Episode Title: PFAS under REACH -- A Conversation with Jane S. Vergnes, Ph.D. DABT®

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Lynn L. Bergeson (LLB): Hello, and welcome to All Things Chemical, a podcast produced by Bergeson & Campbell, P.C. (B&C®) a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I'm Lynn Bergeson.

This week, I had the pleasure of speaking with Dr. Jane Vergnes, Director of Toxicology here at B&C and Vice President, Scientific Affairs and Directory of Toxicology at B&C's consulting affiliate, the Acta Group, about the regulation of per- and polyfluoroalkyl substances (PFAS) under the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. Many of our listeners know the European Chemicals Agency (ECHA) released on February 7 its long-awaited restriction proposal for the regulation of PFAS in the EU under REACH.

The proposal is a monster. It's complex, far-ranging, and very consequential. The six-month consultation period is open until late September, and regulated entities on both sides of the Atlantic are urged to read and comment on the proposal. Jane and I cover a lot of territory in our discussion. We discuss the risk options ECHA considered, what it has proposed, some legal vulnerabilities with the approach ECHA has taken that commenters are discussing, and how best to prepare for the final restrictions, whenever they are issued and in whatever form. Now, here is my conversation with Dr. Jane Vergnes.

Jane, I am delighted you're back in the studio today. Thank you for being here.

Jane S. Vergnes (JSV): It's great to be with you today, Lynn.

LLB: I've been looking forward to this discussion. You and I have been talking about PFAS in many different contexts for a long, long time. But today we're going to talk about the European proposal. As you know, Jane, on February 7, ECHA released a restriction proposal for the regulation of an estimated some 10,000 or so per- and polyfluoroalkyl substances, affectionately known as PFAS. The consultation period began on March 22 and will continue for six months. We've been talking about this now for over a month. The sheer

magnitude of this regulatory action is truly exceptional. Perhaps you can set the stage for our listeners with respect to the restriction process under the European REACH regulation, and consider starting with how PFAS is defined in the restriction proposal.

JSV: Sure, I'd be pleased to. PFAS is defined very broadly. The definition that's being used by the EU is the 2021 OECD [Organization for Economic Cooperation and Development] definition of any substance that contains at least one fully fluorinated methyl (so a CF_3) or methylene (a CF_2) carbon atom without any hydrogen, chlorine, bromine, or iodine attached to it. In general, this defines the group. This definition was never intended for regulatory purposes. It includes fluoropolymers, monomers, fluorinated gases, and so-called future chemicals, basically chemicals that have not yet been innovated but that satisfy the criteria for PFAS.

This is being done to avoid what in the regulatory community is considered to be basically unfortunate or inappropriate substitutions. We don't want to go -- they don't want to have any substitutions of these substances with similar substances that have the same problems. But as you know, ECHA included over 10,000 chemical substances in this definition, while the OECD document identified about 4,700. There is an enormous difference in scope in the EU, and this may in some cases be related to the inclusion of not only the substances themselves as they're in commerce, but also some of their degradate product substances.

The PFAS restriction proposal illustrates both the traditional processes under REACH for regulating chemicals and also the deployment of approaches that are aligned with the EU's Chemicals Strategy for Sustainability to achieve the goals of the Green Deal, including its restrictions roadmap. The essential use concept is expected to be a very key element of the analysis by ECHA's Socio-Economic Analysis Committee, their SEAC. As we go through this, let's talk about the EU's regulatory process, including the current six-month public comment period on the restriction proposal. Does that sound okay with you, Lynn?

LLB: Yes, I think that would be great just to kind of set the table on what the process is before going into some of the granularity of the approach. Thank you, Jane.

JSV: Okay. A restriction under REACH can either ban outright or limit manufacture, placing on the market, or use of a substance, either on its own, in a mixture, or in an article. This also includes incidental inclusion, in other words, where there's no intention, but because of the way something is produced, there are traces of it in the substance -- in whatever is put onto the market.

The restriction can be applied to a group of substances and can specify requirements for the use of the substance or its labeling. In the case of PFAS, the restriction proposal was developed cooperatively and jointly by the member state competent authorities of Denmark, Germany, the Netherlands, Norway, and Sweden. ECHA also has the authority to develop a restriction proposal. It's working cooperatively with the member state competent authorities on this Annex XV dossier. But it is interesting that this started as a member state proposal.

ECHA's Risk Assessment Committee, the RAC, appears to be aligned with the view of the five member states that these 10,000-some PFAS substances should be classified as very persistent "forever chemicals," chemicals that bioaccumulate; these chemicals are mobile, they're considered to be toxic to humans and the environment. ECHA and the five member states also appear to be of the view that there is no derived no-effect level (DNEL) or permissible exposure concentration in the environment. A non-threshold dose response model, in their view, should be used for the human health and environmental risk

assessments. It's the view of these five member states and ECHA that PFAS risk is not adequately controlled by existing or foreseen risk management options and that EU-wide action is necessary, two criteria that are essential for moving forward with a restriction.

Where are we in this process? At the end of the current six-month public consultation, ECHA's Risk Assessment Committee, the RAC, will have three additional months to prepare its opinion on whether the proposed restriction reduces the risk to human health and the environment. Then the SEAC, the Socio-Economic Analysis Committee, will have six additional months to prepare *its* opinion on socioeconomic impacts of the restriction proposal, or basically one full year from the beginning of the public consultation. Then after a 60-day public comment period, ECHA presents the RAC and SEAC opinions to the European Commission (EC) for a decision, and the EC consults with member states, this comitology process, and presents its decision for scrutiny by the EU Council and Parliament.

Then, after it goes through that process, there will be a vote by the EU Council and Parliament, and this isn't expected until after the 2024 parliamentary elections in the EU. We're not expecting that any approval of any legislation associated with this, any addition to what is in Annex 17 on the restriction list will occur until 2025. With approval of the Council and Parliament, it becomes law upon publication in the *Official Journal of the European Union*. This is the date of entry into force. It starts the clock on each of the proposed phases for implementing the PFAS restrictions. We might also note at this point that PFAS and PFOA [perfluorooctanoic acid] and the C9 to C14 perfluorinated carboxylic acids (PFCA) are already restricted under REACH and that perfluoroheptanoic acid and its salts were added to the candidate list for authorization in January of this year.

LLB: That was a terrific overview, Jane, and I want our listeners to just let it soak in for a minute, because we're talking about a truly, in my view, remarkable restriction proposal. I get that we're not looking at something happening next week, and 2025 may seem far off, but for many of us, it's literally right around the corner. We're talking about a class of substances of over 10,000. Interestingly, as you correctly noted, we're talking about future chemicals, chemicals that haven't yet been designed or commercialized, but fit the criteria set out in the proposal, to capture them.

I think also it's important to focus on what is thought to define the longevity of these chemicals. There's no derived no effect levels, no DNEL, no permissible exposure concentration. Pretty much, we're looking at as bad as it can get in terms of the tox assessment of these substances, as a class, right?

There are some in the community of lawyers and regulatory experts that are raising a threshold question with regard to whether the EU PFAS proposal meets the requirements of Article 68 of REACH. That article, as you know well, Jane, requires authorities to demonstrate, as a predicate to risk management, that a chemical poses an unacceptable risk. Risk, of course, requires the consideration of both hazard and exposure. According to some, the proposal in no way on a case-by-case chemical basis makes this showing.

As a class, these substances are believed to be very persistent and pose various other concerns along the lines that you enumerated, Jane, but these specific considerations are not necessarily recognized under the EU law as a hazard. In Article 68(1), for example, it explicitly states a substance must, and I quote, pose a "risk to human health or the environment," close quote. So the question remains, and it's interesting to me, as a lawyer:

Is this entire proposal legally sound, based on the explicit language of Article 68(1) of REACH?

JSV: These are really good points. It's unclear whether the legal construct that these five member states and ECHA have used to base this restriction proposal will withstand scrutiny. And again, that assumes that these proposals move through the regulatory process successfully and are added to the REACH Annex 17 restriction list.

You do raise some good points. I think it's important to understand that, in the view of the member states -- with which ECHA concurs -- that these substances do meet those criteria in Article 68. But you're right. I mean, as you noted, there is no DNEL, and that's based, really, on this understanding, or this assumption, that you can't derive a no-effect level, because -- basically, the argument is that, because of the behavior of these substances, because they are present in so many environmental media -- water, soil, sediments, they're being detected in breast milk -- that as time goes on, you're going to exceed any DNEL that can be calculated based on the existing data sets we have now.

That goes back not only to the criteria in Article 68, but we need to also understand that other articles of REACH come into effect here, particularly the criteria in Article 57, which is basically part of the authorization process but is relevant to this because it does establish the kinds of criteria for phasing substances out of commerce -- for basically not placing them -- not manufacturing, not placing on the market. We need to keep that in mind.

One of the questions in my mind is whether this matter is being handled more or less even-handedly, basically, whether this massive grouping, -- this is a huge group. The read-across and modeling tools, whether the way the member states and ECHA are using these tools -- is comparable to -- are they setting the same criteria for themselves that they're setting when registrants have to produce information on substances and use these tools? In other words, are the member states and ECHA in their substance evaluation, as they come to this restriction proposal, taking liberties that they would not permit in terms of what they allow in terms of grouping and the evidence that they use for being able to establish these groups, as well as their modeling tools, these alternative methods that they're using? I think that that's one of the things that certainly the registrants have the obligation, whenever they register a substance, to demonstrate -- that it's not going to have adverse consequences on human health and the environment -- whereas the member states and ECHA, in implementing REACH, have the obligation to ensure that there is no adverse impact on human health and the environment, not only under the REACH regulation, but also, basically, under the precautionary principle that's embedded in the EU Treaty and underlies all of these activities as well.

LLB: That's a really good question, Jane, and some would argue that ECHA and the member states are not being even-handed. That's one of the core concerns that has been raised repeatedly in this process and I'm sure will be noted extensively in the comments submitted during the consultation period. What is so difficult for me to get my head around is the utter absence of speciation here: Not all PFAS substances share the same risk profile, and yet this conceptual approach -- this ginormous binning of 10,000 or so (and counting) substances are going to be treated similarly, irrespective of evidence to the contrary. That's just a difficult concept to get around, since it's so anathema to the way we here in the United States under TSCA approach chemicals pretty much on a chemical-by-chemical basis, and when there is chemical categorization as chemical categories are identified for TSCA Section 5 purposes, it's based on years and years and years of data that have been extrapolated and have given EPA sufficient comfort that these chemicals are so well researched and so much is known

about them. There's a comfort level in taking certain liberties and assuming new chemicals falling in this class of substances will behave in a particular predictable way. Not so here, under this approach. I know you're going to say something, Jane, so I'll let you respond.

JSV: Okay. I don't disagree with some of the points that you've made. The counterargument is that basically, here again, we go back to the discussions about DNELs and PNECs [predicted no-effect concentration with no adverse effect]. Essentially, you're right that there is no way that there is substance-specific information on this host of 10,000-some-odd substances. No way that that exists. Essentially, the argument that's being made -- and this is done, you are aware of that, in the EU, the grouping concept is more prevalent. When we're looking at substances that are targeted for and are put on the candidate list or nominated as substances of very high concern (SVHC) and evaluated for advancement to the candidate list, there is this grouping concept that once you have a bad actor identified that that sort of starts a grouping concept. We've seen this happen with substances containing lead, chromates, other substances, and that this is more prevalent under the EU's model than it is under other regulatory models, other frameworks.

A number of the points they make here are this lack of a PNEC or a PNEL [predicted no-effect level with no adverse effect] and the use as a surrogate, what they're using as a surrogate of exposure is measurable concentrations in environmental media. Some substance-specific or use-specific information is available for some of these compounds, but not all. And here again, they are taking a precautionary approach and saying, "One of our problems here is that because some of these substances may not even qualify for registration under REACH -- they may be present, but because of the way they're present, possibly as components of articles, presence in mixtures at very low concentrations, there may not be this requirement to register them. They may be present at less than a metric ton per annum." If you don't need to register them, but we know they're in commerce and we know that they're accumulating in our environment, it's this argument that we need to do something, and we need to use the tools that we have available.

Based on the analysis that these member states have conducted, what they're saying is based on what they know about measured environmental concentrations of substances in this group as a whole -- the propensity to bioaccumulate, also this persistence -- that they're using these concentrations as worst-case measures of exposure. So in their view, it's, "Okay. We already know that in worst case, these are the human health effects. Worst case, this is what is happening from the perspective of both persistence, bioaccumulation" -- and now also they're talking about the mobility in the environment of these substances, particularly if substitutions for smaller molecules, not as the long-chain links, which enhances their mobility, particularly in aqueous media. All of these things are coming into play, and I don't disagree that this is challenging, that it is an unprecedented use of these grouping concepts. It's going to be interesting to see how this moves forward, both through the process in the EU, but also what challenges may occur. We have some insight into that, based on decisions that are being made, but also legal challenges. But it's going to be interesting as this plays out.

LLB: Indeed. Well, let's pivot, Jane, to kind of a drill-down to the broad outline of the proposal. As we noted, it was released publicly in February. The comment period began on March 22 and will close in late September, I think the 25th. To my eye, the proposal seems essentially to be a total ban of all PFAS, with specific use derogations and certain exemptions. I know ECHA considered a couple of restriction options, or so-called ROs. Can you help our listeners understand the difference between the two ROs that were considered and provide some insight into why the ultimate approach was selected?

JSV: Sure, I'd be pleased to. As you know, there were two ROs proposed, but only the second, what's called RO2, has been included in the current public consultation. The first, RO1, was, as you note, a full ban restricting manufacture or placement on the EU market 18 months after the restriction would enter into force, meaning 18 months after publication of the addition to Annex 17 of these substances in the *Official Journal of the European Union*. Just so that we're all on the same page, placement on the EU market means a ban on the supply, whether for payment or free of charge, of the substance to an external party, on its own, as an unintentional constituent in a mixture, or in an article at concentrations above those specified in the restriction.

RO1 has not been included in the current public consultation because of its extremely adverse socioeconomic impact. It was recognized right off the bat that there was no way that the potential adverse consequences, including on human health, that the numbers of, for example, medical devices that might be regulated out of the market would be very problematic, in addition to a number of other critical technologies that would suddenly have to leave the market or be phased out within that 18-month timeframe. RO2 is a longer term approach, but it acknowledges that a full ban 18 months after the PFAS restriction enters into force would have socioeconomic consequences that would not only impact the EU economy adversely, but would also have had adverse effects on human health and the environment.

RO2 also restricts at 18 months after entry into force manufacture or placement on the market of PFAS for which alternatives are known and can be available in adequate quantities within that timeframe. The 18-month phaseout period includes about 29 sub-uses of the approximately 78 sub-uses that are included in the Annex 15 document. If a use is not included specifically in a proposal, the ban will apply after that 18-month transition period. But some of the uses that are targeted for this 18-month timeframe include uses in cosmetics, consumer cookware, food contact uses in things like wrappers, paper wrappers and paperboard that may be used, for example, sold to consumers in fast food or other purveying of food to consumers. Things that are not considered to be essential, like -- one of the examples that has been used in public communications from ECHA and the member states are things like snowboard waxes, things that are not considered to be essential uses or uses where there are alternatives. This would also impact some textile and basically consumer use for the home products.

This five-year derogation option, which would mean about 6.5 years from the entry into force of the restriction, is for uses where alternatives are lacking, but they're technically and economically feasible and there is sufficiently strong evidence that they can be developed and deployed available in sufficient quantity within that five-year derogation period, that 6.5 years from entry into force.

There is also another ban, a 12-year derogation, so for a total of 13.5 years from entry into force, in cases where there is sufficiently strong evidence that technically and economically feasible alternatives are *not* available in the near future. In other words, research and development is essential, and this also includes uses that require further development and scrutiny because they may need certification or regulatory approval. That's not going to -- it's infeasible for that to happen within the five years. There are some time-unlimited uses, and those are principally active substances that are regulated in other ways, for example, plant protection products, biocidal product actives, and human or veterinary products. So here again, uses that are outside the scope of the REACH regulation where active substances in these types of products are regulated under other regulations. And according to this

proposal, specific, well-defined, fully degradable PFAS subgroups will be excluded from restriction.

LLB: I think our listeners, Jane, given that very, very good overview, are beginning to appreciate, if they have not already, how important it is to comment on this. We're looking at five-year derogations and 12-year derogations, and these derogations are going to be based on record evidence along the lines that you suggested. There's sufficiently strong evidence that technically and economically feasible alternatives are in development.

Okay, so who's making that determination? Anyone with a dog in this fight, anyone that is dependent upon certain PFAS substances or manufacturing certain PFAS substances, will need to make, I think, some very compelling showings regarding how technically feasible alternatives either exist now or will within these five- and 12-year periods, which are very fact-dependent analyses. In making this showing for purposes of the comment, we're not going to go into in this discussion, Jane, just some of the reputational liability litigation, public perception, court of public opinion kind of considerations. These are just -- if you're in scope and you're manufacturing or relying upon a PFAS for a commercial product in the EU, there is a very strong incentive under the comment period to make these very specific record evidence demonstrations with regard to a phaseout period, because it's not a question of when; it's a question of what bin do you fall in? Five and 12 years, or to your point, 6.5 and 13.5, these are just very, very, very consequential determinations. The demand for record evidence is very clear. When you think that six months is a long time for a consultation period, it really isn't, given the enormity of the ask here and the very consequential scope of this proposal.

I know you agree with everything I just said, but I'm just really emphasizing the need for particularity, the need for record evidence, the need to make these showings in a relatively compressed period of time. In the United States, chances are, given our rulemaking process, there would be a much lengthier period of time to gather this information and present it in a way that meets these very high legal hurdles. September 25 is fast approaching.

JSV: That's true. I think we need to consider before we go and talk about some of the specific information that our listeners, if this affects them, can look at in the proposal and scrutinize carefully and decide how to respond is to backtrack a little bit. Let's consider that, in a situation like this, and here again, this process being directed by member states, which have both the authority and the obligation to do substance evaluation. This also means that a member state, if it believes it's important, it's necessary for it to meet its obligations under REACH and other regulations to request information that goes beyond the information data set that's outlined in Annexes VII through XIII of REACH, those data requirements. It has that authority. Here again, how does that feed back?

Let's say you're in a situation where you have a registered substance. If that registered substance is -- and it will be included in this group, and it hasn't already been dealt with under an existing restriction, hasn't been advanced to the candidate list for authorization, you may not have been asked to provide the kinds of granular information that both the Risk Assessment Committee and the Socio-Economic Analysis Committee, the RAC and the SEAC, will be considering, because when the input from this public consultation is integrated, here again, the next step in the process will be to take this back to ECHA's RAC and SEAC. And each independently goes through its process for evaluation. The process for restriction, when you really look at it, the elements aren't really different from what the RAC considers when it's doing an authorization. It's a very deep dive into information about risk, both the hazard profile and the exposure profile. Here again, the RAC is going to

be using environmental concentrations as surrogates for exposure. But that's its mission, and it will come out with its opinion. The SEAC, the socioeconomic analysis -- and here's where we get to some of the elements that are in the current proposal: the difference between how does something become proposed, as opposed to a potential derogation, and what is being considered. Because the big-picture overview is that -- the bottom line is that there is unlikely to be any deviation from the position that from the hazard and exposure potential, from the risk perspective, from the RAC perspective, these substances are going to be considered to be risks to human health and the environment, not adequately controlled -- not available, not able to be adequately controlled.

Then we pivot to the socioeconomic analysis. And here again, when you look at -- it's important for our listeners, if they are interested, to review Table 9 in this document, because there you will find binning of proposed, meaning that the strength of the evidence is sufficient to warrant a derogation, as opposed to potential, meaning that the evidence isn't strong enough to consider it to be proposed for either the five- or the 12-year bin, that it might in fact be in that 18-month bin, but there isn't enough evidence. This really is an opportunity during the public comment period to present specific evidence to support a derogation and to influence the decisions of or influence or to provide information that the SEAC will consider as it looks further at these socioeconomic consequences, and what it means. Are there going to be adverse impacts on human health or the environment if certain derogations are not permitted, or not for long enough?

LLB: That's an excellent point. I appreciate you describing the difference -- the important difference -- between a proposed and a potential derogation. In addition to our listeners and others providing comment during the consultation period on that aspect of the proposal, what other suggestions might you offer regarding how to prepare for this, I think, unprecedented proposed restriction on PFAS substances?

JSV: It's really important. The Annex XV dossier on this proposal is very detailed. It's available online, and ECHA has stated that it intends to update it with the comments that are being submitted on a monthly basis throughout the comment period. I think that's important to keep in mind, so this isn't just a one and done. You're able -- or should be able to if other processes follow -- to view what's being submitted for public availability. It's important, if you are interested, to prepare and submit comments according to the specific directions that ECHA provides. There is a form that's available; it has five parts, and we can talk about those specifically a little bit later.

It's important to know that you can't save your comments in the form. You have to look at it, know what you are going to put in and where in advance. Areas on which to comment include the legal questions that we've been talking about here. You can comment on ECHA's methodological approach and this grouping concept, the adequacy of the impact assessment. How has a particular PFAS of relevance to you been assessed? Is all the pertinent information in the record, including hazard and also the benefits? What are the consequences going to be if this is regulated out of commerce? Or is it feasible from your perspective for your use, for a substitution of the use that you have right now, to be substituted within the timeframes that are proposed?

It's complex. We know that, with other substances, where it hasn't been realistic to regulate the substances out of commerce, that restrictions or other things have been put into place to allow them to exist in the market. But here again, level of detail is going to be very, very important. It will be important for anyone to comment who wants to defend a substance, to really look at this almost as if they're preparing an authorization proposal. It's going to

require that level of granularity and data, quantitative if you have it, analytical methodologies. If you know of a method for detecting your substance or quantifying it in the environment, or from a biological perspective, in human tissues or fluids, provide that information; be granular; be detailed.

LLB: Excellent advice, both in terms of ensuring our listeners know that it's important to save a copy of that which they submit to the record because you can't save your comments in the form. I think people tend to forget that. Your stressing granularity, Jane, is important, but it raises a fundamental question regarding confidential business information (CBI). I'm presuming that CBI is recognized in the European context here and that you can assert information as CBI because with granularity comes a sensitivity to the type of information you're submitting, particularly with regard to the benefits side of the equation and not just the data side of the equation. So bottom line, can CBI be submitted on the proposal and if so, how?

JSV: Sure. Confidential information -- basically, here again, there are about five parts to the form, and Section 5 of the submission is for confidential information. It should be submitted separately as an attachment. Here again, make sure that the pages in the attachment are marked very clearly as CBI. This confidential information will be available to the ECHA Secretariat, the RAC, the SEAC, also the member state competent authorities, but it will not be shared with the public. There may be a time when one of those bodies comes back, whether basically ECHA acting in its role comes back and asks for permission to share certain pieces of CBI more broadly. But here again, that will be a request which it's your prerogative to grant or not.

LLB: Before we move back to this side of the Atlantic, I wanted to ask a question about what the status of PFAS regulation is in the UK. I know it's taking a slightly different approach, but do you have any insights there, Jane?

JSV: United Kingdom has regulated only PFAS and PFOA specifically to date. The UK's Health and Safety Executive (HSE) in April published a regulatory management options analysis, or RMOA, for PFAS under UK REACH. This RMOA acknowledges the need to address the concerns about impacts to human health and the environment, the information gaps that exist at present, and the regulations currently in effect that can be deployed now to manage the human health and environmental risks. The UK RMOA also considers actions being taken at the international level under the Stockholm Convention on Persistent Organic Pollutants.

The UK is taking a slightly different perspective. It does not want to put into effect measures that will be addressed at the international level under the Stockholm Convention. It is taking a more measured approach. It acknowledges that this is an issue. It does not disagree at this point in time that there are risks to human health and the environment and that the current measures aren't adequate to control these risks. It doesn't differ from the EU in that perspective, but how it intends to approach it and how it outlines current measures in UK regulations and in the regulations both in Great Britain and Scotland and Wales that can be used to mitigate some of these effects now are available -- so it emphasizes that. But it is clear from the proposal that additional action under UK REACH is necessary.

LLB: Circling back to this side of the Atlantic, and aside from our listeners both here in the United States and internationally, commenting on the EU PFAS restriction proposal, could you maybe give us some thoughts about what listeners might be doing to prepare more generally for PFAS regulation? We've got a lot of initiatives ongoing here in the United States, but

none of them is as holistic or as consequential, in my view, as what is going on in the EU. But if even if you are disinterested in what's going out across the pond, either in the EU or the UK, there are things that should be done right here, right now to prepare for the future. I was hoping you could just give us your insights on how best to do that.

JSV: Sure. Even if similar measures are not -- even if things are going to be regulated differently in the United States, I think we all acknowledge that once this type of communication is presented to the public, it doesn't stay in the EU, and there will be public perceptions that must be dealt with. Listeners with PFAS in their products, whether that is intentional or incidental or potentially present, for whatever reason, you should be conducting supply chain reviews to identify, quantify, and assess the need, functionality, and reason for the presence of the substance in the supply chain. With state and federal reporting obligations already here, there's going to be enormous pressure to deselect PFAS ingredients and reformulate. This is, in part, again, going to be driven by public perception. The risk of noncompliance, and as you know, Lynn, the possibilities of litigation are just too strong to ignore.

LLB: Indeed. And for those of our listeners that are interested in EPA's TSCA's [Section] 8(a)(7) reporting rule, many of us had thought it might be out on the streets and final by now. It is not. As we record here in May, we're now looking at probably later this year, certainly in calendar year 2023. But whether it will be in fiscal year before October or not, I think, remains to be seen. But as you note, Jane, there are just many, many, many pressures, some of them brought by the court of public opinion on the presumption that PFAS, at any speed, any speciation, any amount, in any product anywhere, ought to be avoided. I'm not sure I agree with that. I'm not sure my view is relevant, because we do see just a tsunami of litigation ongoing in the United States because we take things a little bit differently. Rather than waiting for regulatory or scientific analysis, we have now a whole spate of state consumer protection litigation ongoing and all kinds of litigation generally in a number of jurisdictions, some of which has been ongoing for years now. But it's really picked up the pace considerably over the past 12 to 18 months.

For those of our listeners in this space, stay tuned, read the EU proposal very, very carefully and comment on it as appropriate. Perhaps work with your trade associations, watch our PFAS page on our website. We try to capture a lot of these initiatives to make sure everybody is aware of this very fast-changing scene, both in the United States and, of course, in the EU and in the UK.

We hope this has been helpful. I found your remarks, Jane, super helpful. I know you're going to be very busy for the remainder of the summer working on these types of issues for our clients. Any parting comments you'd like to make before we say goodbye?

JSV: Just thank our listeners for listening. And as Lynn notes, public perception is going to be a huge driver here. One of my challenges has always been, particularly to business and technical people, explaining that sometimes data don't matter. Sometimes public perception is the driver. This opportunity to comment is a huge opportunity to advocate for your substances, and particularly to point out what the consequences -- adverse consequences to human health and the environment -- might be if the restriction proposal for your substance, for your use, follows the proposed course for restriction in the EU.

LLB: Great advice, Jane. Thank you so much, and thank you for being here today. It was an excellent discussion, and I very much appreciate your perspective.

JSV: Thank you so much for having me.

LLB: Thanks again to Jane Vergnes for speaking with me today about the proposed EU PFAS restrictions. The proposal is extremely consequential and could well set the tone for similar programs elsewhere around the world.

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