Episode Title: PMN Review and Orders -- 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, Dr. Richard Engler, Director of Chemistry for B&C and its consulting affiliate The Acta Group, returned to the studio to discuss a recently filed lawsuit challenging the U.S. Environmental Protection Agency's (EPA) issuance of a consent order under Section 5(e) of the Toxic Substances Control Act (TSCA). Now, judicial challenges to TSCA Section 5(e) orders are really rare, and this one is even more unusual because the petitioner is a non-governmental organization (NGO), and the challenge was filed well beyond the statutory time period for judicial challenge, or at least some might assert that. We discuss TSCA Section 5(e) orders, the process for challenging them, and some of the underlying issues at play here, including the concept of chemical categories under Section 5, concerns with EPA's chemical review process, and EPA's assessment and communication of risk in the new chemicals it reviews under TSCA Section 5. Now here is my conversation with Dr. Rich Engler.

Rich, you are, without question, one of my very favorite podcast guests, so I'm delighted to have you back in the studio today.

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

LLB: There is so much going on in the new chemical area. This week, well, in the recent past, there have been a number of very interesting developments. I thought we could break it down for our listeners. Maybe we can begin at the beginning, and that is to have a nice factual predicate and to put all of our listeners on the same page. Maybe you can just walk us through with a very general summary of the premanufacture notification (PMN) review process.

REE: If a company is going to manufacture or import a new chemical substance, they're required to submit a premanufacture notice, a PMN. They prepare the PMN. When they submit it to

EPA, EPA begins with a completeness check. They go through and they make sure -- EPA looks to make sure that all the required elements are present. And then once EPA determines that it's complete, the PMN gets a day one, so the clock starts ticking on EPA's review time. EPA then reviews the chemistry information, the chemical identity, the composition information, the physical-chemical properties.

Based on that information, based on the chemistry information, EPA then conducts a hazard assessment. EPA is going to look at the potential hazards to health and the environment, and they use the chemistry information as inputs for that assessment. They use models, they use their standard models, they use analogs if they can identify analogs with data. And if there's data on the substance that's provided, EPA will use that as well. That hazard assessment leads to concern levels. If EPA finds there's a low concern level, EPA will basically set the PMN aside because EPA has concluded that based on the information, there is no hazard that needs an exposure assessment.

That's pretty unusual. A small percentage of cases are low for health -- low hazard for health and low hazard for eco. If EPA identifies medium or high hazard, EPA will take it forward for an exposure assessment. They'll start with an engineering assessment using the process diagrams and what EPA knows, and again, standard models. EPA will predict exposures to workers and releases from the facility. EPA then uses another model to take the facility releases and predict surface water concentrations, air releases, concentrations at the fenceline from fugitive and stack air. They'll predict drinking water exposures from landfill. Then they take all those exposures that they've calculated, those exposure numbers, and compare them to the hazard levels that were developed earlier and will draw a conclusion about whether or not there is or may be unreasonable risk.

Then, if EPA finds there's unreasonable risk, they go to risk management and they impose protective measures: release to water limits, worker protective standards, whatever needs to happen to mitigate the risk that EPA identified in the risk assessment. Then those protective measures become the basis for an order, usually a negotiated consent order. EPA offers that consent order to the submitter. They may haggle a little bit over the measures, but they sign them; they both sign. Then when both are signed and the PMN review is done, the submitter can commence manufacture or import. In a nutshell, that's the new chemicals review process.

LLB: So just a couple of questions. Number one, you mentioned that the completeness check, it falls outside the clock. The clock is 90 days by statute, but it's not really.

REE: It's really not. EPA has been very backed up with their reviews, and EPA -- the clock will run until day 89, and then EPA will pick up the phone and say, "We need more time," and they'll ask the submitter to suspend. And those suspensions have gotten quite protracted. Most PMNs are being reviewed -- I looked at the numbers recently -- and it was like 300 to 400 days on average is how long the PMN takes from day one to the signing of that order.

LLB: I know there's a lot of emphasis on this 90 days. It has never really been -- it's always been statutorily required to be 90 days. But through a number of expedient measures, the PMN submitter and EPA negotiate seriatim extensions of that period of time. It's never been the case that the PMN review process occurs in 90 days.

REE: Well, Lynn, before Lautenberg [the Frank R. Lautenberg Chemical Safety for the 21st Century Act], they did. Most PMNs were completed within 90 days. Before Lautenberg, I think the average was like 100-something days, and that included cases that were more

complex and did take an extended period of time. But most PMNs were completed within 90 days before Lautenberg. Since Lautenberg, most cases are taking longer than 90 days.

LLB: Which is a perfect segue to my next question, which is "Has the general scaffolding, if you will, of the PMN review process fundamentally changed as a consequence of Lautenberg?"

REE: My view is that it hasn't. I know people disagree. My view is that -- and when you look at the specifics of what I described earlier, that's basically how the process still works. The primary difference now is EPA has to record its rationale for whatever decision it makes, whether it's a not likely to present unreasonable risk or a may present unreasonable risk, EPA is required to write it down. There's -- a lot of people point to that, the fact that they have to write it down, is why there's additional delay. It's not clear to me why that takes that much more time. The reports, the chemistry report, the exposure report, the hazard report, all those reports existed before, and they exist now. There's clearly something different. I think it's the way EPA is implementing, and that's a much longer conversation. But fundamentally, the process that EPA goes through is still the same.

LLB: Is that to say that how EPA applies the various provisions of the law and its regulatory interpretation of Lautenberg have -- are themselves written down? In other words, how EPA interprets the specific data presented in a PMN, that needs to be written down. But is the playbook for how those data should be consistently applied among all the PMNs submitted, is *that* written down?

REE: Don't know. There is the old playbook. And when we point to the old playbook, EPA says, "Well, yes, those are the old policies. We have new policies." But we don't -- EPA hasn't yet published the new policy. I think there's been some change in the policies, and we certainly hear that from people, but we haven't seen it written down. We've never really gotten clarity on what does it mean to not likely present unreasonable risk under the reasonably foreseen conditions of use, which is sort of that --

LLB: It's the Holy Grail.

REE: -- that's where you're trying to get is you're trying to develop the information to document that. So that's the only outcome where EPA will *not* issue a regulation. EPA hasn't really been able to say, "This is what's required to get to that outcome." The only -- from my experience since 2016 -- the only way to get to that is if you have a "low-low": low hazard for health and low hazard for eco. Then EPA can issue a not likely to present finding. If there's moderate or high hazard for *either* health or eco, then EPA is going to do *something* to regulate.

LLB: Yes. If it is low-low, to use your terminology, that will drop from the PMN review process, and that could even be before the 90-day statutory period has run.

REE: Sure. If EPA can make its conclusion it's not likely to present -- when EPA makes that finding, then, regardless of the date or the day of the clock where you are in the 90-day review period -- once EPA makes that determination, the submitter can commence.

LLB: One more question. In normal PMNs, or in most PMN cases, there will be an order issued. We refer to those as 5(e) orders because that is the section of the statute under which these orders are required. And that is essentially a contract, right? -- between EPA and the PMN submitter.

REE: Yes, if it's a consent order, it's a contract, it's negotiated, and both parties agree. EPA does have unilateral order authority. It's unusual that EPA would use that. I'm not sure that it's unprecedented since 2016, but certainly all our clients have gotten consent orders that they've negotiated. Yes, almost all PMNs are 5(e) orders. [Section] 5(e) is the "may present." There's some uncertainty about the risk. In the absence of sufficient data, EPA uses the 5(e) order. [Section] 5(f) was the other option, which would be the substance "will present an unreasonable risk," and EPA has -- it is a higher level of concern, a higher level of risk. Generally -- a couple of 5(f) orders have been signed since 2016 -- but generally, if you're in that 5(f) bucket, the submitter would probably withdraw rather than taking the order.

LLB: Withdraw, and avert the issuance of that type of order.

In the process of submitting a PMN and EPA's review of that PMN, there are lots of different opportunities for proprietary data to be considered by EPA in reviewing the PMN and by the PMN submitter submitting information to EPA that it has characterized as proprietary. How does EPA balance these needs for confidentiality and proprietary treatment of certain categories of data, both with respect to information shared with the PMN submitter and with information the PMN submitter shares with EPA to review and approve a new chemical application that will be used and ultimately may find its way to being exposed to third parties? There's a lot going on there.

REE: Yes.

LLB: How does that work?

REE: Section 14 of TSCA has a very careful balancing of the CBI [confidential business information] protections. There was significant negotiation during TSCA reform about what level of protection is appropriate. There are still strong protections for information that's truly proprietary, but submitters do need to do more to justify claiming information as CBI. EPA is now required to review all claims for CBI for chemical identity for substances that are in commerce, so it's much more difficult to protect chemical identity.

Then EPA is required to review 25 percent of other information. EPA does that by looking at basically one in four submissions, as opposed to one in four bits of information in different submissions. They take an entire PMN, for example, and they look at that for -- they review that for -- and they push back. We've definitely had clients get CBI claims denied. We've worked very closely with clients to make sure that what needs to be protected is protected. If it really doesn't need to be protected, don't claim that. We are seeing more PMNs that do disclose more information, but there's certainly some that much of the information is still being protected. But information like manufacturing process, customer and supplier information, production volume information, that's still probably CBI, and those among others, those types of information are exempt from a justification. You can merely claim them as CBI, and EPA will not challenge that. You may *not* claim them as CBI if they are already public. Information that's been disclosed already cannot be claimed as CBI. But that's the -- if it's not confidential, you can't claim it as confidential.

LLB: Well, you can, but you're going to --

REE: -- we know that the statute says you may not.

LLB: Not lawfully, right.

I think our clients are very mindful of that, but I think in years past, many people asserted CBI claims with regard to a broad swath of material.

REE: Oh, no question. Prior to Lautenberg, --

LLB: Right.

REE: -- there were definitely submitters that would go through and check every box.

LLB: Every box, right.

REE: It was frustrating. Back when I was there and I was reviewing PMNs, you'd look -- you'd open up the PMN, and they'd claim the thing's CBI, and you'd look at the company website --

LLB: -- Right. There it is!

REE: There it is on the website, and yet it's CBI in the PMN. That was frustrating. Now EPA would challenge that. EPA has the authority, much stronger authority to challenge those sorts of claims. Certainly when we're working with clients, and they're like, "Oh, we need to protect that," I'm like, "I saw it on your website, so don't check that box." We do that sort of evaluation. EPA looks at -- they do Google -- EPA has access to Google.

LLB: EPA does a good job.

REE: They do.

LLB: They do a good job. We know that there are lots of opportunities to keep information that is legitimately claimed to be confidential, confidential. But there -- I think the Agency has also made great strides in making the PMN process and the tracking of PMNs more publicly accessible. Can you walk our listeners through what are the opportunities for tracking a PMN? And once a 5(e) order has been negotiated between parties, when might access to that PMN order be available?

REE: EPA is working very hard to post redacted versions of PMNs promptly after submission. They're trying to develop the system so that there's more automatic -- it's been submitted, EPA has concluded that it's complete, it's gotten its day one. They're trying to, within a matter of days, if not weeks, get that posted to -- generally, the website where it'll get posted is ChemView, EPA's ChemView website. That's the repository that EPA has used for TSCA data for probably about ten years now. They're trying to get these redacted versions of PMNs up onto ChemView fairly promptly. That's also where EPA puts CDR [chemical data reporting] data. And after the consent order has been signed, the consent order will be posted to ChemView associated with the substance.

LLB: The redacted version of it.

REE: The redacted -- right. It's always the version that's been redacted from the CBI that's protected in the PMN.

LLB: Do the parties agree as to what is to be redacted in the consent order?

REE: Yes. EPA will prepare the consent order with what it thinks is CBI from the submission. It'll redact that, but then the submitter reviews that and says, "Oh, you missed this," so there is that. Both EPA and the submitter will agree on what's CBI. Then again, that's posted onto ChemView. I don't know what the timeline is, but again, EPA is trying very hard to get these things posted as promptly as they can. But because of the CBI provisions, they have to -- both parties have to sign, and then it has to get redacted, and then it has to go to the part of EPA that posts it. It's probably a couple of weeks to a month from when it was signed to when it appears on ChemView.

LLB: We began this conversation noting that there have been a lot of interesting developments in the recent past. One of those interesting developments was the recent submission of a petition for review of a 5(e) order by a citizen group. In my way of thinking, Rich, there have not been many petitions for review of 5(e) consent orders, for any number of reasons. Number one, it's a consent order, so the PMN submitter and EPA have recognized their acquiescence to the terms and conditions of the chemical processing of the new chemical in the consent order. It would be unusual for either one of those entities to then sue.

REE: In fact, the submitter agrees -- one of the conditions of signing the consent order is you agree *not* to challenge it. Yes.

LLB: So it must necessarily be an independent third party, whether it's a party that is disaffected or adversely affected, or an NGO, as is the case here. It's not unusual that there haven't been *many* petitions for review. It is also not the case that there have been none, but in my experience, I haven't seen one like this. Maybe you can give us a little background about this recent petition for review submitted in the U.S. Court of Appeals for the D.C. Circuit challenging a 5(e) order.

REE: As far as I can tell -- and I've only been able to review the redacted consent order and the redacted PMN.

LLB: From ChemView.

REE: Right. Those are the two documents that I've been able to review. It looks like the submitter -- in this case, it was Chevron -- submitted a number of related PMNs for petroleum equivalents. Just based on my knowledge of the market, it seems likely to me that these are petroleum equivalents made from something other than petroleum. They may have been made from pyrolysis oils from plastic, or they may have been made from some biomass, or some combination of those. That's not clear because the generic names do not specify, and most of the information related to the chemical identity for these -- and I forget it's the total of something like 20 different substances, these different fractions, probably different carbon range fractions in different processing steps, hydrotreating, desulfurizing, sweetening, whatever those individual process steps are -- not really clear. Those feedstocks that are being used to make those fractions are probably nontraditional feedstocks, not petroleum. These are petroleum equivalent fractions, but they are very much like the petroleum fractions that they seek to replace.

LLB: Petitions for review, as I'm sure many of our listeners know, are notoriously devoid of specificity. It's really notice pleading. Under TSCA, if you file a petition for review of a final Agency action, as is the case here, there's very little information that one needs to submit in order to -- perfect your claim.

REE: -- start the challenge.

LLB: What can you tell us, based on perhaps collateral sources of information, that might be driving the NGO's concern here with this particular 5(e) order?

REE: Based on the reporting and what I've read in the reports themselves or in the order itself, it seems that the thing that's driving the concern is where EPA is laying out its predicate for issuing the order. EPA has gone through its entire analysis. It's looked at the exposures; it's looked at the hazards, at the compositional variability. And for one of those substances, EPA identified the potential for some substantial risk to the general population, a substantial cancer risk to the general population. EPA did its worst-case analysis and said, "If, in the absence of controls, and all these worst-case things happened, there would be the substantial amount of potential cancer risk, basically at the fenceline."

LLB: When you say absence of controls, that's controls under TSCA or controls under *any* environmental law?

REE: Generally what EPA is going to do is EPA is going to assume worst case, basically in the absence of any restrictions.

LLB: Clean Air Act restrictions, Clean Water Act restrictions, river restrictions.

REE: The first-line assessment, EPA will assume none of those protective measures are in place.

LLB: Got it. Got it.

REE: That's been their standard. It's just based on their models. This much stuff going into this facility, this much stuff coming out, these air patterns, this is what the concentration is going to be. Based on the hazard, this is what the risk is going to be. There's a statement that's a fairly alarming statement: The cancer risk is one in four. But that's EPA's worst case. Again, all I can see is the order, and I haven't -- but based on my experience with EPA's assessments and the way EPA normally writes their reports in their orders, what they're laying out there is the factual predicate for issuing the order. EPA, in the absence of the order, is predicting up to one in four risk from that substance and that exposure pathway.

Then the order includes the protective measures, so EPA, they write down the protective measures, and then based on those protective measures, EPA re-evaluates the risk and concludes, with these protective measures in place, that addresses the risks to -- in this case, this stack-air cancer risk. That's the way it would normally work. I expect that that happened here. It would surprise me if EPA found this level of cancer, the potential level of cancer risk, and did not then impose the protective measures to mitigate that risk, because that's what EPA has normally done, certainly in our experience in the last seven years. That's what EPA is doing. They find an exceedance, and then they impose some protective measure to protect against that risk --

LLB: -- Abate that risk.

REE: Exactly.

LLB: The reference that might provide part of the basis of the petition here is a one-in-four cancer risk, which is significantly greater than a one-in-six cancer risk.

REE: One in a million is what they use.

LLB: One in a million, right. It sounds like what you're saying is that that utterance, that one in four might have been taken out of context of the entirety of the consent order and didn't fairly reflect the application of EPA's further analysis that provided the basis for *it* to sign a consent order under 5(e) of TSCA, so the Agency met *its* legal burden not to approve a chemical that posed an unreasonable risk. A one-in-four cancer risk would clearly be that.

REE: Right. There's no question that EPA would identify a one-in-four cancer risk is an unacceptable risk. And what is missing from the record, from what I've been able to review, is the after. That's the before; that's without the controls. EPA predicted up to a one-in-four cancer risk. What I don't see a record of -- but EPA would normally do in developing the order -- is showing that the protective measures mitigate that down to, in this case, it would be a one-in-a-million cancer risk.

LLB: The other interesting aspect that we lawyers find interesting anyway, is this particular consent order was issued last year, I think in August, and yet the petition for review was submitted in April of this year, which is significantly beyond the 60-day time period that the rules allow a petition for review to be filed. Any thoughts on how one rationalizes the great period of time between the signing of the consent order by the parties and the submission of the petition for review?

REE: Yes, it's a good question. Signed orders are not normally posted to the *Federal Register*, so there's not that mechanism for notice. They are normally posted to ChemView. If one was interested in a particular PMN, presumably you're looking in the *Federal Register*, you saw notice of receipt of the PMN, so you knew what the time for -- the day one was -- because that *is* published. Then you can follow -- you can monitor ChemView for EPA posting the PMN -- the redacted PMN -- or the redacted order, basically recording EPA's decision.

You can also look at EPA's website, where they include the status of review of particular PMNs. EPA actually has a couple different websites -- or different parts of its new chemicals website -- where EPA does that. I don't know what a court would say. Would a court take the view that the day that it was posted on -- that the consent order was posted on ChemView -- was the first day of that 60-day review period? Or was it the day that someone found it? Or someone became aware of it? You're the lawyer. You tell me.

LLB: I know. That's why this case raises so many interesting issues. One of them is this procedural issue that gives rise to the question, "How transparent is the PMN review process?" The 5(e) consent order that is derivative of EPA's review of the PMN information against the standards required under Lautenberg in TSCA implementation elicits an order. The order itself is not public, but a redacted version of that order is public. I think a court might reasonably look at what is the relevance of the review period, and when does it actually begin to run for third parties that don't have access to the order on a real-time basis, as the PMN submitter and EPA do?

That's an interesting question, and it raises a lot of jurisdictional questions about the relevance of 60 days. Is it a jurisdictional limit? Might there be equitable considerations that a court might reasonably be looking to review? As I'm sure these petitioners will likely raise, it's not unreasonable for a petitioner that is interested in this particular chemical because of fenceline exposures, for example, where this chemical might be used, that they acted timely when they became aware of it, but it wasn't within the 60-day statutory review period. Lots of interesting procedural questions.

Similarly, this case raises interesting substantive questions with respect to the EPA review process. And one in four, one in six, are these (quote, unquote) "unreasonable risks" being mitigated in a way that is commensurate with the legal burden under the statute? There's a substantive issue there that our listeners may be interested in reviewing.

I think the third very interesting aspect of this case relates to a subject that you and I, Rich, have talked about endlessly, because we love nerding out on things like this. What is the role of chemical categories under TSCA Section 5? For the benefit of our listeners, help us understand what a chemical category is and what chemical category is relevant for purposes of this discussion.

REE: Chemical categories are groups of chemicals with some commonality. Typically, it's a common functional group, some chemical property. EPA has, for decades, been using chemical categories to more efficiently review PMNs. EPA will receive a number of PMNs for some category of chemicals. In each of its reviews, EPA is finding it's making the same sort of determination, that if this substance fits within the boundaries of the category, whatever those boundaries might be -- it might be molecular weight, it might be is it a solid or a liquid? Is it a partition coefficient, a particular water solubility? If the substance is within the boundaries of the category, EPA's basically making the same, drawing the same conclusion again and again. So instead of just doing it *de novo* every time, EPA says, "Oh, we've seen this sort of thing before." They'll go back and they'll say, "Is it within the category?" If it is, they'll cut and paste their assessment from the previous work.

So it's -- this *n*th PMN is within the category. It's within the boundaries of the category, so we're going to reapply the hazard assessment, the risk assessment, and the regulatory outcome. They're all sufficiently similar that EPA is comfortable based on its experience in repurposing the hazard and risk assessment and the risk mitigation measures. That's the way categories work. Again, EPA has been doing this for decades. There's a category document, a new chemical category document.

LLB: Can you give us some examples of categories?

REE: Yes. If you look at the category document, there's an isocyanate category. There's a cobalt category, so cobalt compounds. There's an aniline category. There are categories where if you've got those features in the substance, EPA's going to evaluate the new chemical against those features. It has been colloquially called categories of concern. But EPA -- I mean, formally, it's new chemical categories.

LLB: Right.

REE: But they're basically common concerns between and among the substances that EPA's reviewed with those features. And this category in particular was a relatively new one that's for biofuels. EPA has seen lately a number of biofuels PMNs. They are petroleum equivalents, so they're hydrocarbons with -- they're very complex. They've got some variety of carbon ranges, boiling points, composition. Are they aromatic components, or is it largely aliphatic? All those things come together in EPA's evaluation of a novel biofuel PMN.

But EPA concluded -- about a year ago now, maybe a year and a half; I forget when they first announced the biofuel category -- but EPA concluded that they had enough information about these sorts of biofuels, and the petroleum equivalents that they're replacing, that EPA felt they could reasonably just cut and paste that hazard -- if the biofuel was within the

category, EPA could cut and paste the hazard and risk assessment from those earlier cases into the new one. And then EPA basically had a consent order template. They said, "If you're within this category, we make this risk assessment. Here are the terms that you can expect for a biofuel PMN." And that appears to be what EPA did in this case, although it's not clear to me that these are biofuels because we don't know what they were made from.

LLB: Right. But it -- just for the benefit of our listeners, it is *not* the case that this cutting and pasting is done in a way that disregards the chemical composition of the material. It just provides EPA the years and years and years of experience the Agency has with this category of chemicals. The Agency feels comfortable in making certain assumptions regarding components and its review of those components in a risk assessment context that enables it to make certain assumptions. But it's not a shortcut or --

REE: No, no, no, no, no. That's an excellent point. But step one is, is the new thing within the category?

LLB: In the bucket, right.

REE: If you're not in the category, then you don't get the advantage of the category risk assessment and risk management measures. The predicate is, does it fit within the category? If it fits within the category, then EPA will look back at what it's done. Part of this is EPA behaving consistently.

LLB: And efficiently.

REE: Absolutely.

LLB: It doesn't start the wheel over again for every single chemical review. It is entitled, given its position and given its expert judgment, to make these categories to facilitate the review of chemicals that are so similarly situated and so meeting of certain established criteria that the process is enhanced and made more efficient.

REE: Yes. Let's imagine a new vegetable oil. EPA's got data on corn oil, and they have data on sunflower oil, and they've got data on soy oil, and they've got data on canola oil. They've seen all these different oils, and then they see this new one, this new oil from a different source, so it's a different substance. EPA looks at it and says, "Look, the composition is the same here. It's the same set of fatty acids, it's the same degree of saturation and unsaturation. We're just going to use all the data that we know about these existing chemicals, or these previous chemicals that we've reviewed, and we're going to apply it to this new chemical. And we're going to do it in a consistent way."

It really is -- step one is "Is it in the category?" And if it's not in the category, then you can't use the category. You got to -- you either use a different category or you start from scratch.

LLB: There are lots of categories.

REE: Yes, dozens.

LLB: They've been around a long time. One of the newer ones is the biofuels category. We also had one for EV --

REE: -- Right, for the cathode active materials (CAM).

LLB: Cathode active materials -- that came after the biofuels. I would imagine that there are a fair number of TSCA stakeholders out there that wish the Agency could evolve using more categories because some chemical components are simply amenable to a category approach. But I'm also confident EPA has very little time to devote to the development of new chemical categories.

REE: It's tough because you want to be efficient in your review, but it takes time to develop the categories. Which do you do? Do you just continue to do them on a one-off basis, or do you try to develop a category? I know we certainly have clients that are interested in the category approach. If you are a submitter or group of submitters, and you're looking for EPA to take a category approach to your category, I think you need to do a lot of the work for EPA to show: "Here are the boundaries. Here's how the boundaries should be set. Within these boundaries, here's the science that supports a risk assessment." Presumably, the order, the template order that would result would be modeled on past orders.

LLB: That's the third component of why this petition for a review of this 5(e) order was interesting to us. Do you see this as a potential way of revisiting the prudence, the wisdom, and the efficacy of a category approach generally, or just for biofuels? Or is that not an issue in your view?

REE: It's hard to know until we know what the underlying facts are. Maybe this PMN didn't fit in the biofuel category, and then was the biofuel category sufficiently protective? Don't know.

LLB: Don't know. Right.

REE: If the biofuel category -- it may be that EPA has all the facts to support that this order was sufficiently protective, with the protective measures in place. That's not written down in the order. It might be in the reports that EPA will publish when EPA proposes the corresponding SNUR [significant new use rule], we'll get a chance to see those redacted reports. We don't know what the facts are under here, but based on what we've seen EPA do recently, that information's in the record. It's just not in the order; it's not written into the order. That may come out in this, as a result of this appeal, where EPA is going to have to justify what EPA did, how EPA concluded that these measures were sufficiently protective.

LLB: Yes. You spent 17 years at EPA before you joined our team. Have there been other challenges to the development of categories for new chemical review? I'm unaware of any.

REE: I'm unaware of that as well. There's certainly much more scrutiny at this point from the NGOs on the new chemical process as a result of Lautenberg. There have been allegations, including in this case, of industry interference. I don't see that here. This looks to me like every other biofuel order that we've seen come down the pike, so I don't know what's different in this case.

LLB: Here. We just don't know what we don't know.

REE: Right. But yes. The categories -- the old categories have been around for a long time. These new categories have -- both the CAM and the biofuel categories have been around for --.

LLB: -- A couple of years, tops.

REE: -- Six to 18 months, so it's definitely not news that EPA's taking this approach. Frankly, it is both scientifically justified and it's good governance for EPA to be efficient in its PMN reviews, building upon its extensive experience.

LLB: Right. One of the most talked-about aspects of Lautenberg implementation is the new chemical program. And to my mind -- call me crazy -- I think categories might help move things efficiently through the process so we're not reinventing the wheel on chemicals that are so structurally, toxicologically, and from a risk profile, identical to something the Agency has reviewed many, many times before, that it can make calculated decisions and informed judgments and be efficient and not compromise human health or the environment.

REE: Yes, that's exactly --.

LLB: That's the goal.

REE: That's the goal of the category approach.

LLB: Right, so at some levels, stakeholders can understandably be expected to want to develop more categories. If EPA had all the time and all the money in the world, it probably would.

REE: Yes.

LLB: But sadly, very few of those ifs are true here. It doesn't have all the time, and it certainly doesn't have all the money in the world. Therefore, the development of categories can be expected to be a slow process, and a careful one at that.

We began our discussion with noting that this lawsuit raised lots of interesting questions. One of my questions, one of my fears is that might this lawsuit give rise to enhanced concern about the idea of a chemical category? I hope not, but again, without knowing why the petitioners are bringing the lawsuit that they are and where it might lead, and a couple of Congressional utterances in the recent past. We know at least one senator, Senator Merkley [D-OR], has expressed concern with the biofuels approach. We don't know where it's going to go, but it's something that we should be watching.

REE: Absolutely. It might be -- and it would be a shame if it were -- true that this scrutiny leads EPA to back off entirely from the category approach and go back to *de novo* review of every PMN.

LLB: Of every single PMN.

REE: EPA might do that out of an abundance of caution, but that doesn't change the fact that EPA is going to base its review on the history, on its experience, and seek to be consistent. The category approach, again, is better for TSCA implementation writ large --

LLB: Right.

REE: -- because it requires a factual basis, and it leads to a consistent result. We may -- reasonable parties may disagree whether the result meets the criteria, so maybe the biofuels category needs additional protective measures as part of its boilerplate consent order. That may be the outcome. But to abandon the category approach entirely, I think, is not a good practice and not good for the TSCA stakeholder community writ large, including the general public.

LLB: Right. And for the record, no one here is suggesting that that might be even a possible outcome. But to the extent that this lawsuit raises many interesting issues, we just thought it would be helpful for our listeners to be aware of the procedural issues, the timing issues, the potential impact on chemical category and EPA substantive review, because there is no better person on Planet Earth, Rich, than you to comment on these issues.

Maybe we can just step back for a minute and wind up with a "How is EPA doing on new chemical reviews?" I think we've seen some measurable progress?

REE: Yes, we've seen some improvement, starting last fall and continuing. There was, of course, a little lull around the holidays because everything has a little lull around the holidays.

LLB: Because there always is.

REE: But we've seen that progress continue this year, and we've heard, both from private conversations, but also public utterances by EPA, that they've hired a number of new assessors, especially health assessors, because the health assessors was their -- where they had the shortest bench -- and they brought some senior health assessors back. They're in a better position now than they were last summer, say, and we are seeing some progress. They've still got hundreds of PMNs to get through, but the pace is definitely picking up.

REE: Which is good. Any speculation on the outcome of this case? Or will you be your usual prudent self and say, nope, no clue?

REE: No, I think the primary difference that this is going to lead to is more transparency on EPA's before and after risk assessment. In the absence of the protective measures, EPA -- which is, I believe, what you can read in the order -- in the absence of measures, this is the predicate for the order. And then what I suspect EPA will do is, "Then with the protective measures in place, here's what the risk looks like." So that they have a record in the order that the order is sufficiently protective to meet the extent necessary provision in Section 5(e).

LLB: Right. Greater clarity in that area and more information would certainly limit or diminish the possibility that people might misinterpret some of these references in the 5(e) order -- or that which is made publicly available via ChemView. Rich, as always, a pleasure.

REE: It's been great. I'm always happy to be here.

LLB: Really enjoy your insights and would urge our listeners to just keep their eye on this case. It's captioned *Cherokee Concerned Citizens v. EPA* in the U.S. Court of Appeals for the D.C. Circuit. All right. Thanks, Rich.

REE: Thanks. I'm sure we'll be talking about more TSCA topics very soon.

REE: We will indeed.

REE: It's going to be a busy year.

REE: Take care.

Thanks again to Rich Engler for speaking with me today about new chemical review, the identification of risk, how EPA communicates such risk, and the new chemical categories under TSCA Section 5.

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