# Episode Title: New PFAS: Is Anything NOT Reportable? — A Conversation with Richard E. Engler, Ph.D.

Episode Number: 20210708
Publication Date: July 8, 2021

*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/lynn-sits-down-with-rich-engler-to-talk-about-a-new-proposed-component-to-t.*

*PLEASE NOTE: At the time of recording, the comment period was set to close on **August 27, 2021**. On August 3, 2021, the U.S. Environmental Protection Agency (EPA) published a Federal Register notice extending the comment period until **September 27, 2021**. Comments can be submitted to docket ID number EPA-HQ-OPPT-2020-0549 on www.regulations.gov. Additional details can be found in our July 29, 2021, blog item, "EPA Extends Comment Period on Proposed TSCA Reporting and Recordkeeping Requirements for PFAS."*

**Lynn L. Bergeson (LLB):** Hello and welcome to All Things Chemical, a podcast produced by Bergeson & Campbell (B&C®), a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I am Lynn Bergeson. This week, I sat down with Dr. Rich Engler, Director of Chemistry with B&C and The Acta Group, our consulting affiliate, to discuss a very new component of EPA's PFAS Action Plan. The plan represents EPA's "all of agency" approach to address the risks posed by per- and polyfluoroalkyl substances, otherwise known as PFAS, that can accumulate in humans and remain in the body for long periods. PFAS have been widely used in many consumer articles for many years, and the action plan represents the totality of EPA's actions to identify areas of risk and the steps to address risks posed to human health and the environment. EPA very recently proposed a PFAS reporting rule under the Toxic Substances Control Act that would compel the submission of certain information on some 1,000 listed PFAS chemicals. The proposal was pretty controversial because of how it defines this class of chemicals, the standard of knowledge that triggers reporting, and the types of entities subject to the reporting requirements.

Rich Engler is here today to help us understand what these issues are and why you should be concerned. Now, here is my conversation with Dr. Richard Engler.

Hello, Rich, thank you so much for joining us and talking today about one of our favorite subjects, TSCA reporting obligations.

**Richard E. Engler (REE):** It's always a pleasure to be here speaking with you on the podcast.

**LLB:** Please share with our listeners general overview terms about EPA's proposed reporting rule for per- and polyfluoroalkyl substances, otherwise known as PFAS, published June 28 in the *Federal Register*.

**REE:** From a very high level, EPA proposed a TSCA Section 8(a) reporting rule to require retrospective reporting of manufacture or import of PFAS in the last ten years. TSCA Section 8(a) is the same authority that EPA uses for its quadrennial Chemical Data Reporting or CDR.

**LLB:** I know the proposal is part of EPA's so-called "whole of agency" approach to addressing PFAS contamination. It has been discussed literally for years, but it has really picked up a lot of momentum in the recent past under the Biden Administration. What other initiatives has EPA announced relatively recently with respect to PFAS contamination generally?

**REE:** EPA announced that it would no longer be granting low volume exemptions (LVE) under TSCA for PFAS substances, and EPA would seek to have submitters of previous LVEs to voluntarily withdraw those LVEs. EPA is also considering action through the Office of Water and the Office of Land and Emergency Management.

**LLB:** That LVE withdrawal strikes me as something that EPA has done before, actually sought other voluntary withdrawals of previously issued LVEs under TSCA. Or is that a relatively recent phenomenon?

**REE:** I am aware of some isolated cases. I am not aware that EPA has ever systematically gone through an entire class of LVEs and sought to have submitters withdraw those --

**LLB:** -- which could be difficult under some circumstances, right? If you have an entire business line premised on the import or manufacture of a particular chemical, voluntarily saying, "Never mind" could be challenging.

**REE:** That will all be in conversation with EPA, maybe with a voluntary withdrawal. I don't know what the follow-on conversation would be. I would be very interested to hear how that goes.

**LLB:** Why don't we focus a little on this very important proposed Section 8(a) reporting rule? I did look at it, the prepublication version of it, and of course, we did a fairly detailed memo on it, which is posted on our web page. However, the reporting rule strikes me as unique in some respects. Let's talk first about the derivation of the TSCA Section 8(a)(7) provision, which itself was not part of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and was not really part of TSCA at all, correct?

**REE:** Correct. It was part of the National Defense Authorization Act. This is very unusual, in my experience. It's unusual that Congress would tack on a specific reporting rule. This is really omnibus legislation, in my view. This is regulation by legislation where Congress said EPA shall issue this reporting rule by a date certain, **January 2023**. The language really limits EPA's flexibility on what it must require or what it can require. It's quite prescriptive that EPA shall require data on these particular data elements.

**LLB:** Let's focus on that. First off, what class of entities is subject to the reporting requirement once it kicks into final?

**REE:** It appears to be an extraordinarily broad group of potential reporters, a much broader group than is typically considered to be a TSCA reporter. It appears to only exclude manufacturers


©2023 Bergeson & Campbell, P.C. All Rights Reserved

and importers of products, substances, and articles that are used exclusively for excluded uses -- food uses, medical uses, and cosmetic uses, the uses that are regulated by other federal statutes. All other manufacturers and importers of substances and articles that meet the definition of the PFAS class, which EPA does define, appear to be subject to this reporting rule. That's an extraordinarily broad set of potential reporters.

**LLB:** Indeed. We'll circle back to that. Before we go into how broad that cohort is, let's talk a little bit about how far back reporting is required. Over what period of time must you submit information? What are the elements of the report that EPA is hoping to receive?

**REE:** The reporting period is ten years, and it's set by the statutory language. EPA cannot change that in the rulemaking. I don't know why Congress picked that timeframe, having reviewed the legislative history. The statute itself is about 1,200 pages. I am not even sure there is proper legislative history for why Congress picked ten years. But it is an odd timeframe since companies need only maintain records of compliance for five years. It's requiring companies to go back further to look for records that are potentially responsive.

**LLB:** Presumably, if you don't maintain records that far back, which is probably not an unusual state of affairs for a lot of companies, that would mean not having information responsive to that period of time that would discharge your obligations under the proposed rule.

**REE:** Yes. First you look to see if you have records that demonstrate that you are manufacturing or that you have or have not manufactured or imported a PFAS. If you read the responses, one of them is "not known or reasonably ascertainable." However, even if you look back and have records to say, "I have no records of any manufacture or import," the fact that you can make that representation would presumably relieve you of the obligation to report. You would need a record where you look. If EPA came and audited, you could say, "Oh yeah, I looked and didn't find any records that I manufactured or imported a PFAS." There is an obligation to look at your supply chain, even if you can't find a record that would be responsive to the rule.

**LLB:** What kinds of information is EPA eliciting under the Section 8(a)(7) reporting requirement?

**REE:** The typical fields that would go into CDR reporting include the name or identity of a substance, including a trade name; what it's used for; the quantity; any byproducts resulting from the manufacture, or processing, or use of the substance; health and environmental effects of the substance; the number of people that are potentially exposed during manufacturing, processing, or use; and the manner or method of disposal. It is a pretty wide set of information related to the particular PFAS substance. For some reporters, it's going to be challenging to find that information or predict that information. One of the responses is "not known or reasonably ascertainable." I expect there's going to be a lot of that.

**LLB:** With regard to the actual listed PFAS in the proposed rule, it looks like there are more than a thousand. You noted that there is an attempt here to define the class of substances that fall within the PFAS definition. Help our listeners understand what that's all about.

**REE:** The list is not an exhaustive list and specifically states that it's just examples of substances that it has found that meet the category. The category definition is two saturated carbons to adjacent saturated carbons. One has at least two fluorine atoms, and the other has at least one fluorine atom, and neither one of those carbons has an attached hydrogen. That's the definition of the PFAS category. It is extraordinarily broad, as evidenced by the long list of substances that EPA published, but EPA's list does not even include polytetrafluoroethylene


©2023 Bergeson & Campbell, P.C. All Rights Reserved

(PTFE), which is the most common fluoropolymer in this class. It is not an exhaustive list. EPA has stated that they will update the list in the final rulemaking, but even then, you have to look at individual substances in your supply chain to see if they meet the category. It's not just reporting on the substances on the list.

**LLB:** Let me get this right. PTFE is not listed, but is an element that falls within the scope of the category defined in the proposed rule. So the omission of that on the list does not mean it isn't reportable. It simply means that it wasn't identified on the list, which is illustrative only.

**REE:** Exactly. That's exactly right.

**LLB:** You are a Ph.D. chemist, Rich, and in my view, the smartest regulatory chemist on planet Earth. How are people going to interpret this category definition to understand what they need to report on? Give us a really basic example of what, say, an importer of record of chemical substances coming in from overseas might be expected to encounter once this rule is issued in final.

**REE:** If I were trying to respond to this rule, I would start with the list of substances that my company manufactured or imported. I would look for not even the keyword, but the text string F-L-U-O- to see if that appears in the name of any substance anywhere in my supply chain, whether it's a particle, or a mixture, or a neat substance, or an impurity, or a byproduct. If I can match that text string, then I can look to see if the structure meets the category. Then I would know whether that particular substance or the product that contains that substance is reportable. It's not going to be an easy job.

**LLB:** Again, the rule applies to manufacturers, including importers, which is why I use the import example. I see a lot of the potential challenge arise with regard to imported products over the past ten years that might have any of these chemicals in the import. As you correctly noted, the usual class of entities that typically are exempt from these obligations are not exempt from this proposal. That would include impurities, these chemicals found in articles, and most important, small manufacturers are not exempt, correct?

**REE:** Yes. This rule does not include most of the standard, or really any of the exemptions to CDR. There's no exemption for small business. There's no exemption for byproducts, for polymers, for articles. There's no quantity threshold. The R&D exemption doesn't apply, as far as I can tell. There are no exemptions other than the things that are defined out of TSCA by Section 3, the food, drugs, cosmetics, and pesticides, things that are regulated by other federal statutes. There is a much broader universe of potential reporters here than for any TSCA action that I'm aware of.

**LLB:** Listeners might be starting to hyperventilate right now. This is a proposed rule. Written comments on this proposed rule are due on or before August 27 -- at least, that's what the *Federal Register* reads right now. [*NOW comments are due* ***September 27, 2021****. See more information at top of transcript.]*

There are opportunities to identify some of these reporting challenges and anomalies, but as you also correctly note, some of this is driven strictly by Section 7351 of the National Defense Authorization Act, which compels some of the confounding factors set out in the proposed rule.


©2023 Bergeson & Campbell, P.C. All Rights Reserved

Why that is might be just a function of the legislative process. It's often been compared to making sausage. You might like the result (or not for us vegetarians), but you sure don't want to be an eyewitness to the process. What it elicited here is a very challenging proposed rule for some of the reasons we've been discussing.

One other aspect that I find very interesting is the standard of diligence with regard to the scope of your investigation. The standard, as I understand it, would require that submitters conduct a "reasonable inquiry" -- and this is the interesting part -- "within the full scope of their organization," and not just the information known to managerial or supervisory employees. Can you break that down?

**REE:** Yes. It's interesting that EPA is getting into the weeds of what is known or reasonably ascertainable -- and I'm pleased that they are -- but EPA does seem to be putting a special emphasis on the expectation that whoever is preparing the report needs to work with the entire organization to find out what the entire organization knows about key facets in the organization supply chain. It's not just, "I went and looked in this one data system or in this one filing cabinet. This is what I found." It's broader than that. Also in the proposal, EPA does seem to be expecting companies to do some inquiry within their supply chain. But then EPA states that the "not known or reasonably ascertainable" has the same definition for this rule as it does for CDR. I would have to review the specific CDR guidance. My impression is that this proposed rule does include a broader or a greater expectation of inquiry to satisfy that due diligence requirement.

**LLB:** That was my take as well, because the preamble discussion in the *Federal Register* goes into this point in some detail. However, what that means in the real world and what standard manufacturers and importers will be held to from a compliance perspective, of course, remains to be seen. I would imagine there would be some interpretation given -- this is an evolving standard. It's not just the person that's filling in the Section 8(a)(7) response; it's the entire organization.

To your point, Rich, EPA has made it abundantly clear that members of the value chain are on notice. When these reporting obligations come out, they really want a reasonable inquiry. What constitutes reasonable under the circumstances, given some of the nuances here and the challenges to supply-chain transparency, really makes these confounding standards for the regulated community.

**REE:** I don't want to downplay the importance of EPA's need for information. My concern is that EPA is going to put a lot of burden on potential reporters who have no responsive records, but they're going to have to do a lot of work to figure that out. This is a *retrospective* reporting rule, not a *prospective* reporting rule. It will be a lot of burden for people to look back and find nothing or find very little.

**LLB:** Exactly, and with regard to the inclusion of chemicals in articles, you know that's been a topic of considerable discussion among our clients. We have been having these discussions now since much earlier in the year with regard to the TSCA Section 6(h) persistent, bioaccumulative, and toxic (PBT) rule and the reporting obligations pertinent to phenol, isopropylated phosphate (3:1) (PIP (3:1)), for example. My sense is that this reporting obligation is going to invite many of the same issues that we've been talking about for the last seven months now with regard to PIP and the other four PBTs regulated under the rule that became effective on March 8 of this year, correct?


©2023 Bergeson & Campbell, P.C. All Rights Reserved

**REE:** Yes. You have all the article issues related to the PBT rule, and the importers were surprised by the sudden obligation to know that the PBTs -- PIP (3:1) in particular was the one that surprised the most people, that PIP (3:1) was or was not present in articles that are imported and distributed.

We'll also have the loss of the article exemption in this rule, but the loss of the wide range of other exemptions reminds me of all the angst that was related to fee payers for a risk evaluation. I want to encourage listeners to be aware of the loss of these exemptions and what that means for them or their entities. I want to make sure that EPA is aware -- because this is a proposed rule -- this is the time to explain to EPA what the implications are going to be for your organization or for you if you're a trade association for your members. Trade associations, do not miss out on this opportunity to comment.

**LLB:** You have raised a couple of really interesting points, Rich, one of which relates to outrage that PFAS substances are used for a variety of functionalities. But is there a constellation of products that you would expect to be more likely than not relatable for purposes of PFAS inclusion in their supply chain?

**REE:** Lots of products include PTFE -- gaskets and components -- that there are going to be a lot of high-tech products that relate to that, but PFAS as a coating could be on any textiles, any piece of cloth, apparel, furniture, upholstery -- any of those articles might have PFAS. A T-shirt retailer might not be aware of TSCA at all, yet clearly, under this rule, they will have an obligation to look at their supply chain and figure out if there is PFAS, and if there is, they will have to report.

**LLB:** I would imagine these supplier certification forms that we have been talking so much about become all the more important to help understand what chemicals are in the products you receive from others. Chances are, if you are a product formulator or in any position in the value chain, you're either asking and sending requests for information or receiving them. It really emphasizes the need to be aware of virtually every chemical component in the products that you market, sell, and receive, and that is not going away. The pressure on businesses is quite intense right now, and this new reporting obligation that EPA has proposed makes it all the more important to be aware, even the inclusion of presumably trivial levels. There's no *de minimis* exemption here.

**REE:** There is not a *de minimis* exemption, there's not an impurity exemption, and there's not a small business exemption. You are absolutely correct about going forward. The problem is this is a retrospective reporting rule. Last year you weren't asking for those records, so you don't know. You may know that there was a PFAS. Maybe you're a furniture retailer and you imported a sofa that had some stain-resistant coating on it. And that's all you know, so you might be subject to reporting, but might not be able to provide any more information to EPA than a vague sense that there was a coating on this, and that's all we know.

I think it's going to be a real challenge, first of all, to reach these folks that don't think that they're subject to TSCA and then help them understand what their reporting obligations are, what the expectations are. What sort of information is EPA going to get? Is EPA going to get meaningful information that's going to be useful in figuring out what has happened in the past ten years? I think that's a different calculus than going forward and expecting people to have better line of sight in their supply chains. Perhaps this is the signal that going forward, EPA is going to be expecting more or more frequent reporting on PFAS in substances and mixtures and on articles.


©2023 Bergeson & Campbell, P.C. All Rights Reserved

**LLB:** Just for the sake of anyone who might be concerned about a sofa that they imported from Italy recently or within that last ten-year period, this reporting obligation applies to import for commercial purposes, not for personal consumer uses, right?

**REE:** That is our understanding. We kicked that around over the weekend. It appears that if you were an individual that ordered something that was imported, the individual doesn't have that obligation because the individual did not import it for a commercial purpose.

**LLB:** I wonder if EPA intends to engage in any kind of community outreach. I recall in our discussions earlier this year with regard to the PBT, and in particular the PIP (3:1) rule, I think EPA was a little understandably grumpy when everybody pushed back when the compliance date was March 8 by saying, "But wait a minute. We proposed a rule in 2019. Why didn't you focus on it then?" And to your point, Rich, this is a *retrospective*, a look back. And so whether people have this information or there's anyone they can ask about it, this is a very different regulatory creature.

Part of our desire to have this podcast is to put people on notice now that this rule is coming and there's a really important and valuable opportunity to help EPA discharge its obligations under the National Defense Authorization Act, which requires that EPA issue this PFAS data call. Section 7351 of that act added TSCA Section 8(a)(7) to TSCA, and hence this reporting rule, and also to help EPA identify more precisely. How can the information it is compelled to seek under the rule really align with what drove the reporting obligation from the get-go? I'm struggling with aligning the data elements with how it will help EPA in addressing its PFAS Action Plan. And that's probably an area that people may wish to comment on and also seek opportunities for the reintroduction of some of the historical exemptions from reporting that we have come to know and respect, like *de minimis*, and article, and byproduct, and impurity, and small business. Any other thoughts that you have, Rich, on what people may wish to comment on between now and the **end of August**? [*NOW comments are due **September 27, 2021**. See more information at top of transcript.*]

**REE:** As I've been digesting the rule over the past few days, I'm trying to find the balance between understanding the majority of the PFAS in commerce and asking for every last possible PFAS manufacturer or importer without any of these exemptions. And how much of that information -- for the burden that this rule, as proposed, will put on a huge number of potential reporters -- I think it's disproportionate to the information that EPA will receive. Some 80, 90, 95 percent of the information is probably going to come from less than 20 percent of the potential reporters to this rule. How does EPA strike that balance to get at the majority of the potential risk from PFAS, to find out what those substances are or what the conditions of use are, and not putting a tremendous burden on everybody else that is really a minor contributor?

Part of the challenge is that articles might be significant contributors in the past, but importers don't necessarily know because they were never required to ask or look. It's not that it's not an important potential source of PFAS in commerce, but the records may not be there to provide any insight.

**LLB:** Let me ask one question, too, about the identification of the PFAS in the *Federal Register*. There are over a thousand, and as you noted earlier, it's not an exhaustive list, it's an illustrative list, and there may well be others.


©2023 Bergeson & Campbell, P.C. All Rights Reserved

In other offices of EPA, there's been some talk about categorizing the large community of chemicals known as PFAS, starting with perhaps the five Organization for Economic Cooperation and Development (OECD) categories. There has to be some effort to identify PFAS that might be presumptively riskier than others. The fact that you fall into a category of PFAS doesn't necessarily reflect any particular hazard associated with that chemical, right?

**REE:** That's true. There's a very wide range of hazards among the PFAS, even within the categories as EPA defines it, which is at least narrower than all per- or polyfluoro substances. Yes, there's an enormous distribution of properties and hazards. Part of the point of this rule is to understand what that universe is. The breadth of this is really quite astonishing.

**LLB:** Right. There are opportunities for broad EPA communication as to what the reporting rule includes and doesn't include, and trade associations and others who are presumptively likely to be caught in this reporting obligation may wish to reach out to their members so we can all provide EPA with information that is helpful and responsive and not burden the Agency with information that is unlikely to elicit any meaningful regulatory response. EPA has to sift through this stuff and make sense of it. And I know now, based on my second read of this somewhat lengthy proposal, I am still struggling to understand how EPA can reasonably go from getting the information under this Section 8(a)(7) reporting obligation to translating it into something that will be helpful for its mission in achieving its PFAS Action Plan.

**REE:** I agree. I think the majority of data that EPA will receive under this -- if the full breadth of reporters are aware of their obligations and report -- I think EPA is going to get a lot of reports that have very little value that they're going to have to sift through and essentially set aside. They'll find that there is a relatively small number that contain the key nuggets of information. The health and safety information requirement, EPA could do that with a Section 8(d) data call-in. They would get a similar response. But EPA doesn't really have that option here. EPA's required to request that information under this rule. This is going to be tough for EPA because they don't have a lot of flexibility. It's going to be tough for a whole lot of reporters.

**LLB:** Maybe EPA will be, down the road, issuing a more traditional Section 8(d) data call-in. Who knows? But as you note, EPA must issue this proposed rule. It must issue a final rule by **January 2023**. I think we, as responsible members of the regulated community, should do everything we can to help EPA fashion a final rule that is sensible and elicits the information that the drafters of the National Defense Authorization Act were trying to achieve, right?

**REE:** Oh, yes.

**LLB:** There is going to be a whole lot of effort to elicit information that really doesn't move the regulatory ball forward at all.

**REE:** Yes, you make a good point. The commenters need to be aware of the statutory requirements that EPA is operating under, because if you comment that EPA shouldn't be asking for this information, EPA doesn't have that option.

**LLB:** That was my point exactly. Don't yell at EPA because it has a job to do, just like the rest of us. So let's try to be helpful and not unnecessarily critical. Any other words of advice, Rich, before we let you go?


©2023 Bergeson & Campbell, P.C. All Rights Reserved

**REE:** Please tell your friends about this. People really need to be aware, so tell your friends, tell your neighbors, tell your trade associations. We need to get the word out about this. There is no excuse on the regulated community to not weigh in at this point, given what happened with the Fees Rule and what happened with the PBT rule. We need to tell EPA what's involved and give them some constructive comments on how to frame this rule in a way that's responsive to the law but understands the limitations of what information might be available.

**LLB:** I will go out on a limb here and speculate that given the time of year that the proposal came out, June 28, and the **August 27** request for comment to be submitted by then, I guess it wouldn't shock me if somebody were to request an extension of the comment period, because the Agency does have until **January 2023** to issue a final rule. Summer is always a miserable time for people to be pulling comments together. Can't count on that, but it wouldn't shock me.

**REE:** Yes, and I hope EPA does spend more time and effort doing outreach. I think the industry codes they identified in the rule are woefully too narrow. EPA is aware of other uses of PFAS. They could include more North American Industry Classification System (NAICS) codes so that more trade associations -- that it will pop up in more people's radar, based on NAICS code if they monitor the *Federal Register*. There needs to be more outreach all the way around EPA and the regulated community to make sure that people understand the implications of this rule.

**LLB:** On that, Rich, I will let you go. Thank you. I hope our listeners find this helpful. We may even do a webinar on this proposal only because it's very important, not just for the elements that the Agency is seeking here, but more broadly, this whole concept of broader application of reporting obligations, narrowing of exemptions from TSCA obligations. This is a growing important issue of which many more people need to be aware than they are.

**LLB:** My thanks again to Dr. Rich Engler for speaking with me today about EPA's proposed PFAS reporting rule under the Toxic Substances Control Act. We hope this overview assists our listeners in understanding and perhaps commenting on this important proposal.

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

*All materials in this podcast are provided solely for informational and entertainment purposes. The materials are not intended to constitute legal advice or the provision of legal services. All legal questions should be answered directly by a licensed attorney practicing in the applicable area of law.*


©2023 Bergeson & Campbell, P.C. All Rights Reserved