Episode Title: EPA Adds Two New Chemical Categories: What It Means to Chemical Innovators -- A Conversation with Richard E. Engler, Ph.D.

Episode Number: 20230105
Publication Date: January 5, 2023

All Things Chemical® is a podcast produced by Bergeson & Campbell, P.C., a Washington, D.C., law firm focusing on chemical law, business, and litigation matters.

This podcast transcript has been lightly edited for accuracy. It is an approximation of the podcast audio, and the audio recording remains the definitive record.

Let us know about any topics you would like to hear about in future episodes at podcast@lawbc.com.

A full recording of the podcast is available at https://www.lawbc.com/podcasts/epa-adds-two-new-chemical-categories-what-it-means-to-chemical-innovators-a.

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 The Acta Group, our consulting affiliate, returned to the studio to discuss the U.S. Environmental Protection Agency's (EPA) bold moves in developing chemical categories to help streamline the review of new chemicals under the Toxic Substance Control Act (TSCA) Section 5. While the so-called categorical approach to new chemical review is by no means new, it has stalled out in recent years, and EPA's renewed work in this area is both timely, if not essential. Rich and I discuss the new category for mixed metal oxides (MMO) and cathode active materials (CAM) and another category for biofuels. We answer the questions Why now? How are these categories developed? Where is EPA headed? and why you should care. Now, here is my conversation with Dr. Rich Engler.

Well, hello, Rich, and welcome back to the studio.

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

LLB: We're going to return to a topic that is near and dear to your heart, and I think the hearts of chemical innovators everywhere. And that's EPA's recent initiatives to help jump-start the chemical review process under TSCA Section 5. EPA's Office of Pollution Prevention and Toxics (OPPT), as you know well, Rich, has been relatively active recently in developing categories of new chemicals. As I understand it -- but we're going to talk a little bit more about this -- this is intended to help streamline the review of premanufacture notices (PMN) under TSCA Section 5. So perhaps to get started, maybe you can help our listeners understand the so-called standard approach for processing a PMN for a new chemical, and then we can launch into what a categorical approach might include.

REE: Okay, when EPA receives a premanufacture notice, or PMN, they review that essentially *de novo*. They're looking at all the facts that they have within the PMN: Are there data on the substance? Are there data on releases or exposures? And if there are not data, they'll use their various models to predict -- for instance, aquatic toxicity releases and exposures -- in their assessment for unreasonable risk. During that assessment, EPA will look for data on analogs, so they'll search to see what data are available in their own databases or in the public literature, or perhaps dossiers from registrations elsewhere, and use that information to inform its judgment about the hazards of the PMN substance. They're looking, essentially looking at each chemical in isolation, just saying, "What do we know about this? What do we know about things that are close to this?" and starting that review anew for each PMN.

LLB: That's the so-called standard approach. Perhaps now we can talk a little bit more about this not-so-new new approach to reviewing PMNs by the so-called categorical approach.

REE: Yes, the categorical approach is essentially EPA's recognition that they've seen a number of similar substances, and EPA has found a consistent data set and a consistent set of concerns and probably a consistent set of conditions of use, as well, but that's not necessarily the case. It's really about EPA assessing the hazards of substances in that category. And EPA has long recognized that small differences in, say, the structure or maybe the composition really don't change EPA's concerns about the hazard. The hazard is consistent across the category. So EPA has used this experience, or EPA takes that experience and then uses that to inform, to basically streamline the review of a new substance that's in that category.

LLB: Okay. I get the conceptual approach, but what is confusing to me -- a non-chemist -- is that -- and in other podcasts, you've made *much* of the fact that each chemical is its own unique -- or has its own unique chemical identity and that every chemical is unique and different. If that's true, how can you categorize broad categories of chemicals that may be structurally similar, but distinct?

REE: There's a difference between EPA's nomenclature standard, which is to be as specific as possible, and EPA's assessment of hazard. It is frequently the case that substances elicit essentially identical concerns, despite those substances having different names. EPA's approach to nomenclature is much more specific than is reflected in the hazards of those substances. Other authorities recognize this fact and take a categorical approach to the regulation of chemicals, but under TSCA, EPA's nomenclature standard listings on the Inventory are as specific as possible.

LLB: Okay, so that helps clear that bit of confusion up. Now, this category approach is not new, but it seems to have stalled in the more recent past. How far back does it go?

REE: Well, decades. EPA has their chemical category document. It was last updated in 2010, and that was a refresh, so it had been years before that that EPA relied upon its chemical categories for PMN review.

Obviously, there haven't been any updates since 2010, but EPA after 2016, after the Lautenberg amendments were put into place, EPA started to assess new categories, in particular categories for surfactants, polycarbonate polymers, photo acid generators, and low-solubility polymers that might lead to an endpoint called lung overload.

EPA began assessing PMNs with these draft categories, and EPA has been working since then to formalize those categories and publish those, and then presumably they'll include them in the category document at some point.

LLB: I'm presuming that perhaps EPA has stated this explicitly in the more recent past, but is the categorical approach largely intended to help accelerate the backlog in new chemical applications and the fact that EPA is struggling to adhere to the 90-day review time for PMNs? Or is that just a figment of my imagination?

REE: The category approach has *always* been about reviewing new chemicals more efficiently, relying upon many reviews of substances within the category, allowing EPA, to the extent that it can, to find the boundaries of the category, what things might be in or out of that category, but then using that body of evidence to assess more efficiently. You don't have to go back *de novo* every time if the concerns end up being the same every time. You don't have to search the literature again, you don't have to look for analogs again because you've already done that work. So the point of the categories is to make review more efficient. And that's true whether or not you have a backlog; it's just about doing the job more efficiently.

I think the announcements recently about the new categories are EPA trying to shine a light on the categorical approach, perhaps trying to give submitters hope that EPA's reviews will be more efficient. I wonder about the announcements now, but the categorical approach has not gone away, and we've certainly seen its implementation in PMNs that have been reviewed since 2016. Perhaps the announcements are more a formal -- well, I think there are two things. One is EPA assessing these substances in a categorical approach to make the risk assessments more efficient, but also use essentially cut-and-paste consent orders so they don't have to rewrite consent orders each time.

LLB: Sure.

REE: So that may be -- I think these are a couple of potential reasons that EPA is making these announcements and making more of a splash with the categories, with *these* categories rather than the ones that they've done in the past.

LLB: Got it. Okay, let's talk about these new categories, because EPA announced relatively recently two such categories, one for mixed metal oxides, MMOs, and cathode active materials or CAM, and another for biofuels. EPA also restated, as I understand it, its view on whether MMOs are mixtures under EPA's statutory mixture guidance.

There are a lot of concepts embedded in those two relatively short sentences, Rich, so let's first talk about MMO CAMs. Why did EPA make this announcement and perhaps delve into a little bit about its relevance with regard to the statutory mixture guidance and the restatement of EPA's position about whether MMOs are in fact mixtures under the statutory mixture guidance?

REE: Yes, as I understand it, EPA was approached by one or more manufacturers of CAMs, cathode active materials, regarding EPA's review of CAM PMNs, especially as the manufacturers are adding small amounts of other -- of additives, frequently called dopants. CAMs are the subject of a lot of [research and development] R&D right now. CAMs are a critical part of making rechargeable batteries that are used in electric vehicles (EV) or in buildings that have, say, battery walls. The effectiveness and efficiency of the CAM is critical to the performance of the battery and, say, the battery in the vehicle.

People are doing a lot of things to tweak the CAM by adding a small amount of another metal or small amount of another nonmetal, and that changes the speed of charge or discharge, or the -- how much can be held, how much power can be held. There are a lot of things that people are trying, a little bit of pixie dust here and there. EPA's view -- that

they've restated -- is that by doing that, you change the identity of the CAM, and therefore, because you change the identity, it necessitates another PMN. So even if the original CAM has been listed on the Inventory for 15 or 20 years, it has a significant data set supporting it. If you put in a tenthth of a percent of a different metal, that's a new substance that requires a PMN.

It doesn't change EPA's view of the concerns of the CAM because it's such a minor amount of whatever that minor metal is and the hazards driven by some other aspect of the CAM. So how can EPA use this experience with CAMs, *undoped* CAMs, to inform its review of these *doped* CAMs so that it can review them more efficiently and not have them linger in the PMN review process for months or years, to have EPA go back and review them *de novo*. If EPA can look at its past scholarship, look at its past consent orders, essentially cut and paste those, assuming that the facts on the doped CAM support that conclusion that's within the category, EPA can cut and paste its risk assessment and its consent order and allow that CAM into commercialization to again enable -- more speedily enable -- their adoption in commerce.

LLB: As I understand it, it makes a lot of sense. You have probably a standard number of core ingredients, and you mix in a little bit of, as you say, pixie dust, these dopants, that cause it to be considered a separate chemical substance that requires a submission of a PMN. But because the Biden Administration is prioritizing electric vehicles and other projects that support electric energy storage, hastening the review is both expedient and necessary for our new EV economy. That makes a lot of sense.

REE: And frankly, it falls within the statutory standard. They're not shortcutting the standard. What they're doing is they're using their substantial body of knowledge and an explicit effort to reuse that body of knowledge in this category approach.

LLB: No, it makes a whole lot of sense, as you say, *de novo* review for these chemicals that might have new dopants in them, but are not expected to be dramatically different. You can comfortably and scientifically rely upon the historic review of these CAMs in a way that doesn't shortchange the review process at all. It's simply an expedient, so it makes a whole lot of sense.

The piece that doesn't make a lot of sense to me relates to the relevance of the statutory mixture guidance and why EPA appears to have reinforced its prior view with regard to the applicability of the statutory mixture guidance to MMOs. That might require a little explanation, Rich, because it's a complicated concept and one that has invited quite literally *years* of vigorous debate among TSCA nerds like us.

REE: Yes, and as you know, Lynn, we and others in industry have had extensive conversations with EPA over -- I'm afraid to count the number of years about --

LLB: Too many.

REE: -- the meaning of the statutory mixture guidance, especially as it relates to the MMO provisions in that statutory mixture guidance. And in this announcement, EPA restated its view that the CAM MMOs -- most CAMs are MMOs. I don't know that they all are, but certainly many are, that EPA views those MMOs as *not* being eligible as statutory mixtures. EPA's view is they do not fall within the statutory mixture category. But when I read the statutory mixture guidance, it appears as if these CAMs *would* fit within that category that's described; it's in the guidance. Unfortunately, despite significant effort on our part and

others' parts, industry has been unsuccessful in obtaining a clear explanation how *these* MMOs are different from the examples that EPA uses in its guidance. EPA has an example in its guidance.

And we look at that and say, "Looks just like that."

And EPA says, "No, it's different."

And we say, "How is it different?" And in the time that we spent on the matter, we got six different explanations of how it's different. And none of them really answered the fundamental question.

LLB: Let's step back for a moment and just refresh the recollection of our listeners as to what the heck the statutory mixture provision is and what the relevance is of the guidance that has been on the books for a long time and has been unchanged by EPA. The statutory mixture guidance. What is the statutory mixture exemption, if you will, and what is the relevance of the guidance for purposes of this anomaly that you've just identified?

REE: So that the -- EPA has a document called its mixture guidance, and it really breaks mixtures into two chunks, two buckets. One is formulated mixtures, or what I like to call simple mixtures, where you simply take two substances and you mix them together. There's no chemical reaction. They're just mixed together in -- whether it's in a liquid, or mixed solids. No reactions occur, so there's been no change in chemical identity. And mixtures, under TSCA, mixtures are simply considered to be a combination of individual substances. There's no change in identity, so there's no separate obligation for the mixture, apart from the individual substances that are in the mixture. But the mixture guidance also provides a section that EPA calls *statutory mixtures*.

And in this case, they are cases where things are combined and a reaction *does* occur. But EPA nevertheless considers the product to be a mixture of the substances that make up that final product. There are a variety of examples. Glasses is an example, where you take a variety of oxides and you mix them together. You make an amorphous glass. EPA views that as a mixture of the individual oxides in the glass: the silicon oxide, the boric oxide, and the other oxides that are used to make up that glass. Zeolites is an example. Aluminum silicates make up zeolites, and EPA basically doesn't care what combination are used. Aluminum silicates that make up zeolites are a statutory mixture. A reaction occurs during their formation, and EPA just views that as a combination of alumina and silica.

Another example is supported catalysts. In platinum plate, platinum has been deposited on some sort of solid support. EPA views that -- even though a reaction occurs -- EPA views that as a mixture of the platinum and the solid support, and not a reaction between the two. And mixed metal oxides is one of those categories. And that's the category in which we -- my read is the CAMs squarely fall within the MMO category, and EPA views that otherwise.

LLB: So the relevance of our position -- because I think institutionally this firm has taken that position in many advocacy contexts, both enforcement and in urging EPA to clarify the scope of the statutory mixture guidance. The relevance of falling into a category is that you would not need to submit a PMN, because the thought is that it's already listed on the Inventory, correct?

REE: Right. As long as *each* of the oxide components that results from the reaction -- as long as each of those oxides is individually listed on the Inventory -- then the MMO is considered to be a -- no PMN would be required because the MMO, if you've got five different metal oxides in there, as long as each of the five metal oxides is listed, then the MMO product, for instance, a CAM, would be considered to be a mixture of those five, and not a separate substance. That would not -- you could add a dopant, and as long as the dopant oxide is on the Inventory, then the CAM would not require its own listing, would not require a PMN.

LLB: It seems to me if EPA was wishing to make the EV technology even more efficient for purposes of TSCA, it would clarify that MMOs that are listed on the Inventory and including the dopant that is added, clarify that under the statutory mixture guidance, PMNs would not be necessary, as opposed to doing what it did, which is to have this categorical approach with regard to MMOs and CAM. Help me understand, or help our listeners more to the point, understand. This guidance has been on the books -- I don't know, Rich, when it was first issued, it was --

REE: I think it was '95.

LLB: Yes, it's very old, and it has been unchanged by EPA. So why do you think the CAM MMO categorical approach seems to be inconsistent with the 1995 statutory mixture guidance? And my sense is that it's not, despite our advocacy and the advocacy of others on this point. My sense is that EPA is not expected to clarify the statutory mixture guidance anytime soon. At least it's not given us any indication that it intends to do so, right?

REE: They certainly did not do so when we were explicitly asking them to clarify the guidance, so I don't think they'll do it now, absent a very strong push. I agree. If EPA really wished to facilitate the implementation of new CAMs, it could point to the MMO guidance and say, "Hey, these --" EPA could have stated then in its view these MMOs are statutory mixtures. And as long as the individual oxides are listed, then PMNs are not required. But because of ten, 15 years at least of EPA pushing the other direction and pushing *strongly* in the other direction, trying to *narrow* the applicability of the statutory mixture guidance, I think that would be a -- it would be a remarkable reversal on EPA's part institutionally. We've been asking institutionally on behalf of individual clients and groups, been asking for EPA to clarify its guidance.

EPA did, back in -- I think it was 2010 -- EPA did clarify its view of doped phosphors. EPA put out a *Federal Register* (FR) notice defining its view, or clarifying its view on doped phosphors and why doped phosphors were *not* eligible for the statutory mixture exemption, and it clarified what circumstances something would be considered a doped phosphor and when that would trigger that requirement. And it also allowed for people that had relied upon the statutory mixture guidance for years or decades to submit plans so that they could come into compliance. They allowed for safe harbor provisions so that people could -- if they'd been relying on statutory mixtures and EPA said, "Well, now you can't do that anymore" as of the date of its announcement. I believe there was at least a one-, maybe two-year glide path for people to prepare and submit PMNs and place those doped phosphors on the Inventory.

LLB: Which is a really important concept, Rich. I don't want our listeners to overlook the significance of what you're pointing out here. And I think the 2010 doped phosphors initiative provided, to me anyway, a very clear kind of template for other instances where the statutory mixture guidance might be revisited by EPA for one reason or another. And

neither of us is suggesting that the Agency is disallowed from doing that. The 1995 statutory mixture guidance, like any other TSCA concept, is amenable to reconsideration.

REE: Absolutely.

LLB: But the due process concerns here that I know have challenged our clients and I think stressed the approach the Agency has taken here is that it doesn't allow entities that have historically relied upon the statutory mixture guidance to revisit the characterization of materials that they are making and now find themselves possibly in an enforcement context, because the Agency has changed its interpretation but not its guidance.

REE: Right.

LLB: And the amnesty period, or as you suggest, the safe harbor period that the Agency allowed for doped phosphors was, to me, a very amenable and very fair way of changing the guidance, letting everyone know if they have historically relied upon that guidance that they now need to do things differently. And if I recall, you could continue your business operations while you submitted a PMN to come into compliance with the safe harbor provisions of the doped phosphors initiative in 2010, correct?

REE: Yes, that's my recollection. And I believe it was -- the two years was to have the PMN review complete, so prepare, submit, and have the PMN review be complete within two years. So as long as -- it meant that after that two-year period, you could no longer manufacture something that met the doped phosphor category, as they defined it in that FR notice. After that two-year period, you could no longer manufacture something that met those criteria.

LLB: And the pendency of the PMN also inoculated the entity from enforcement reprisal as well. So those are very important considerations that EPA seems, for MMO purposes, not to have applied the same thinking, for reasons that are completely unclear to me.

REE: Yes, I agree. We talked to EPA extensively about this for -- was it, two years, about?

LLB: Two years, yes. Lots of meetings, lots of correspondence.

REE: Yes. Just trying to understand how -- we were trying to get clarity on why we -- EPA felt we were misinterpreting the guidance, and all we ever got was, "No, you're wrong." That was how I felt all -- the letter was like, "What don't you understand? We told you 37 times." And one of the things that EPA has pointed to in the past and points to again is that others have filed PMNs for MMOs, so *those* manufacturers know that they're not statutory mixtures. "What don't you get? Get on board because people have been submitting PMNs for MMOs for years or decades."

But just because somebody else doesn't avail themselves of an exemption doesn't mean that a particular manufacturer has to go along with that strategy. If that were the case, the polymer exemption criteria would be meaningless because as soon as one person placed an exempt polymer on the Inventory, then EPA could say, "Well, *they* submitted that exempt polymer as a PMN, so everyone else should." The point of the exemption is that manufacturers get to choose whether they define the thing -- whether they use the exemption or not. So just because one doesn't choose to use it doesn't mean that someone else cannot choose to use that exemption.

LLB: Right. And that's long troubled, I think, those of us that are TSCA aficionados, that EPA shouldn't rely upon the business practices of one entity in the community or an entire sector to dictate what is and is not legally correct. A lot of entities choose to put their chemicals on the Inventory strictly for business reasons, because claiming an exemption sometimes gives rise to commercial disarray. Their election voluntarily to submit a PMN for an exempt substance does not change or vitiate the underlying exemption that would otherwise apply to others, and yet that's precisely one of the arguments that I recall EPA used in our advocacy. It's like, well, golly. These guys are doing it, right?

REE: And just restated in their announcement on the CAM category.

LLB: In the notice. Right.

REE: Yes, yes.

LLB: Well, that's disturbing. Well. What can CAM submitters expect going forward?

REE: If you are in the business of manufacturing CAMs and you are submitting a PMN, you can look at other recent CAMs. Probably the two dominant ones are NCA, which is lithium, aluminum, cobalt, nickel oxide, and NCM, which is lithium, cobalt, manganese, nickel oxide. Those are the two dominant base CAMs that have been the underlying technologies for a lot of the recent, especially EV batteries. You can look back at those PMNs, look at the consent orders that have been issued for those and the corresponding significant new use rules (SNUR), and use those as a -- basically a guide for how EPA's going to review a new CAM. Assuming that you've got nickel -- really, it's nickel, cobalt, manganese are the drivers of the concerns there.

There's also lithium. Lithium is in there because it's a lithium ion battery. Presumably the new CAM is probably also lithium. Again, looking at the concerns that EPA identified, the test data that EPA received, and its approach to managing the risks, that's essentially how EPA will view a new doped CAM, especially if you're adding a metal for which there's not an identified hazard that's significantly greater than the nickel, the cobalt, and the manganese, all of which are pretty high-hazard metals.

If you've got your new thing, you add a little bit of pixie dust, and you say, "This is doped NCA" or "doped NCM." Then you can look at those PMNs at EPA, review those PMNs, and say, "Well, this is what we think EPA is going to do, based on what it's done in the past," and expect those cookie cutter consent orders. Hopefully, we'll see what the timing is as these -- as CAM PMNs start to get submitted, how quickly EPA can turn those around. But that's the point, is for EPA to do those reviews more efficiently. But if you're in that business, I would -- if you're in that business and you're intending to submit a PMN, I would read back to -- I would look at those old PMNs and design your new PMN in a way where you make it clear you are operating within the boundaries of those orders or SNURs and can operate within those restrictive conditions. Make sure you've got those processes described, and your waste management procedures described, and the worker protections described, that you're within those boundaries. And then I think you can expect a fairly prompt order from EPA. How prompt is prompt? I don't know.

LLB: Right. I want to make sure we're not setting ourselves up for --

REE: Overpromising, yes.

LLB: Not 90 days, guys. It's going to be anywhere from four to 60 months or more, right, Rich?

REE: Yes. Hopefully, if EPA sees a CAM under this CAM approach, it'll be less than six months. But I certainly hope that it's less than a year. Most PMNs these days are lingering for more than a year. I would expect the category approach gets you under that threshold at least. EPA has brought a whole bunch of new reviewers on, and we are starting to see movement in the Fiscal Year 22 cases. So perhaps, with their greater capacity now, it will actually be less than six months. But until we see it, it's hard to know.

LLB: Well, one question that comes to mind has to do with how these categories are selected. We know the Biden Administration has expressed its support for the EV sector and EV technology and doing what it can to promote that technology, given its commitment to climate change and related considerations. But how do you think EPA's balancing the need for fair and transparent priority setting and its wish to align with Administration priorities? Because I would imagine there are a fair number of industry sectors out there that would really, really love to have their favorite chemicals or chemicals of choice going into *their* technology to be part of a chemical category. So how do you think EPA is sorting that out?

REE: I do think that these announcements are driven by the Administration priorities, but they're also driven by the fact that EPA has had a reasonably large body of similar PMNs. So the biofuels EPA got received a number of PMNs for renewable -- essentially petroleum equivalents, or petroleum fractions, distilled fractions that were made from a renewable source instead of petroleum. EPA's nomenclature dictates that those are new chemicals, but they're not really novel from a hazard standpoint. EPA got a bunch of these biofuel PMNs and recognized that these are all pretty much the same. They have some slight differences, but it can apply this categorical approach to the biofuels and review those more efficiently.

Similarly, for the CAMs, EPA has received a number of CAMs and modified CAMs, and EPA has enough information to now conclude that they can be reviewed as a category. I think if you are in an industry and you haven't received a category and you think one is justified, I think you could approach EPA and say, "Hey, EPA, look. You've received -- whatever it is, five, ten, 20 PMNs of this type of chemical, and you're making the same decision each time. Can we create a categorical approach for this group of PMNs?"

I think EPA would be open to that, if the facts support it. I think EPA would be open to that because, again, the point of the category approach is to review PMNs more efficiently. If the facts support that the hazards and the use patterns are consistent across the set of chemicals, then EPA can justify taking the categorical approach. It is in EPA's interest, as well as the submitters' interest, for EPA to do that review more efficiently, so I think EPA would be open to that. If they got 50 requests in a week, they're going to have to pick and choose, but if you're in an industry sector that you think you've got a strong argument and you can assemble those facts and bring it to EPA -- rather than waiting for EPA to decide, "Oh, yes. We've received a dozen of whatever that sector's type is," say, "Hey, EPA, you received a dozen of these. You made the same decision. Can this be a category?"

LLB: Let's dig into a little bit more on the biofuels category. I think many of our listeners know that the Biden Administration issued fairly recently a new Executive Order (EO), 14081, titled "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy." The EO is very broad, and it will have many important implications for the biotechnology community, both for purposes of the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and EPA. And there is

a little bit of something for everyone in there, and I would urge our listeners to take a look at EO 14081.

To the extent that this biofuels category was issued, is that a reflection of the Administration's commitment to yet another kind of bio aspect of the economy and further evidenced by the EO? Or is it just serendipitous that the biofuels category came out and -- which I think preceded the September 12, 2022, signing of the EO -- but are they related, or just serendipitous events that happen to have occurred in 2022?

REE: Yes, I don't know that there was a causal relationship. I think the biofuels category -- again, it also -- EPA also issued guidance about the nomenclature of those fractions of those petroleum equivalent fractions. EPA reminded manufacturers that if a hydrocarbon distillate fraction was not manufactured -- or if a hydrocarbon distillate fraction includes the source in the name -- and most petroleum distillates are specified as coming from petroleum, that if you do not make it from petroleum, for instance, if you make it from biomass, it's not that substance. It is a similar substance that's made from biomass.

EPA reminded the regulated community of that nomenclature standard. And I suspect that led to a number of submissions where people said, "Wait a minute, EPA's now told us that we can't make, whatever, the petroleum distillate from biofuels." So now, the manufacturer of that biobased stuff submitted the PMN. It was also a reflection of EPA's view of, again, an order that EPA -- an order template that the restrictive conditions that EPA felt and apparently had negotiated with a number of submitters that they felt was protective and minimize the supply chain effects of a consent order. There's a specific boundary of when the order no longer applies. That all happened, I think, a little bit before the EO. It might have reflected -- the EO might have reflected a recognition that there are regulatory hurdles to new technologies that are perhaps more sustainable, such as using biomass or other waste material as feedstocks to -- in place of petroleum.

The White House issued the Executive Order to say, "Hey, pay attention because this matters. We're trying to move to a more sustainable space, so make sure that the things that these individual departments or agencies are doing are facilitating that transition from a petroleum-based world to a renewable-based world." It's probably a reflection of the reality of where the industry is, where these things are starting to take off, and a recognition within the Executive Branch that there are lingering barriers and that the President is now directing those departments and agencies to pay attention to and do what they can to minimize those barriers.

LLB: Do you see, Rich, any big differences between the two new categories?

REE: Well, I'm most dismayed by the biofuel consent orders. It struck me in particular that those were instances where an order really wasn't required. There's really nothing novel about the hazards or the risks associated with hydrocarbon fuels. They're heavily regulated under the Clean Air Act and the Clean Water Act, so the existing chemicals that are in those petroleum fractions are already heavily regulated by the Clean Air Act and the Clean Water Act. It didn't strike me as necessary that there was a gap to fill by issuing these orders. I know OPPT and the New Chemicals Division tried to frame the orders in a way that minimized duplicative regulation, but these are well-known hazards. They are well-managed, well-regulated hazards. The orders, to me --

LLB: Why the order?

REE: Yes. What was the point? What was EPA protecting against that wasn't already being managed? This goes to all the discussions we've had about "reasonably foreseen," what are the reasonably foreseeable conditions of use that necessitated this? And I think it goes back to EPA's institutional view that if there is a hazard, there *must* be a TSCA regulation, regardless of whether or not there are other regulations. I was a little more disappointed by -- and I know a lot of the manufacturers are like, "Oh, thank goodness. We're going to get these more efficiently." I'm like, "You're getting the wrong outcome. My view is you're getting the wrong outcome more efficiently." It's still great, you're getting it more efficiently, but this should not have been a place where EPA's exercising its authority.

The CAMs right there -- they're so well-recognized that some of the mammalian testing on the CAMs showed that there's some pretty significant hazards that do need to be protected against. That's a case where, in my view, it's more appropriate for EPA to say, "Okay, in this group we have this set of significant hazards, but this is the way that -- we're going to manage them consistently across the category." A cut-and-paste consent order approach did make sense to me, so with any other category, looking at the totality of the circumstances makes a lot of sense. How is that class of substance used in that sector? What are the hazards? How are they managed? Are there other regulatory structures in place to protect against those hazards? Or is it something where TSCA really does need to be brought to bear because the other regulations are not sufficient to protect? I guess I have two very different views for these two relatively new categories, but I'm pleased that EPA is rediscovering and re-implementing the category approach, because it's going to be better for everybody.

LLB: No, and that's -- it sounds like a little good news, bad news here. The good news is there's a categorical approach for both. But to the extent that this formulaic approach necessarily means the order requirements are going to be part and parcel of the category is maybe not such great news, but EPA might relent on that, too. I'm not sure. A lot of people have started to advocate on, "Gee, we need a chemical category," and, because of the nature of our industry and our category, maybe an order is necessary. That could be part of the advocacy package going forward.

REE: Yes, I think you're right. And it'll depend on the specifics of --

LLB: -- exactly.

REE: -- of the sector and the class of substance here.

LLB: Well, to the extent that a category approach is intended to streamline the PMN review process and in light of the fact that EPA recently issued its supplemental proposed rule for TSCA fees, can submitters falling into a category expect a break on their PMN fees? You think, Rich?

REE: No, I don't think so.

LLB: Why not?

REE: EPA's never done that. The category approach is -- the benefit of the category approach to the submitter is that EPA is making a more predictable determination. You have a clearer picture of what -- if there's going to be an order, what the order conditions are going to be, what EPA's hazards are. And presumably you're getting a shorter review time because EPA does not have to do a *de novo* review.

LLB: Well, but that's my point exactly. There's a shorter review time, less effort for the Agency. And if the 45,000 bucks per PMN fee holds up in the final, the Agency is still saving resources. So why can't you expect a comparable smaller fee?

REE: But there was the work that EPA put in to come up with the category, so there's -- it's not that the category itself -- creating a category, coming up with this category approach requires effort on EPA's part, and presumably on the submitter's part to work with EPA to define the category.

LLB: But at some point, that commitment is paid back though, right?

REE: Well, I guess EPA could, and commenters could make this point in their comment to the fees rule is that if a PMN fits into an existing EPA category, then there is some lower fee. That will make the categories even more important. And when does that, air quote, "discount" attach? Is it when EPA formally updates the category document and adds the new category to that category document? And that could be a long time because it's been since 2010 since EPA's cracked the category document open, even though EPA created new categories after 2016, sort of created draft categories, but hasn't formally finalized any of those and placed them in the category document. I do -- the construct is very appealing. I doubt that EPA will -- it's worth commenting on.

LLB: I agree. The comments are due January 17, 2023. And again, it's to me a very intuitively logical argument.

REE: Sure. I think EPA will be very resistant, for a variety of reasons. They may reject that, but it doesn't hurt to ask.

LLB: Exactly. My point exactly. What might be next? Do you see other categories on the horizon here? Or what do you think EPA's next development might be in this regard?

REE: I'm aware of EPA's desire to update the 2010 category document to reflect the Lautenberg amendments. I know there's a drive internally to do that. As we all know, EPA has been extraordinarily burdened with work. So that's really a voluntary effort. I mean, it is an efficiency expedient, but again, it requires effort to do so. It hasn't been a high enough priority to come up.

But the inhalation categories that EPA put into place after 2016 and the biofuels in the CAM category, I do think those will become more well-defined, and at some point will work their way into an updated category document. And it may be that for some time to come, these categories will be fairly stand-alone and not be incorporated into the existing category document, which is okay. It's important to have the category, to have the predictability, to have the clarity and the transparency of the category. They may be much more stand-alone than something that's in a nice, tidy document tied up with a bow and a government document ID.

LLB: Last question, Rich, and I think our listeners are seeing one of the takeaways from this podcast is that this is an opportunity for chemical innovators: the category approach. What do you think innovators can do to focus OPPT on an approach for other chemical innovations?

REE: As I've said previously, you need to -- it's about having a body of evidence, about EPA having a sufficient body of evidence to conclude that it can rely upon a set of scholarship --

tests, test data, analogs, boundaries of a category, and say, "As long as things are within this -- boundaries of a category, that the hazard data that EPA has already is sufficient to inform its risk assessment -- during a PMN review."

If you are interested in creating a category with new chemicals, you need to have that fact set available. You need to have -- go search the PMNs that have been submitted. If you're taking a proactive approach, which I think is worthwhile, that sector needs to be proactive, and do the research, and find what that group is, and find that common data set that supports the view that within this category, EPA can reliably make these predictions about risk, make these, and do these risk assessments. So that's where the effort is. I think that would be an approach is going to EPA with the fact set that supports your category, or you can wait for EPA to come to its own conclusion. But then that's going to be subject to EPA's prioritization. They may prioritize -- EPA, the administration said, "Hey, we want to do a category for CAM. We have a decent data set. This is important for the administration, so we're going to put in the extra effort to define this category." You can wait for that. Once EPA gets enough PMNs in that category, they'll probably do that. But because it does take some effort, that may take longer, so if you do the work for EPA, I think you're more likely to get -- do the work, gather the data, do the assessment, convince EPA that yes, within the category there's not an unreasonable risk. Take that complete scholarship to EPA. That would be how I would approach an advocacy to create a new category.

LLB: Excellent. I would agree. Well, Rich, great conversation.

REE: It's a pleasure.

LLB: Really always enjoy chatting with you, and I hope our listeners enjoyed this conversation about chemical categories. Appreciate it. Thanks so much, Rich.

REE: Thanks very much, Lynn.

LLB: Thanks again to Dr. Rich Engler for speaking with me today about EPA's newest additions to the chemical category list for TSCA Section 5 purposes. The categorical approach has significant implications for new chemical innovators, and we hope the podcast helped explain why.

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