Episode Title: CLP Changes -- A Conversation with Lee Bowers and Karin F. Baron

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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 Lee Bowers, Vice President, Environmental Health and Safety (EHS), of RPM international Inc. and B&C's own Karin Baron, Director of Hazard Communication and International Registration Strategy, to discuss the consequential changes to the Classification, Labeling and Packaging of substances and mixtures -- so-called CLP -- system in the European Union (EU). As many of our listeners know, in April of this year, 2023, the European Commission (EC) entered into force significant changes to the CLP Regulation. The real-world impacts of these changes are now being felt in a host of commercial transactions. These challenges arise because of the lack of alignment between CLP and the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), which may sound less urgent than it is, but Karin, and I, and Lee have been beating the drum on this for a long time now. Today we're going to talk with Lee and Karin about real-world actual instances of how these challenges are bearing out in commercial transactions. Our hope is that you will find these case studies and real-world instances really helpful. Now, here is my conversation with Lee Bowers and Karin Baron.

Good day, Lee, and good day, Karin. I am just so thrilled you're here in the studio to talk to me today about CLP.

Karin F. Baron (KFB): Good morning. Thank you, Lynn.

Lee A. Bowers (LAB): Morning. Morning, Lynn, Karin. Thanks for having me join you.

LLB: We're going to have a great discussion. Let's start with you, Lee. You are Vice President (VP) of EHS for RPM International, which is a huge multinational corporation with an exceedingly diverse portfolio of operating companies. I know from our work with you that operating companies are organized roughly into four operating groups. As its VP over this sprawling empire of consumer and industrial products, you are challenged, in my view, as I

witnessed over the years, by a daunting diversity of issues. So first, can you tell us just a bit about your background and then help our listeners learn more about the scope of your responsibilities as they relate to our context of our discussion on CLP.

LAB: Sure. Thanks, Lynn. First off, I appreciate the opportunity to participate in the podcast today. I've been with RPM for 25 years now, serving in various EHS and regulatory management roles at Stonhard, RPM Performance Coatings Group, and now heading up our Center for EHS and Chemical Regulatory Management functions globally for RPM Corporate. In addition to my regulatory experience at RPM, I also served as an adjunct professor at Saint Joseph's University in Philadelphia for six years, where I developed the curriculum of a new graduate level course on global chemical regulations and compliance management. RPM is a Fortune 500 parent company of a diverse collection of subsidiary brands, who are leading manufacturers of coatings, sealants, and construction products serving both the industrial and consumer markets globally. This diverse and global business model inherently presents complex regulatory management challenges for our product stewardship and EHS managers. As you mentioned, the myriad of issues, I consider them a myriad of opportunities.

LLB: Well, always positively, and that's a great way of looking at it.

Karin, you need no introduction. You've been on the podcast many times, but just to refresh our listeners' recollection, maybe you can explain all of the things you do as they relate to CLP and GHS.

KFB: Absolutely. I am currently the Director of Hazard Communication and International Registration Strategy with B&C and its consulting affiliate, The Acta Group (Acta®). I have been dabbling in the world of hazard communication [HazCom] for --

LLB: Dabbling? Really, Karin? Not really.

KFB: Dabbling (laughter) -- for about 25 years now. I've seen a lot of change, a lot of evolution in the space over the last 20 years. When you talk about one, CLP to begin with, it was introduced in 2008, and I remember being part of teams that were implementing CLP. And then as we talk a little bit more today, we're going to talk a little bit about UN [United Nations] GHS [Globally Harmonized System of Classification and Labeling of Chemicals], which came onto the picture around 2000, 2001. It's just been a really interesting time to be part of this space, just to see how countries are implementing GHS, just to see how now we're going through a lot of revisions of GHS, and then just to see how the UN Subcommittee is managing it, and now just seeing how the EU is diverging from it.

LLB: Much to everyone's consternation.

KFB: Yes, it is definitely -- I always tell people I have a lot of job security.

LLB: You two are on each other's speed dial, I know, in no small part because of what happened on April 20, 2023, when the EC entered into force and effect these very significant changes to the Regulation of the Classification, Labeling and Packaging of Substances and Mixtures (much easier to say CLP).

Karin, you and I spoke in October about the context of these revisions, but now they are right here, right now, in your face, and incumbent upon people to start implementing those

changes. Maybe you can provide our listeners with just a very brief overview of some of the more critical changes to these regs.

KFB: Yes, absolutely. When we talked about this in October, we were talking about what we felt was a lot of silence from stakeholders in commenting about these changes. And then to see from October to April it already being entered into the delegated regulation, with little to no change, with what we were discussing in October, is fascinating to me.

But essentially what they have decided to do -- and we've spoken before about the EC's Green Deal, about the Chemicals Strategy for Sustainability. The incorporation of these elements into CLP -- and I'll tell you a little bit more about what they are -- is a big part of that Chemicals Strategy. What they have opted to do, instead of waiting to try to maneuver this through the UN GHS Subcommittee, they have gone ahead and added six new hazard classes directly into CLP that are not part of the UN model.

One is being added to the health effects, and that's endocrine disruption for human health. Then the remaining five are a heavy focus into Part 4 of CLP, which is environmental hazards. We're going to add endocrine disruption to the environment, and then we're going to incorporate some elements from REACH [the EU's Registration, Evaluation, Authorization of Chemicals regulation]. So while they look foreign to CLP, the addition of persistent, bioaccumulative, toxic (PBT), very persistent, very bioaccumulative (vPvB) is actually a REACH element that is being added into CLP. Then we're going to add an entirely new element that was *not* part of REACH and not part of CLP, obviously, and that is the concept of persistent, mobile, and toxic (PMT) or very persistent and very mobile (vPvM).

It's more than just adding these hazard classes. In each hazard class, you have to describe the criteria for classification, because CLP is not a testing driven legislation. It's meant to be a criteria-based approach where, using weight of evidence and expert judgment, you should be able to take your substance and then determine whether it's classified or not. You incorporate definitions, you incorporate categories -- for endocrine disruption, for example, we have a Category 1, which is known, Category 2, which is suspected. You incorporate hazards statements, you incorporate new hazard statement codes, precautionary statements, signal words. It's very large, and I think that's the part people don't appreciate. This is a significant thing. They're adding six entirely new -- for lack of a better word – like, chapters into this already incredibly complicated piece of legislation.

LLB: And before I pivot back to Lee, I know these changes present some implementation challenges. Can you just briefly describe the timing for these changes and the expectations this sets for entities that are subject to these regulations?

KFB: Absolutely. I will just tell you what's on the EC website is a little bit confusing, and I actually found it easier to go into the delegated regulation and read how they wrote it.

LLB: Really?

KFB: Because that's -- it just -- the chart that they put up there, it seemed like, what are they saying? Essentially, it is enacted now. The new rules are in force as of April 20, but that doesn't mean everybody is subject to the new rules. The reason that they entered the new rules into force now was to allow member states, as part of the classification and labeling harmonization process, the opportunity to start to use them now. We could start to see harmonization activity for substances with these new hazard classes at any time.

The transition period, they split it, which is what they did with CLP as well. They recognize that it's pretty complicated to begin with, so they split between substances and mixtures. They did this before, and primarily the goal of that is to allow mixture manufacturers an opportunity to see how the substances they're formulating with are classified, because with each of these categories, we have incorporated mixture thresholds, so if your substance is classified as an endocrine disruptor, Category 1, and you're formulating with it at 0.1 percent or greater, then your mixture is going to be classified as endocrine disrupter, Category 1. I think that was also part of the consideration. Essentially, anything that was placed on the market -- and here I know I get that question a lot: "What does placed on the market mean?" If you supply it, or you make it available, whether in return for payment or not, to a third party, you have placed it on the market. And consider that means within the EU -- remember where you're selling --and then that's also importation.

Anything placed on the market before the transition period begins has an extension, so that's where it gets a little sticky. The transition period for substances begins May 1, 2025, so roughly two years where you're enjoying an opportunity to place substances on the market. But once that transition period begins, if you had it on the market before, then you have another 18 months. We can kind of look at this as all in by November 1, 2026, for substances.

LLB: Got it.

KFB: Similarly, for mixtures, we have 36 months, so they're giving another year beyond. From now until May 1, 2026, there's a transition period, so anything placed on the market in a mixture before the transition period kicks off has until May 1, 2028. But just be aware of that May 1 deadline, because regardless, if you did not place it on the market before May 1, 2025, then you would be subject -- May 2 --

LLB: Right. 2025, not 2028.

KFB: Exactly. It's really important to have an idea with your marketing and your sales folks. We ran across some issues with some clients in the past where if you -- say, you rebrand a product, it's -- you could be essentially triggering an earlier obligation because of that rebranding, because it would look like that material, that product name, has not been on the market before. Just consider some of that, too, when you look at these transition periods. And it is; it's complicated. To me, it feels -- I think everybody is going to wait until the last minute, but that's just me. Lee's much more positive than I am.

LAB: Karin, I'm writing down right now a note to all of our companies in Europe: No rebranding for the next three years.

LLB: Lee, I was going to ask you about mergers and acquisitions, because I know RPM has grown just exponentially by acquiring, and developing, and innovating, so I would imagine that these deadlines are now very important in that context as well.

LAB: Absolutely. It's complex, obviously, and this was fast-tracked by the EU Commission, and it's not 100 percent flawed, but it's certainly not going to be an easy lift for any of our businesses doing -- having operations or sales in Europe, or manufacturing in Europe. But the key thing is knowing the staggered timeframes, knowing what you have to comply with -- and we manufacture both substances *and* mixtures, so we've got that complexity to deal with. And then yet, you're relying very heavily, frankly, on your supplier base to also meet the timeframes and update their safety data sheets (SDS) and HazCom so that we have the

latest information available from our suppliers to review and apply to our own regulatory database management systems so we can update labels and SDS in time for the mixtures. It's complex and certainly a heavy lift, especially for an organization as diverse as RPM.

LLB: Exactly. You're very used to complex legislative initiatives, and your beat, Lee, is, of course, global. But to my eye, these CLP changes -- or amendments to the CLP regulation, even with what some might regard as a generous phase-in period -- which I would disagree with; these 2025, 2026, 2028 deadlines sound like tomorrow. This strikes me as one of the more complex pieces of legislation. It's infused with an element of science, too, like what is an endocrine disruptor? How do you know if your product is? How do you balance the need for regulatory precision and compliance with also just acclimating yourself to fundamentally new concepts like endocrine disruption and "very persistent and very mobile." That's a pretty tall order.

LAB: It is. It is, and having the right team of experienced, knowledgeable regulatory professionals, product stewardship professionals, to weed through all the information that's coming, not just from the regulators -- in this case, the EU Commission and ECHA (the European Chemicals Agency), but also all the information coming from our suppliers and other stakeholders to make sure that we're interpreting the data correctly, we're applying that data to our own systems in HazCom and SDSs and labels downstream -- it's difficult. And although important to not just meet the requirements, but also provide the most accurate information to our customer base, we also have to make sure that we're providing the best information, the most accurate, and not putting junk in, junk out. We've got to make sure that data is correct.

LLB: Do you anticipate amping up your communications team? Because a lot of this is hazard communication. It's not just acclimating your own internal operations and protocols, but also being prepared to address your customer inquiries. I would imagine that places a burden on you as well.

LAB: Absolutely, and training the folks that deal with the customer base to understand the changes is also a big portion of the responsibility that our regulatory and product stewardship managers have, specifically in Europe, handling the new amendments to CLP here. This will happen over -- as Karin pointed out -- the next three to four years, as substances, and mixtures, and new formulas, and inventory that was already on the market. As we go through this implementation to make these changes, a large portion of our responsibility is making sure our customers understand what's this new information, and what's it mean to them. There certainly will be concerns as they're learning about endocrine disruptors and persistent, mobile environmental hazards, probably for the first time.

LLB: Exactly. Karin, transitioning to a really important and complex aspect of these new CLP regulations is the interface with the Globally Harmonized System of Classification and Labeling of Chemicals, GHS. You and I have spoken often -- and you in particular, passionately -- about the non-alignment with some of these CLP regulations. What issues does the introduction of the non-GHS element bring to parties that are subject to these regulations?

KFB: I haven't been shy about this.

LLB: No, no.

KFB: No. Listen, I don't want to just pick on the EU because when I've given talks about this topic in the past, it's not just the EU who's guilty of incorporating non-GHS. The United States did it as well, so we can't necessarily say one or the other. They are incorporating elements that are strategic parts of their framework.

I guess my only issue with the introduction of these particular elements is that they are incredibly complicated. There isn't a uniform alignment or agreement globally on these terminologies, these definitions, these criteria, and that when they brought it to the UN GHS Subcommittee a couple of years back, I believe, there was this, I guess, understanding from the Committee that they themselves were resource-strapped, and trying to incorporate these would take a significant amount of time. When you look back at the work that the Committee has done to try to make a harmonized system, and then you look at the EU, who just basically said, "We're going to take it to the Committee," but the Committee was admittedly indicating that they just didn't have the resources to incorporate all these the way that the EU wished for it to be done, in the timeframe that the EU wished for it to be done. And the EU then just opting to add them to CLP with this -- what you and I would both agree is a bit of an aggressive timeline -- just creates so much confusion for interested stakeholders. Because now you really are going to have companies who were already struggling to comply with CLP. Let's just be totally honest and blunt. CLP has to be one of the most difficult UN GHS adopted type pieces of legislation. And now you're adding layers of complexity and concepts that are just --

LLB: And new concepts. Yes, that's what gets me.

KFB: Yes, new concepts that folks just don't particularly comprehend and don't agree on, on the science front. It's not like we all agree how you're supposed to define an endocrine disruptor. That's not true. We don't. We don't know. If we did, we would have seen more harmonization occurring at a UN level. I definitely see this as creating further disconnect. And I'll just make one point with this in that -- unlike OSHA's [U.S. Occupational Safety and Health Administration] HazCom standard, which is only applicable to workers, and employers, and employees -- CLP is a consumer legislation, not just workers --.

LLB: Right.

KFB: -- so the CLP legislation also applies to consumer products. So you're going to start to see new mass confusion on the consumer level when these elements start showing up on -- I don't know, I'm just going to toss it out there -- your sunscreen, or your paint!

LLB: Yes, really common products that are popular among consumers. It's going to be rough. It's going to be rough.

KFB: While there are exceptions to certain things within CLP, just like there are under REACH, there are always going to be products that are placed on the market that are consumer, where we're going to find people now asking questions about why it's classified as "May cause endocrine disruption in humans" and what that actually means. I think it's just -- I think it's going to be problematic, and I think that -- I just believe that this is just going to create more confusion for just folks who are trying to comply. I don't believe anybody purposefully does not comply, just leave --

LLB: No, there's no misdirection.

Yes. When you add this level of complexity to a system that's already pretty complicated, you're going to get errors.

LLB: Lee, you are in the trenches. You have these four operating divisions, and you've spanned the entire commercial horizon: consumers, industrial customers, B2B [business to business], B2C [business to consumer]. What are your thoughts on trying to manage some of the disconnects that you can anticipate and those that are probably the unintended consequences of a piece of legislation as massive as this, and managing multiple product lines in multiple geographic regions? It's one thing to comply with CLP, but it's kind of like squeezing a balloon, right? If you're changing something in Europe to comply with that, you've got global implications. Are you quietly freaking out right now?

LAB: No, no, no, it's a good question, certainly a somewhat loaded question. As these disconnects pile up between national GHS adoptions globally and the differences with the EU CLP regulation being the most drastic example, frankly, in my opinion, it's important for suppliers like RPM and our peers to know the specific requirements in the markets they operate and the differences between those markets. This is especially true for companies that export to various global markets or *import* from those global markets. Communication with your supply chain stakeholders to ensure understanding of differences and hazard communication requirements in those markets and the appropriate classification labeling rules that are applied for each of the varying imports or export scenarios. That's key to staying in compliance with the ever-changing regulations.

We can't assume that what works in one market will automatically be accepted in the next. This is true actually in some Latin American and Asian markets. But even in Europe, labeling requirements in the Scandinavian countries differ from the rest of Europe and require additional elements. We have found that it's best to partner with local companies or firms for regulatory support in these varying supply chain scenarios to make sure we get it right. But they keep moving the target on us, and just trying to keep up is a full-time job for several folks in our organization. As you pointed out a couple of points ago, the hardest part is communicating this to our stakeholders, the customer base, and making sure we keep open channels with our suppliers.

LLB: You kind of have a secret weapon, Lee, because you're so rooted in REACH. You've been playing in that space for years, and there are other EHS-ers here in the States who are less familiar with REACH and the interface between REACH and CLP, and might be more challenged to anticipate the scope and breadth of these changes. You speak so eloquently, and you sound confident that whatever comes your way, you'll be there to meet the challenge.

LAB: Specifically with the CLP amendment, as Karin rightfully pointed out, this doesn't just apply to industrial commercial products. It applies to consumer products in the EU. RPM's got half a dozen large consumer brands that we market every day and sell and place in the market every day, new formulas and rebranded formulas in the EU. That communication to the stakeholders and to the customer base and just finding space on a consumer product label to meet all the requirements is a challenge.

LLB: Just a tiny little piece of real estate to work with. Some of these changes strike me as being very challenging.

LAB: Absolutely.

LLB: In that regard, I'd like to circle back to the E word -- endocrine -- because the revisions incorporate endocrine disruptors for human health and the environment into the classification scheme. As I understand it, this will require both elements to be noted on the SDS and the label, for both -- as you noted, Lee -- industrial and consumer products.

Karin, help our listeners understand what that means exactly in the real world. Can you provide an overview of these definitions for this hazard class? Because I know *endocrine* is a scary word, and I don't know if people are fully cognizant of the impacts of these label changes, both the consumer product label and the SDS.

KFB: This has a tale of woe that goes with it, Lynn. This is one of these really interesting concepts, because the way that they defined it in what's now CLP was a substance or mixture that alters one or more function of the endocrine system and then consequently causes an adverse effect -- and then they actually define "adverse effect" -- and that's whether that effect occurs in an intact organism, its progeny, populations, or subpopulations. But what's interesting about this is that the concept of endocrine disruption on the SDSs predates this change to CLP, meaning that the EU and the Commission decided back in 2020, when they amended REACH, to incorporate endocrine disruptions into the SDS. What they did -- and a lot of people, we often refer to CLP as, we talk about SDS and label with CLP, but it's actually -- REACH is where the SDS requirements are outlined. Annex II to REACH is where you find the SDS requirements.

With the changes to Annex II in 2020 -- which entered into force last December, so December 2022 -- you were required to include endocrine disruption in various sections of the SDS. There were Sections 2.3, 11, and 12. But because that definition didn't exist within the CLP regulations, they actually had to refer you to other Commission delegated regulations, so they referred you to a regulation from 2017 and another regulation in 2018. What's interesting now --

LLB: That seems to be circuitous.

KFB: It's kind of a big hot mess, in my mind, because one, now you've done the right thing here by -- CLP was always meant to be the key piece of legislation that held all of the hazard classes and definitions. That was the vision, and that's what the Chemicals Strategy still does. By adding these things to Annex II of REACH and not reconciling them to CLP, you already were creating some problems. Now we have double problems, because we have sections of the SDS through Annex II that refer to the Commission delegated regulations that predate these visions that are already required to talk about this. Now we have the addition of these elements, and one would hope -- and I can't swear by it -- that these would be the same, but they are not. So there is a little bit of a disconnect between how they define these in the 2017 and the 2018 Commission delegated regulations versus now how they've been incorporated into CLP.

What you're going to find is -- you could find this actually requiring an endocrine disruptor for human health to be noted in Section 2.1, Section 2.2, and then a different definition or a variable definition in Section 2.3.

LLB: Oh my gosh. That's just a nightmare.

KFB: It seems -- there's a little -- what I'm hoping is that we'll see some reconciliation, that we will see revision to Annex II again -- which for Lee, I know what this takes when software

companies have to incorporate changes to templates and changes to definitions and terminology. It's a lot.

LAB: Absolutely.

KFB: I do caution people to look at the differences between how this is now currently being addressed on the SDS and what the future holds with it being incorporated into CLP, because there will be some variability here, and it will be a little bit -- it's a little disconnected. This is one issue that I think folks -- probably, it's a detail that I think people may not be 100 percent aware of right now.

LLB: Lee, what's your take on that? You heard that background, and I know you and Karin have discussed this previously, but what issues do you envision as being most prominent and challenging as a consequence of this endpoint?

LAB: Believe it or not, Lynn, I think within the EU, due to the staggered compliance dates afforded by the CLP amendment, we're going to have product labels and SDSs with different content and formats from now and until the end of 2026, which will likely be confusing for various levels of the supply chain and certainly for our end customers, both in the consumer and industrial markets. That's the biggest challenge. We'll get through the complexities of making the changes to our software databases and getting the SDSs and labels updated, but making sure that the end users, and folks in the supply chain, and downstream users understand the changes --

LLB: Right.

LAB: -- and are comfortable with them, and still want to purchase the products. That's a whole nother element that our teams, our sales team and our commercial teams, are going to need to face, and our product stewardship managers are going to have to work with those folks to make sure that we're giving them the best information to help our customers and end users understand all these changes and how it may or may not affect their use of the product.

LLB: I think that's an excellent point, Lee. Brand managers and others who really value the relationships they have developed between themselves and their customers. The communication aspect is so critical. We've been talking about these deadlines, which may sound like a land far, far away from here, since we're in 2023 -- and these deadlines stagger over a period of years -- but the enormity of the program and the complexity of the communication challenges tells me that starting now is pretty important, because communication is just the -- it's the essence of this program.

LAB: That's absolutely true. The regulatory three managers and product stewardship managers that are either in Europe or supporting businesses exporting to Europe, they really can't breathe a sigh of relief at this point, even though there's somewhat of a runway with a staggered implementation period through 2026 for substances and mixtures, the work really needs to start right now. We actually are going to have to hound our supplier base to get the information from them as far as how they're classifying the substances and the raw materials that we purchase from them and make sure that we can work with our software companies to have the platforms that are ready to make the content changes on the documents and labels that are necessary, and then rolling that out and doing that implementation for several RPM companies. Like others in industry, have thousands of SKUs [stock keeping unit] that are going to be affected by this. It's a heavy lift. If anybody's sitting saying, "I've got a few years," they're going to be caught off guard when

it's time to come to compliance. Know that the large part of the work's going to have to start right now, and just making sure our folks are ready to do that, and folks in the industry that have the regulatory product stewardship responsibility are, first of all, getting themselves up to speed with the amendment and the changes in the classification rules and how it's very specific to Europe, and then making sure that they're working with all the various stakeholders to meet the compliance deadlines. It's more than a full-time job now for them for the next few years.

LLB: Just to pile on -- as the expression goes -- Karin, you mentioned the inclusion of persistent, bioaccumulative, and toxic, aka PBT; very persistent and very bioaccumulative (vPvB); persistent, mobile, and toxic (PMT); and very persistent and very mobile (vPvM) substances. Boy, that's a mouthful! What does all of this mean, and how are companies expected to address the inclusion of *these* new endpoints in addition to all the others that we've just talked about?

KFB: When we talked about this in October, we did talk about the somewhat redundancy of these endpoints and now their incorporation into CLP. But these endpoints -- persistent, bioaccumulative, toxic (PBT) address -- and it's all three; I think that's the most important thing. If you have P and you don't have B, then you don't have PBT. That's what it's going to come down to. But that doesn't make the concept of PBT any less precarious. And PBT and vPvB, as they were defined under REACH, are somewhat what we've done here under CLP. The only exclusion is the T definition has been expanded to include now endocrine disruption.

I think the best way to navigate through it is to understand, one, if you have P, then you need to make sure you don't have vP; these are going to be very staged. That's going to be -- looking at the definition of your degradation half-life, and if your degradation half-life in various levels -- whether that's marine or estuarine or sediment or degradation in soil, which -- a lot of folks may not have that data. This is going to be a very interesting thing to see what happens, because these endpoints, the endpoints around PBT, especially P and B, are ones that typically, you're going to need some level of data to define. And especially when you talk about B, a lot of folks just don't have that data. That's bioconcentration factors; these are incredibly complicated endpoints. Once you've determined you have B, you have to verify that you don't have vB. Once you have P, you have to also make sure you don't have M.

LLB: Good grief.

KFB: I don't think you can just stop. I think my point being -- you're going to have to spend some time on these. And when you look at T, you're going to have to look at -- we're not just talking about toxicity here as it relates to the environment. T is actually multiple things. So T can mean, yes, ecotoxicity, but T also means carcinogens, mutagens, reproductive toxins. Yes. T also means specific target organ toxicity, and now T also includes endocrine disruption. I think for PBT, it's going to be very important to look at the way that you *have* been classifying. If you have something that is a reproductive Cat 2, you then need to pursue the concept of PBT or PMT, depending on its behavior in the environment.

There are places to begin, because, as I said, PBT and vPvB were part of REACH, so they were part of your registration obligations you were supposed to be as a registrant carrying out a PBT and a vPvB assessment, so there are available data on this. The only caveat is under REACH, T did not include endocrine disruption --

LLB: Oh my goodness.

KFB: -- so if you see that the conclusion was not PBT, you do need to verify that the T part isn't now met, because somebody has determined that it did meet the endocrine disruption criteria. There are throughout the incorporation of these elements, non-methods, QSAR [quantitative structure-activity relationship], and modeling and things like that, but I -- having worked in registration for substances that are pretty complicated when their environmental profiles are being investigated, QSAR is not always an option. You are going to need to look at that.

What I'm hoping we'll see is guidance. I would love to see some guidance, because right now, since it's not a UN GHS adapted criteria approach, you have to look to the EU to provide you guidance on how to address these when you don't have all of this data, when you don't have a bioconcentration factor, when all you have is an optimal water partition coefficient. How are you then supposed to evaluate these endpoints? I think it'll be really important to see what kind of guidance they start to develop to help navigate these, and that they create some decision trees, because that's one of the beauties of the UN GHS model. There's a lot of decisions trees --.

LLB: -- which are super helpful.

KFB: Yes, they're very helpful. I would love to see some of that happening, too, because I don't -- I just don't see a lot of companies being very well versed in these endpoints and these definitions when it comes to their mixture and substance classifications.

LLB: Lee, what's your game plan in tackling all the PBTs, and v's and Ps, and PMTs, and so on and so forth? It's a tall order.

LAB: Yes, it's another great question, and Karin made a lot of good points there. Conceptually, the more information we, the supplier, can provide our downstream users and customers, the better. However, all the EU CLP labeling requirements already take up a lot of space on limited label landscape, especially as I mentioned before, for consumer products. Adding the new environmental persistent, mobile classification information and warnings to our SDS, that's much more realistic for suppliers to accomplish because you've got space to contend with, versus trying to achieve labeling compliance with these new CLP requirements on a limited amount of space.

Probably most importantly, we have to remember our end customers and downstream users, they're typically not environmental toxicologists. Keeping the information something simple enough for them to understand and make it not just understandable to the end user, but helpful, is also a key achievement that we've got to reach. We can't -- that's a goal that we've got to set for ourselves and make sure that we're not going to put out information that's not understandable to the customers, but we've got to comply with the regulation. And as Karin mentioned, that information is going to change over the next three or four years, as suppliers populate their SDSs and labels for substances with the endocrine disruptor classifications and the new environmental hazard information required under the CLP amendment. We'll get that in a staggered pace. It's not going to come in automatically, so creating an SDS for a mixture six months from now is going to be much different than three years from now, because there's going to be more information that comes from the suppliers. It's a bit of a moving target. Karin also pointed out they have not published any guidance, so from an industry perspective, that's huge. Receiving guidance that will help our regulatory managers, our technical teams understand the information that's coming from

the suppliers and how it'll apply for mixtures, that, frankly, it's absolutely necessary for us to meet these requirements.

LLB: Great thoughts, Lee. Thanks.

This has been a great discussion. I have one final question for both of you. Lee, you first. What are your concluding words of advice for our listeners, and where should they go for help?

LAB: Lynn, it's paramount that regulatory and product stewardship professionals supporting EU businesses and/or companies exporting into the EU stay abreast with the new CLP requirements for products classified as endocrine disruptors or persistent, mobile environmental hazards. Perhaps even more important is keeping close communication with your supply chain, to ensure receipt of the necessary classification changes from your raw material suppliers so you can accurately apply these changes to your own product formulations, and/or to seek alternative materials that don't pose the same hazard classifications for the customers and downstream users. Maintaining our in-house CLP regulation knowledge base, updating the databases to meet the new classification labeling rules, and frankly, having a solid consulting firm like Acta Group on your mobile speed dial are all good ideas for ensuring compliance.

LLB: Thank you for that, Lee. You're so sweet. And it's true. Karin?

KFB: We've been tracking this for a long time now. We've been talking about this for a long time now. I would encourage folks to continue to monitor the ECHA website. As I mentioned, there is still (hopefully) pending guidance that will be available. I would hope, this year, but I'm not very optimistic. Lee's more of an optimist than I am.

LLB: You're not a pessimist, Karin. You're a realist, right?

KFB: Realist. I would say also -- I would be looking, too, at the UN GHS delegates and the subcommittees to see where they go with these topics as well, because this is on the table. It is being talked about. The delegates meet twice a year. The next meeting is in early July. This is part of the agenda. Looking at the notes, seeing kind of what's happening at the UN GHS level will hopefully be helpful in navigating some of this. Then, I am speaking about this with the Society for Chemical Hazard Communication fall meeting. This topic is near and dear to my heart, so I will be giving a talk on this topic and will continue to talk. This is part of our operations here: podcasts, newsletters, things like that.

LLB: I just want to remind listeners that we post tons of information, thanks to the gifted professionals we have on our team here under the leadership of Karin. Look at our website actagroup.com to be aware of the changes as they are coming down the pike, as it were. Guidance is going to be huge. I'm confident, guys, that we will be seeing guidance. It probably won't be out immediately, but perhaps by the end of the year, or in early 2024, there might be more tutorials, decision trees, and guidance that will help affected communities understand how best to address these regulations. At least, that's my hope.

LAB: That's been ECHA's track record is typically they run anywhere from three to nine months behind the announcement of the new regulatory change.

LLB: Exactly.

KFB: They also -- they do host a lot of web content. Even if you're not willing to get up at 3:00 a.m. to participate in one of their live sessions, they do provide them online. Yes, I suspect guidance, as well as maybe some additional training content, will be available.

LLB: Lee Bowers, VP, EHS, RPM International, they're lucky to have you. Thank you for joining us today. Karin, you're just spectacular at what you do. This has been a terrific conversation. I hope it's helpful, and I hope our listeners take at least one message away, and that is: Be prepared. Don't be deceived into thinking these deadlines give you oodles of time to come into compliance. This is going to take a long time to get there, so start now. We hope the words of advice from Lee and Karin have been helpful. Thanks so much, guys. Really appreciate it.

KFB: Thank you. Thank you, Lee. Thank you, Lynn.

LAB: Thanks. Take care.

LLB: My thanks again to Lee and Karin for speaking with me today about the newly enacted CLP regulations in the EU. There are reverberations globally in how these changes are making the lives of EHS professionals even more complicated than they already are.

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