



## Episode Title: Section 6 Advocacy and the Importance of Being Early -- 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<sup>®</sup>), a Washington, D.C., law firm focusing on chemical law, litigation, and business 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 (Acta<sup>®</sup>), our consulting affiliate, the importance of engaging early and often with the U.S. Environmental Protection Agency (EPA) and the Toxic Substances Control Act (TSCA) Section 6 risk evaluation process. We discuss the conditions of use (COU) of a chemical being evaluated by EPA, the reasons why educating EPA on COUs is critically important to regulated businesses, the relevance of ECEs, or existing chemical exposure limits, and the consequences of a significant new use rule (SNUR) for COUs outside the scope of a risk evaluation. We also discuss EPA's evolving thinking regarding ECEs and why EPA's thinking is a really hot topic of discussion today. Now, here is my conversation with Dr. Richard Engler.

Rich, thank you so much for coming back to the studio. We, meaning yours truly here and our listeners, love having you here.

**Richard E. Engler (REE):** I appreciate it. It's always a pleasure to come speak with you, Lynn.

**LLB:** Let's frame the debate that we're going to talk about in this episode. Under TSCA Section 6, EPA is required to review existing chemicals and identify exposures that are believed to pose unreasonable risk. That much is very clear. Lautenberg, the 2016 amendments to TSCA, identified the First 10 chemicals to be assessed. In December 2019, EPA identified 20 additional chemicals, high-priority chemicals, to be evaluated. More recently, in June 2021, EPA announced really big policy changes, including that EPA would start considering exposure pathways addressed by *other* federal laws, like [the Resource Conservation and Recovery Act] RCRA (Superfund), the Clean Air [Act], the Clean Water [Act], and so forth. Fenceline community exposures, EPA decided to reverse the assumption that workers routinely wear personal protective equipment (PPE), and that EPA would make risk

determinations based on a so-called “whole chemical” approach. Now, we in the TSCA world get that, but maybe in plain English, you can explain to our listeners how radical some of these changes were and are.

**REE:** When EPA initially did the risk evaluations for the First 10, OCSPP [Office of Chemical Safety and Pollution Prevention] did exclude pathways that were regulated by other federal statutes, RCRA, Clean Air Act, Clean Water Act. I personally don't agree with that approach. My view is that OCSPP should assume that there are exposures up to whatever level is allowed under the Clean Air Act, Clean Water Act, so that it's not that there are no exposures, but that those exposures are managed. That's basically what's happening in the redone First 10 risk evaluations.

**LLB:** Because EPA did go back and reevaluate.

**REE:** EPA did go back and reevaluate. And it's appropriate for EPA to evaluate fence-line exposures. I am less in agreement with the assumption about worker PPE. Dr. Freedhoff has stated that OCSPP will no longer assume that workers always wear appropriate PPE. But effectively what OCSPP now assumes is that *nobody* wears appropriate PPE, which is not the same as not assuming that they always wear it.

**LLB:** When Dr. Freedhoff, the Assistant Administrator for OCSPP announced, somewhat surprisingly, on June 30 -- 2021, excuse me -- that these changes were afoot, there wasn't a lot of background provided in the moment. Has that been clarified over the last couple of years?

**REE:** Only in the updated risk evaluations. There's not a lot of additional clarity about the whole chemical approach, which I guess I understand what it means because -- the key change is that rather than making COU-specific risk determinations and saying, “Under these specific circumstances, the chemical does not present an unreasonable risk” and issuing orders to memorialize that finding, EPA now makes a single determination for the entire chemical, even though there are some COUs that are not an unreasonable risk.

That is, as far as I can tell, what is meant by the whole chemical approach. What happens when it's half and half -- half the COUs are not an unreasonable risk and half are -- I don't know. What happens when ten percent of the COUs are an unreasonable risk and 90 percent are not? It seems to me that the strict interpretation of it is that if *any* COU is an unreasonable risk, the entire chemical is an unreasonable risk. But we don't know how that's going to play out because we're still working through the First 10, of which the majority of the COUs were an unreasonable risk. As we get through -- maybe not even the Next 20, but as we start to get further down in the risk evaluations, it'll be interesting to see how that plays out. Don't know what that's going to mean in the future.

**LLB:** It's *not* the case that for every chemical EPA has reviewed, EPA has made a whole chemical unreasonable risk finding.

**REE:** For the First 10, EPA has reversed its findings of no unreasonable risk for some COUs. Either the reevaluation led to a few more COUs being unreasonable risk, or the COUs were the same, whether they were unreasonable risk or not. But EPA has been withdrawing -- I don't know if they've gotten through all ten, if they've withdrawn *all* the no unreasonable risk orders for all the First 10. I haven't checked the status on that in a while, but for every one EPA -- every risk determination that EPA has issued in final -- it has withdrawn the

orders, the no unreasonable risk orders. You and I have discussed in the past whether they can do that, or should that be legally challenged, but so far, no one's filed suit.

**LLB:** Right, as best as we can tell. You mentioned these COUs, Rich. In my view, the scaffolding supporting EPA's risk evaluation consists of EPA's review of these individual COUs of the chemical that is being evaluated under TSCA Section 6. Maybe for our listeners, you can explain a little more about what are COUs, as we refer to them. The acronyms used in TSCA can be a little overwhelming, and we're trying hard to explain them all in the moment. But what are COUs, and how does EPA assess them for purposes of Section 6 risk evaluations?

**REE:** The statute defines COUs to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." It's the releases and exposures throughout the life cycle of the substance. It includes is it going up the stack? Are there fugitive air releases? Is it being released to surface water? Is it going to a landfill? Is it being incinerated? What are the incineration byproducts? How are workers exposed? How frequently, how long are those exposures, as well as the levels? Is it in consumer products? So it's really anywhere that a human or the environment might interact with that particular chemical substance is a COU.

EPA has been -- historically, EPA uses their models and measured data. They use a variety of information sources. EPA has been doing, I think, a good job of trying to bring in more data to do a more -- better informed analysis. But in the end, they're still going to have some data gaps, and they will have to go back and rely on some assumptions and models to fill those gaps.

**LLB:** In the definition, in the statute, for COU, you mentioned "intended, known," and that "reasonably foreseeable" COU is probably somewhat speculative, possibly problematic, and likely to cause heartburn, correct?

**REE:** It certainly does in new chemicals, in Section 5. In existing chemicals, there's still, I think, some question about what are the boundaries of what is reasonably foreseen, and that may go to the worker PPE assumption. Is it reasonably foreseen that workers will not use PPE? And is that assumption different in an industrial setting, versus a commercial setting, versus -- consumers basically rarely use PPE. I use -- I have disposable gloves at home that I'll use when I'm doing projects with adhesives, or paint, or other things, but a lot of people don't. So I think it is reasonably foreseen that *consumers* don't use PPE. But I do not agree that in an industrial setting, that it's reasonably foreseeable that workers do not use it.

**LLB:** A view that I share with you. But thus far, EPA is unpersuaded.

Existing chemicals, given their pervasive use, and the number of applications that any chemical might be put to, and the conditions under which a chemical is used, obviously can be in the hundreds or thousands, given the different applications of COU. A couple of questions. First, how does EPA -- or is it a joint process between EPA and the regulated community? -- identify COUs, and how reliable, in your view, Rich, is EPA's review? And what information has EPA traditionally relied upon to establish COUs?

**REE:** Probably the first place the EPA goes is Chemical Data Reporting (CDR), the quadrennial data reporting, which requires reporting on some COUs to the extent that they are known or reasonably ascertainable. Frequently, a company will know that a particular substance is

used as a solvent, but they may not know exactly how their customer uses it as a solvent. *Solvent* is a very broad term. And is that solvent, where it's being used in a big reactor that's closed, or a big reactor that's open, or is it being used as a degreaser solvent in some sort of open system, or is it being used as a solvent in a laboratory? There are lots of different COUs that go along with the specific use of solvent.

**LLB:** Right.

**REE:** EPA, again -- they will look to data that have been submitted. I don't know if they've been using [premanufacture notification] (PMN) data, but frequently they get data in PMNs that they could potentially use, if it's analogous. They'll certainly go to the open literature to see what's been published, and they will search the Internet. The Internet is a terrific tool. For all I know, they're using ChatGPT [Chat Generative Pretrained Transformer] and AI [artificial intelligence] and asking questions.

**LLB:** Oh, that's a good question. I wonder.

**REE:** I don't know. I don't particularly think ChatGPT is providing accurate results, so I wouldn't want to rely on that. But EPA also does outreach to companies, to trade associations. They engage with industry seeking input, saying, "Hey, we understand this substance is used as a solvent. Help us understand more how you're using it as a solvent." We've certainly seen varying levels of that sort of engagement, and right now, I think there's a lot more of that engagement on the Next 20. We've heard from clients that EPA's now reaching out to individual companies, as opposed to just consortia to better understand COUs.

Frankly, I think that is a good thing. I think the regulated community should engage with EPA and should inform EPA: "This is what we use it for. These are the specifics. These are the engineering controls." Let EPA know how these substances are being managed. How are workers being protected? What are the releases and exposures? How much might be lost to fugitive air? Is any of it sent -- is it all sent to hazardous waste? Those COUs are very important for EPA to understand.

I generally encourage our clients to engage with EPA and help inform what they're doing. What EPA wants to do going forward, what they propose with tiered data reporting, which is going to be the cousin of CDR, is -- EPA will seek more detail on chemicals that EPA is going to undertake for risk evaluation, and they want to get more granular. They'll ask for more information on a smaller set of chemicals, and I think that will help as well.

**LLB:** Absolutely. So, bottom line, EPA obtains information based on all the data sources that you identified, solicits information from the regulated community, and puts all of that together to try to identify a rulemaking record on which risk management provisions would ultimately be based, right?

**REE:** Yes, all that goes into the risk evaluation.

**LLB:** Exactly. Start to finish, how long does this process take?

**REE:** The risk evaluation is three and a half years. It's been taking longer than that for a variety of reasons that we don't need to go into. But it's an extensive process. There's a lot of back and forth between the EPA and industry. I think one of the things we're learning, especially with the risk management rules that are coming out, is that there were people that were avoiding engaging with EPA in the initial rounds, in the scoping of the risk evaluation, and then

commenting on the risk evaluation itself. They were kind of laying low to see what would happen.

What we're seeing is that EPA -- when EPA had information that documented no unreasonable risk, then EPA would let -- well, in some cases, EPA would let those COUs go forward with a regulation of workplace chemical protection plan (WCPP), some combination of dermal protection and inhalation -- an ECEL to protect against overexposure by inhalation. But if EPA didn't have information about a COU, EPA was seeking to ban those uses, basically close them off, because EPA didn't have information that they were ongoing, and if it was ongoing, they hadn't evaluated them for unreasonable risk. With the Next 20, EPA is now going to start issuing SNURs for COUs that it's not going to evaluate. The scope, the earliest part of the risk evaluation, EPA defines the scope of the risk evaluation. And what I expect to see is that EPA will say, "These COUs, which are outside the scope -- [that EPA at that time does not think are ongoing] -- those are significant new uses," and close those off while EPA continues with the evaluation of the ongoing COUs under Section 6.

**LLB:** -- of which it is aware.

**REE:** Of which it is aware. So it's going to be important that EPA understand -- if that's one of your COUs, you need EPA to know that it's ongoing so it doesn't become SNUR-ed -- they don't prohibit that on an ongoing basis, so make sure you're inside the scope rather than outside the scope.

**LLB:** Right. I've heard you speak often and eloquently, Rich, with clients, and trade associations, and many of our consortia urging our clients to appreciate that, as smart as EPA is, and as experienced as it is in amassing and analyzing large amounts of data, it is unreasonable to expect EPA to know everything about a particular chemical, its COUs, and its utility in a particular sector of the economy. So reinforcing your message -- Engagement early and often with EPA is not a bad thing. It could be your salvation.

**REE:** No, I think it's critically important. Even as early as prioritization, when EPA is giving indications of what's being prioritized, I would suggest standing up a consortium -- get together. Whether it's a consortium of a user type or a consortium of the manufacturers or processors, or across the supply chain, but you do need to band together and leverage the -- a lot of the effort that goes into responding to a risk evaluation can be done more efficiently as a group. But whether you're going it alone or in a consortium, it's critically important that EPA understand what you're doing, how you're doing it, how you're protecting your workers, how you're protecting your neighbors from the substances that are potentially harmful.

**LLB:** At what point in the process will it become clear what COUs are within the scope of the risk evaluation, and ultimately risk management rule, versus those that will be the subject of SNURs and hence outside the scope of that? Especially with regard to the 20 that are ongoing or are soon to be ongoing?

**REE:** Yes, I think it's going to be different for the 20 that are in the process of risk evaluation now and the 31st, the first one that's going to be prioritized after EPA finishes one of the 20. Let me answer the question going forward first. I think what we expect to see is EPA will identify something for prioritization. It'll go through that yearlong prioritization process. And then in the first six to 12 months of risk evaluation, EPA will define the scope. These

are the COUs that EPA is going to evaluate. At the end of that process, they will propose a SNUR for other COUs, so the things that are outside what is --

**LLB:** -- which is everything else.

**REE:** Which is everything else. They'll say anything other than this is a significant new use.

**LLB:** And that will be proposed.

**REE:** That'll go through proposed rulemaking. So, if at that point, you think, "Oh wait, my COU is ongoing," then you would identify, you would step forward, comment on the rule. "This is an ongoing use." And then EPA would presumably put that in the scope and include that in the risk evaluation. I think that would be an effective mechanism for EPA to elicit the information that it needs, to find, to really search the nooks and crannies for COUs to make sure that everything that's ongoing is inside the scope.

EPA's trying to layer that on right now for the Next 20 that are under there. It's a little more awkward because they've already completed scoping. They're very deep into risk evaluation. They're still going on. They're still ordering data collection. I'm really not -- it's not clear to me when EPA -- EPA has planned on releasing final draft risk evaluation this year for some of the Next 20. That is going to be a heavy lift, I think, but we'll see. It's the beginning of September, basically, so EPA doesn't have a lot of time left. I would not be surprised if those didn't slip into next year. EPA is already overdue on them. They're working hard. They're certainly engaging with our clients. But I do expect, with this next round of engagement, that EPA will propose SNURs, saying, "All right, this is what's inside. This is what's going to be in the risk evaluation, and everything else, if it's not in here, everything else is a significant new use."

**LLB:** Right. That's a concept that people who are not in this space are sometimes slow to appreciate -- that it's not new to the user. It's considered new to a defined use of known uses that necessarily take it outside the scope of the existing risk evaluation, and hence part of the risk management process. It's not new -- necessarily. It *could* be new, but it could be ongoing, so if the entity that is pursuing the ongoing use is unknown to EPA, it is by definition in the quirky world of TSCA, new to the Agency, and hence prohibited --

**REE:** -- right.

**LLB:** -- if you are not timely in alerting EPA to your reliance and existing use of that chemical. That probably is going to pose some formidable legal challenges for entities that have open, known, notorious uses of chemicals (but are not part of an administrative record) -- and hence technically new, and hence prohibited under a SNUR.

**REE:** Yes. It is a very interesting space, where there was an open and known COU and EPA knew about the COU. And then EPA proposes a SNUR, but the person who is undertaking the significant new use or the use, the COU that was known to EPA, didn't comment on the SNUR. The SNUR went final anyway, defining that as a significant new use. It poses a very interesting legal question of was the rulemaking properly undertaken? Or was it EPA's fault for not taking into account what was known at that time? Or was it the company's fault for not commenting on the SNUR and putting that particular information in the rulemaking record? Those are legal questions I think we're going to -- we may hear about in the next six to 12 to 18 months, as some of these cases go forward.

**LLB:** In the one [per- and polyfluoroalkyl substance] PFAS case we are both monitoring, what is known to EPA, whether it was legitimately part of the scope of a significant new use restriction. Reasonable people can disagree, so stay tuned on that front.

**REE:** We'll have another podcast on that next year.

**LLB:** That's right. Maybe after the Eastern District of Pennsylvania renders its decision.

What are some typical SNUR conditions? We've heard a lot about ECELS. What is an ECEL? What are the SNUR conditions, and how are they relevant to our discussion?

**REE:** An ECEL is a workplace inhalation exposure limit. An ECEL is distinct from a new chemical exposure limit. A NCEL, or new chemical exposure limit, is typically derivative of a review of a premanufacturing notice (PMN). That becomes part of an order, usually a Section 5(e) order, and then that would become part of a SNUR when EPA issues the SNUR related to that order.

An ECEL, it's for an existing chemical, and it's resultant of a rulemaking under Section 6 instead of Section 5. They act a lot like an enforceable limit under OSHA [Occupational Safety and Health Administration]. It is an enforceable workplace exposure limit. They typically come with specific requirements for how to measure, how to document compliance with the exposure limit, frequency of testing. If you make changes, you have to test again. So it's not just, "Here's the exposure limit. You have to comply with it." It's "Here's an exposure limit, and here's how you document compliance with it." TSCA is a documentation-driven statute. You have documents that demonstrate compliance with whatever the requirements are. When EPA audits, you produce those documents. The documentation for compliance with an ECEL are not trivial. They're significant requirements. EPA is just laying out, "This is what you have to do to document compliance with that ECEL."

Other SNUR conditions. I expect that the SNUR -- outside the scope, SNURs will be "not use as a" -- well, "any use other than" --

**LLB:** -- those that are listed, right.

**REE:** -- "in the scope" is probably how those will be written, but it might be "consumer use is a significant new use," or there might be some specific uses that get named. I think it'll depend on the specific facts and what's the most expedient and efficient way to write those SNURs.

**LLB:** ECELS that are applicable under risk management provisions and final rules could be relevant for purposes of significant new use restrictions, right?

**REE:** Yes, they could. They could if EPA had facts to show that there was not ongoing exposure above a particular limit, then EPA might propose that in the SNUR, in a proposed SNUR. But EPA has to be confident that whatever they're defining as a significant new use is not ongoing at the time of the SNUR. I don't think we'll see ECELS proposed in SNURs that are related to bounding the scope of a risk evaluation. I think those ECELS will come up during a risk management phase. I think we'll see use restrictions, maybe some "operating without PPE" might be a SNUR. If EPA is confident that all the uses are industrial and workers are being properly protected by PPE, we might see a COU like that. But an ECEL in an existing chemical SNUR would surprise me.

**LLB:** One of the topics that we have chatted about many times with clients is the -- they're not necessarily at odds, but permissible exposure limits (PEL) and PEL conditions and [short-term exposure limits] (STEL) conditions derivative of OSHA's authority will be trumped here by newer, more recent ECELS for chemicals that are used in the workplace and subject to risk management rules. I know that continues to come as a bit of a surprise to some clients, "But wait a minute. OSHA manages workplace exposures." Sure, it does, but in these instances where the Agency is reviewing existing chemicals in manufacturing operations, they are subject to ECELS *and* PELs, the ECELS largely trumping whatever preexisting PEL that is in all cases, not nearly as recent as any ECEL. Correct?

**REE:** I think the question -- I mean, I know there's a fair amount of debate. I don't think there's any question that TSCA requires EPA to evaluate risk to workers and requires EPA to protect workers. It's clearly written in; workers are a potentially exposed or susceptible subpopulation. It's in there. EPA does have that authority.

There are times, I think, an OSHA PEL would be more effective than a TSCA ECEL, because TSCA has specific limits in the industries that are protected, whereas OSHA has much broader authority. The question is, in my mind, is the OSHA PEL, the current OSHA PEL sufficiently protective? As we all know, a lot of those PELs are very old, and they're quite permissive. I'm not going to *a priori* say that all the PELs are not sufficiently protective and all the ECELS are based on the best available science. The question is, what is the best available science? What are those exposure limits? What do we have the science that supports a particular number and a particular exposure limit?

That's number one, is what should the exposure limit be? Most PELs are probably not sufficiently protective. But the second question is, what is the best way for EPA *and* OSHA to take action to protect workers? I would have hoped -- in particular on methylene chloride, because methylene chloride has a number of nontoxic uses -- I would like to see EPA work with OSHA to convert the methylene chloride ECEL into an OSHA PEL so that that protection extends way past the boundaries of TSCA. I don't know that they'll do that. EPA seems to be pushing ahead 100 percent. Maybe there'll be an ECEL, and then maybe later there'll be a matching PEL. I don't know what that timing is going to look like, but both OSHA and OCSPP have a role. So rather than arguing over, "Oh, but there's a PEL, therefore it's --" What does the science support as an exposure limit? Then let's talk about the most effective way, using *all* the regulatory tools, whether it's across EPA authorities, OSHA authorities. What is the best way to make sure that you get maximum protection at that exposure, that justifiable exposure limit?

**LLB:** No, couldn't agree more, Rich. I think some legal beagles like myself tend to linger over some jurisdictional issues, and also just the process. I think EPA and OSHA both have been subject to some -- maybe too harsh a word "criticism for the lack of transparency" -- in the evolution of both enforcement of existing memoranda of understanding (MOU) between and among OSHA, NIOSH (National Institute for Occupational Safety and Health), and EPA and the development of new MOUs. We heard Brian Symmes, for example, talk at a conference earlier this year about how the agencies are now working through a new MOU to try to sort out who's doing what with regard to workplace chemical exposures. A little more transparency to the regulated community might be a good thing, because I, for one, haven't seen hide nor hair of anything in the trade press, or meeting minutes, or --

**REE:** Yes, what we hear is, "They speak frequently."

**LLB:** Right. What does that mean?

**REE:** Monthly, quarterly. They get together, they talk about stuff. Okay, but how are they going to work together to implement -- I don't debate that there needs to be more protection, especially with the inhalation exposure limits. But what is the -- how should that be done? How can -- and again, maybe it's a TSCA ECEL first and then an OSHA PEL rulemaking, so you do it stepwise. Would the PEL -- would the TSCA rule be written -- some of the old consent orders when they would put an ECEL in place, the consent order would say, "This ECEL applies under TSCA unless and until OSHA imposes a PEL that's this protective or more protective. Then that part of the consent order automatically expires." EPA could do something like that for the Section 6 rules, where once the OSHA PEL is in place, then that part of the Section 6(a) rule sunsets, so that OSHA takes primacy there.

Will they do that? I kind of doubt it. I don't know that anybody at OCSPP thinks that anybody at OSHA's *ever* going to lower a PEL. That's sort of the attitude that we hear is like, "OSHA doesn't do anything." You know, our clients certainly think otherwise.

**LLB:** It certainly has a role in worker protection and exposure. But again, where the jurisdiction of one begins and the other ends is just a very fluid area. MOUs are one way to go. The lack of a transparent process in which *all* stakeholders, including industry, the labor unions, people living in and around the area of the facility, are all necessarily interested in that process. It might be a good message to try to be a little more transparent on that process.

What are some of the most surprising things you think our listeners would be interested in hearing from you, Rich, regarding ECELS, SNURs, and maybe not appreciating some of the interpretations that you've been hearing from senior EPA officials in this regard?

**REE:** One of the things that surprised me lately is hearing Dr. Freedhoff take a position that if OCSPP -- before it proposes a risk management rule -- if OCSPP does not have data showing that workplace exposures -- that they don't have quantitative workplace exposure data, then EPA cannot impose an ECEL or WCPP, a workplace chemical protection plan, including an ECEL, that EPA *has* to impose a ban. I don't understand why the exposure metrics precede the imposition of a WCPP with an ECEL. The ECEL is a hazard-based standard. If you are below this, there is no unreasonable risk. For the workplace, it's important to know whether you can meet that, so I think for a workplace, it's important to know how well are you protecting your workers? Can you meet whatever that limit's going to be, so that when the regulation is in place, you know on that day, "Yes, we're already compliant," and you can operate under those protective conditions.

But that's different than EPA having those data in advance of proposing the ECEL. It's a sort of cart before the horse thing, but that is her stated position. That means it's even more important for people to -- if you are in one of the, frankly First 30, that you are planning on doing some industrial hygiene monitoring, doing some of that data monitoring, so that at least you have that information in your pocket. Better yet, develop it, share it with EPA. Some people are just reluctant to commit the resources to do that. But, look, if you don't monitor in advance -- so let's say, Dr. Freedhoff's position is not tenable legally. I'm not the lawyer here.

**LLB:** -- or someone pushes back.

**REE:** -- or someone pushes back. Whatever the outcome is, if there's going to be an ECEL -- and there will be an ECEL for probably most, if not all of the First 30.

**LLB:** I would think so. Yes.

**REE:** No, I think we're going to see a lot of ECEs. You still need to have that monitoring data before the rule goes final. Otherwise, you're going to have to stop what you're doing the day the rule is final and then develop the data. You need to plan on monitoring in advance of the rule being effective, so you've got to do the measurement one way or the other. Or you've got to plan to be out of the business on the day that the rule goes final, which is an entirely legitimate choice to make.

**LLB:** Sure. I've already heard one of your take-home messages, which is, -- well, I have -- my first one is you need to know what the First 30 chemicals are, because the First 10 are pretty -- everybody knows what they are, but the second 20. If one of those chemicals is near and dear to your chemical manufacturing operations, or God forbid, you're a manufacturer of one of those 20, you need to be thinking about identifying data points, gathering data, working with others, and being intimately engaged in this process. That's one take-home message.

Your second message is monitoring data. These ECEs are here to stay, and without knowing what your exposure limits are in a workplace environment or elsewhere, could put you at a distinct disadvantage. What are the two or three other take-home messages you urge listeners to be mindful of?

**REE:** I totally agree. Knowing which of the First 30, the First 10, or the Next 20 are in your supply chain, *anywhere* in your supply chain, is very important. Maybe you're an article manufacturer, and you're looking at the plasticizers that are among the Next 20. You need to understand because you need to be able to engage with the rules, and hopefully engage with EPA, to say, "These are the COUs, and this is why they're not an unreasonable risk." I completely agree with that, and I want to particularly call out formaldehyde.

Formaldehyde is among the Next 20, and I think it hides in people's supply chains in places that they don't necessarily expect. Maybe they use formaldehyde to manufacture something. It is a feedstock in their manufacturing process.

**LLB:** It's a byproduct, too.

**REE:** It may be a byproduct. There are a lot of places that formaldehyde may lurk in your supply chain, so understanding that, I think, is very important. We talked about industrial hygiene monitoring. Oh, and the other thing is you need to be watching the rulemaking record for chemicals that *aren't* in your supply chain. What EPA's doing for methylene chloride and PERC (perchloroethylene), and carbon tetrachloride, these are precedent setting. If EPA is taking actions that, in your view, are not supported by the statutory language or supported by the scientific record or the rulemaking record, you need to step up and comment and say, "Wait a minute, EPA. This is what's required: the best available science, reasonably available information. The statute says X, Y, and Z, and you're doing A, B, and C."

EPA needs to get it right, and these first handful -- asbestos, methylene chloride, PERC, and carbon tetrachloride -- the way that EPA does these rulemakings is the way that EPA is *going* to do these rulemakings, so commenting on every one that EPA -- if there's a weakness in -- no matter which side of the issue you're on. If there's a weakness in the rulemaking, you need to comment. You need to get it in the record.

**LLB:** Agreed. Rich, you're prolific writer. You speak a lot; you do a lot of conferences. Where might we direct our listeners to more information? Because we packed a lot of points in this

podcast, many of which are kind of complicated. Where can people find additional information?

**REE:** We have a number of webinars, past webinars that we've done, that are available on our website. There was the panel at the -- TSCA at Seven, which is available for streaming. Look back at our Forecast document, our 2023 Forecast document, at what we talked about, how we discussed a lot of these issues. We'll continue to write, and podcast, and we'll hold webinars. EPA's continuing to hold webinars. There are many opportunities to learn more, either generally about Section 6 or more specifically about some of these specific substances.

**LLB:** I would urge listeners also to watch our TSCA blog<sup>®</sup>, because we tend to report relentlessly, almost daily, on the whole spectrum of issues that, as you properly point out, Rich, even if your chemical is not under the microscope right now, the policies and the procedures that are evolving will apply to a forthcoming different solvent or different chemical.

**REE:** Yes, and on the blog posts and the memoranda that we provide, sometimes they're very in-depth summaries. You can skip to the commentary, and we try to call out some of the key things that people need to be aware of, and perhaps focus on those issues, even if you're not -- even if that substance is not in your supply chain.

**LLB:** Rich, as always, I appreciate your wisdom. You bring an awful lot to the table. My bottom line is engage, engage, engage, because in today's world, there's no good reason not to be kind of up to speed on these topics. Even if they seem somewhat arcane and unrelated, they're not. They really are not unrelated to your operations.

**REE:** I think trying to keep your head down and hope that you squeak through in a risk management, I don't think that's going to be effective. If that risk management rule drops and you're suddenly like, "Wait a minute. Now, I'm not going to be able to do what I need to do," now, you only have 60 days to comment on that rule. It's a very limited amount of time to pull together a really coherent, well-supported comment. In a way, it's too late. Maybe you can try to slip it in, but it's -- you really need to be engaging in advance of that risk management rule. Talk to EPA; work with EPA during the risk evaluation. Make sure that they've got a good fact set.

**LLB:** No truer words have ever been spoken, Rich. Thank you for being here today. Really appreciate your thoughts.

**REE:** My pleasure.

**LLB:** My thanks again to Rich Engler for speaking with me today about risk evaluation, conditions of use, the role of SNURs and ECEs in the Section 6 process, and the critical importance of engaging early and often with EPA in the risk evaluation process.

*All Things Chemical is produced by Jackson Bierfeldt of Bierfeldt Audio LLC.*

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