fifth Circuit decides anytime soon.

Rich, you've already talked a lot about TSCA Section 26 and the legal burdens on EPA to justify its decisions based on best available evidence, and so on and so forth. But the risk management proposals, the five that are likely to come out soon, how would you generally assess EPA's adherence to the Section 26 standards under TSCA? I think it's probably characterized as uneven?

REE: Yes, I was going to say a mixed bag.

LLB: Got it.

REE: Internally, as we've looked at these things -- and we haven't reviewed them all to the same degree of depth because -- some we have clients that we're assisting, and others we don't. But generally, there are a couple where like, "That's probably right." There are some where there was just like some arithmetic errors, that may not make a major change, but still it's -- I mean, you've made arithmetic errors. Go back and do that right.

LLB: Yes, fix it.

REE: Yes. Go back and fix that. Then there are some where EPA had previously rated studies as lower quality and not relied on those studies for an exposure limit, and then changed their mind and said, "Oh, no. We rated those as high quality," and then *is* basing their exposure limit on those studies. That, to me, is much more questionable scientifically. EPA may have a good reason, but they haven't memorialized that anywhere. I was always taught if the result is not reproducible, it's not the best available science, so if you repeat the experiment and you cannot reproduce that adverse outcome, then there was something, some fluke in that experiment. And it's not a, air quote, "real effect."

LLB: Right.

REE: So why EPA would use that as a basis for a regulation, I think is -- under Section 26, that's quite questionable. What will happen? I don't know. What will the final rule say? Will there be a legal challenge, and then what will the court say?

LLB: Right.

REE: And will there be *Chevron* deference when that court's adjudicating it?

LLB: The up-in-the-air-ness of *Chevron* is adding to the complexity here.

We've got some reporting obligations coming up under TSCA Section 8. We've got CDR.

REE: Yes. CDR year.

LLB: CDR, chemical data reporting. Then I know PFAS Section 8(a) reporting can start as early as this summer. But the reporting deadlines are May and December of 2025, depending upon the size of your business.

REE: Don't forget asbestos reporting is in the --

LLB: -- and asbestos reporting, so we've got a lot of reporting obligations. Any general advice you wish to give listeners regarding any or all of these reporting deadlines?

REE: Yes, it is hard to keep track of all of it. And the three different actions have three different exemption criteria. The 2024, thankfully, I think EPA wisely left the 2020 rule in place. They had enough on their plate that they didn't need to tweak it, so the 2020 rules are again in place for 2024. That makes EPA's life easier. It makes reporters' life easier.

The asbestos rule -- I think it'll be a relatively narrow group of reporters. I think most people are -- have no reason to expect that there's asbestos in their products, so that their burden for reporting, I think, is going to be relatively light. The folks that actually *do* import asbestos or import articles that contain asbestos, or contain asbestos as an impurity, that's where that reporting burden is going to be. But that's going to be a relatively small set of reporters.

The [Section] 8(a)(7) rule is going to be a huge hairy mess, because there are no exemptions, except for municipal solid waste. That's a lot of people looking at a lot of aspects of their supply chain and trying to figure out what was imported. Might there have been a PFAS? Do I have any way to find out? Do I know what was in there? Do I have any way to find out what was in there? That's separate from the people who *know* that there's -- if you know there's PFAS, that's much more straightforward to answer. It's those unknowns where you really don't know, and can you find out? What's the burden of figuring that out? I think EPA was a little dismissive of the burden of that. They kept saying, "You can respond 'not known or reasonably ascertainable,'" but I think they completely dismissed the burden of determining what's known or reasonably ascertainable.

LLB: Right. And the level of awareness in the commercial sector, if you've never, ever, ever done kind of TSCA reporting. You're an importer, for example.

REE: Yes.

LLB: I think, how does that echelon of the commercial sector even know that there's an obligation they need to be mindful of with regard to PFAS?

REE: Right. I import kitchen tables.

LLB: Right now. That's the tricky part.

REE: I've never thought -- I don't import chemicals, I import tables, but suddenly I'm a TSCA reporter, and I have to figure out if there was a PFAS in the table that I imported? And how much is there? And what was it? No, that's a challenge, and EPA's struggled to reach out to those folks, and we've certainly talked about it before. How do you reach these people who don't think of themselves as in the chemical industry, but they clearly are under the TSCA rubric but have been exempt from most of their TSCA obligations because of the article exemption. Now that they've lost that, they have to stand up an infrastructure to report for PFAS.

LLB: They have to register for CDX [Central Data Exchange].

REE: They can't *spell* CDX, and they're like, what's a primary authorized official? It's going to be a tough challenge for those nontraditional reporters. But even our clients that have been in this space, they're trying to figure out, "How do we figure this out?" And part of the problem is coming up with a strategy, like this is how, from a corporate standpoint, how are we going to search? What are going to be our criteria? To what extent are we going to ask our suppliers, and then make sure that there's a good record, so that you have the documentation of what you've done. Because it's not just going to be for PFAS 8(a)(7). We've got all the state actions as well.

LLB: Exactly.

REE: There's a lot of overlap there. Part of the problem -- part of the challenge for the PFAS rule is it's a 13-year look-back, not a "Hey, what's happening going forward? What did we have in 2011? We don't have our records from back then. Maybe there's a hard drive somewhere with records on it. Do we have to go find that?" This comes -- part of what's the interpretation of known or reasonably ascertainable.

LLB: Right.

REE: These aren't easy issues, and we're still having conversations with clients about all these things.

LLB: Yes, and to your point, Rich, there are many state reporting obligations that are both existing and emerging. There are many commercial business concerns and optical concerns. How do you manage just the outflow of all these reporting obligations in a way that is consistent, coherent, and aligned with your corporate values? How do you define due diligence? You have due diligence for this 13-year look-back. How does that relate to due diligence with regard to state reporting obligations, and due diligence regarding litigation in which you may be involved?

Harmonizing all of these disparate reporting obligations and the inevitable public-facing nature of the information that will be reported is challenging, but it's manageable, and it will get done. But it is causing a good deal of stress in client land.

Last question, Rich. Regardless of who wins in November, this is an election year. You were 17 years with EPA, and you have now nine years of practice in the private sector. I'm wondering if people think that, even if we have a new administration in January, will the TSCA program be administered in a way that is radically different from what we have now? It's almost kind of the poster child for *Chevron*, that whiplash effect that we might be looking at if there is a new administration, if Mr. Biden is not reelected, and Donald Trump *is* elected, how do you -- what are you telling clients that might be holding off because of a

promise of a very different TSCA implementation program? And also given where we've been, right? I mean, to some extent, there were a lot of policy changes from the Trump Administration to the Biden Administration. Is that a reasonable expectation, or are a lot of the policies that have been hatched over the past three and a half years baked into the program?

REE: I don't expect an administration change to make much of a difference in New Chemicals implementation. During the Trump Administration, about 80-odd percent of PMNs were being regulated. The percentages were down a little bit when NCD started assuming that basic PPE [personal protective equipment] would be worn in the workplace. The big change was when Dr. Freedhoff reversed that. We went from about 80 percent of PMNs being regulated to 90 percent of PMNs regulated. That's not that different from my perspective. It's still --

LLB: A very high percentage.

REE: The vast majority of PMNs are getting regulated. If we go back to the assumption that basic PPE -- that it's not reasonably foreseen that people will *not* wear basic PPE, then maybe we get a few of the cases through faster. Is that whiplash? I mean, it's sort of whiplash-y for those handful of cases, that ten percent of cases that were getting not likely determinations. I don't think it's that drastic a difference.

It's always been true, at least historically, it's been true that TSCA NCD flew under the political radar. That's much less true now. But the fact of the matter is, day-to-day PMN reviews are very detail-specific. It is an arcane skill. How does it work? How do the models work? What's the standard operating procedure? What do these NCD reports mean?

And then the outcome, the order or the not likely determination. It's not -- generally, it's not very sexy from a political standpoint. I don't expect much of a difference if the administration does change. I think EPA getting through their new hires, getting all those folks on board and getting them trained, getting their policies and procedures in place and the things that were inefficient use of resources in the discussion between the Senate and Dr. Freedhoff, I think those will be much more consequential. Then if there's a lawsuit, if one of the lawsuits that's pending clears up some of the terms, then that could make a difference as well, because that could change the way EPA imposes orders.

LLB: Right. Fair enough. We've talked about our *Forecast*, a copy of which is available for download online. We've talked about the most recent Senate oversight hearing and the document that was made available, called Commitments to Prioritize Resource Allocation to Improve the New Chemicals Program. And our Firm Clients and Friends memo on it, all of which is available on our website. Anything else you wish to add about the *Forecast*, Rich? Other than looking forward to producing the 2024 version?

REE: Yes, it's almost time to start.

LLB: Yes. For 2025. Exactly.

REE: No. It is a labor of love. It's a huge amount of work for all of us throughout the firm. It's a fabulous resource to look back at what's happened and our crystal ball for what's coming. If you're in any of these spaces, it's worth a read so that you have an idea of what to pay attention to.

LLB: Exactly.

REE: We all have some limited bandwidth. Being able to say, "Oh, I've got to pay attention to -- like, I need to pay attention to the asbestos rulemaking, even though I don't use asbestos, because these are going to be some key things." Or in the REACH [European Union Registration, Evaluation, Authorization and Restriction of Chemicals regulation] space, or the pesticide space -- all the things that we cover in the *Forecast*. There are key tidbits in there of what's coming up that people -- we help you figure out how to focus.

LLB: That is our goal always is trying to give back to the community, and not only report on the regulation or the guidance, but also what it means for your business. That's our sweet spot. Rich, thank you so much for being here. Thank you for everything that you do to the chemical and for the chemical community and being the thought leader you are. We really appreciate it.

REE: It's great to be here, Lynn. Thanks for asking me back.

LLB: Thanks again to Rich Engler for speaking with me today about TSCA developments in 2024. It will undoubtedly be a busy and eventful year.

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