Episode Title: Keeping up with CLP Changes -- A Conversation with Karin F. Baron

Episode Number: 20221110
Publication Date: November 10, 2022

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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 welcome back to the studio Karin F. Baron, Senior Regulatory Consultant at B&C and our consulting affiliate, The Acta Group. Karin and I discuss the very controversial changes proposed by the European Commission (EC) to the Regulation on Classification, Labeling and Packaging of Substances and Mixtures, better known as the CLP regulation. As our listeners know, no one knows the space better than Karin Baron. Karin explains why the proposed changes are likely to inject even greater disharmonization in the area of the global harmonization of packaging and labeling at a time when global commerce can least afford it. Now, here is my conversation with Karin Baron.

Karin, welcome back to the studio. It's such a delight to speak with you.

Karin F. Baron (KFB): Thank you.

LLB: Well, set the table here for our forthcoming conversation on CLP. On September 20, 2022, the EC kicked off yet another public consultation on a draft act intended to introduce new hazard classes for industrial chemicals. As best as I can tell, Karin, these would be considered in the context of revisions to the regulation on the classification, labeling and packaging of substances and mixtures, better known as CLP. I welcome your thoughts in putting this into a conceptual framework for our listeners. What is CLP, what this act would do if enacted, and why the Commission is considering these revisions at this time?

KFB: Sure. CLP is probably one of the most complex hazard determination legislations that are in play right now. We have a lot of hazcom [hazard communication] law that exists. We have -- OSHA's [Occupational Safety and Health Administration] HazCom Standard. Canada has a Hazardous Products Regulation. CLP is European Union's (EU) classification, labeling and packaging for hazardous substances and mixtures. It's actually a fairly robust piece of legislation.

It was originally entered into force in 2009, but what it did at that time was repeal and replace two much older pieces of legislation, the Dangerous Substances Directive, which had been in existence since 1967, and the Dangerous Preparations Directive, which had been in existence since 1999. This was essentially the EU's version of GHS [Globally Harmonized System of Classification and Labelling of Chemicals] -- and we'll talk about what that means -- and it was enacted over what they call a phase-in approach. So it's been fully enforced in the EU and its European Economic Area since roughly 2015. It is regularly updated, so it's not unusual to see an update. But what's unusual about this update is it's not an update to amend certain aspects of CLP. It's basically an update to add hazard classes to CLP that are not currently part of the framework. And that's part of why you're seeing such a large consultation period occurring.

LLB: Yes. That's one of the reasons I wanted to sit down and chat with you. This is draft, the CLP. It has existed for quite a long while now, and just listening to you over the years, I appreciate that there have been lots and lots of changes, as there should be, right? I mean, chemicals change; our understanding of them change. Of course, things need to be updated. But to your point, this would add brand new hazard classes. So maybe you can help us understand what's in this draft act, and why is the consultation so protracted? This is one of multiple periods, as I understand it, and I think the comment period just very recently closed.

KFB: Right. I think it was October, the comment period closed. Basically, this would insert entirely new hazard classes and their criteria into the CLP regulation. And as I said, CLP is not a -- it is updated quite a bit. But what's unique about these hazard classes and their criteria is that they're not currently part of a UN [United Nations] approach to hazard classification and labeling. So these -- what they're talking about doing is actually in response to the European Green Deal, where they're looking to protect consumers, vulnerable groups, and workers from harmful chemicals, with an eventual target of zero chemical pollution in the environment, so this has a very large environmental focus.

It's also being amended or proposed to be amended to align better with REACH [Registration, Evaluation, Authorization and Restriction of Chemicals]. I will say that CLP has a lot of interaction with a lot of pieces of legislation in the EU, but the regulation REACH, known as Registration, Evaluation, Authorization and Restriction of Chemicals, has a big part to play in CLP as well. You're seeing in this draft inclusion of elements that are currently part of the REACH legislation, and because of that, they did have several consultation periods -- and we'll talk more about some of the specific criteria. But the consultations began roughly a year ago. The first consultation was open for, they say 14 weeks, and it was a public consultation. And then there was a second, more targeted consultation, and it started roughly after the public consultation closed, which was open for specific stakeholders, like Member State Competent Authorities (MSCA), people who answer the help desk questions for CLP. And that comment period closed, I want to say some time in December 2021, and then we have this additional consultation period, which recently closed -- because this is pretty significant, what they are proposing to do. You are seeing a lot of comments coming in. There have been, I think, over a thousand comments received on this particular proposal.

LLB: Yes, it's kind of overwhelming.

KFB: It's a lot; and it's very mixed. We will talk more about that. But it is very mixed, and it's in the comments, and not surprising.

LLB: You mentioned the other related legislative initiatives that CLP is associated with, REACH being one of them, and you also mentioned the EU Green Deal. I get all that. And I get that CLP needs to be chronically updated because of changes in hazard classification and new information and so on and so forth. But one of the things that still kind of puzzles me is how CLP and GHS relate to one another, GHS, of course, being the global harmonization system that I think has tended to elude global harmonization for all these years, something that you and I have talked a lot about. But based on what I've seen in the comments received, not all of them, obviously, since there are so many, but many seem to be of the view that these *new* hazard classes -- these are not amendments to existing hazard classes; these are brand spanking new hazard classes -- should have perhaps been first vetted by and endorsed by the United Nations Subcommittee of Experts on the GHS. And I assume that that did not happen. So my question is, why not? And what is the consequence of that lack of vetting?

KFB: Yes, this is a really interesting -- there's a lot of politics at play here. And as you mentioned, the UN subcommittee, I understood that this may have been part of what the EU delegates brought to the subcommittee, but the subcommittee moves at a snail's pace. And it could be that the EU felt the subcommittee was not addressing these particular endpoints in a fashion that was deliberate enough for them. But I will say the EU historically has had a very loose take on its GHS interpretation, and when they did implement CLP, it is somewhat based on Revision 2 or Revision 3, because of the timing, obviously 2009 timing, and they have updated it. But they never fully embraced the whole idea of the UN model system, which is now in Revision 9. They have specifically excluded certain building blocks that were part of the UN model. They have added their own labeling elements that are not part of the UN model.

They have included a very robust annex of specifically -- mandatory classification of specific substances. And that's part of the constant updating, is they have this large annex that contains all these mandatory classifications for substances, and those substances in mixtures. They also include elements that are completely outside of classification notification obligations, and then poison centers -- we won't talk about that. But CLP in its entire structure has some alignment with the UN model, but it is probably one of the largest departures from the UN model, when we look at other countries that have implemented GHS. So it isn't surprising to see them not wish to stay within the delegates' subcommittees and tried to push this momentum forward but for them to go off script and --

LLB: Go off on their own.

KFB: On their own. Exactly.

LLB: Okay. No, that helps put that into a -- because I saw that kind of a constant refrain through the comments that were received most recently. It was like, "Well, golly, if we've got this GHS global harmonization, why were these new hazard classes not at least run by the subcommittee?" So that helps a lot, Karin.

Well, let's get to the nub of the nub, as it were, and talk about these proposed new hazard classes. According to the Commission, and this is a quote, "the need to insert new hazard classes into the CLP regulation has been recognized as one of the primary commitments under the Chemicals Strategy for Sustainability." End quote. As you correctly noted, this is part, and a very significant core component, of the EU Green Deal. What are the -- what are we talking about here? What are the hazard classes that you can help our listeners understand what they are and why these are so significant?

KFB: The hazard classes we're talking about are the introduction of endocrine-disrupting properties for both human health and for environmental, the inclusion of the persistent, bioaccumulative, and toxic, or PBT; the vP, very persistent, and very bioaccumulative, vB. It becomes a mouthful very quickly.

LLB: Yes. Say it quickly five times.

KFB: Then this new category of persistent, mobile, and toxic, so PMT. And then very persistent and very mobile, so vPvM. This is what they're talking about adding. As you can hear from the text, a lot of it is very environmentally focused. You've got concepts of persistence in the environment, concepts of bioaccumulation in the environment, endocrine disruptors in the environment, and then things that are persistent and mobile and their impact on the environment. Those are the new hazard classes that they're going to add. They're going to actually amend several parts of CLP. The first amendments would occur in the parts that address human health, which are Part 3, and they would actually add a hazard class for endocrine-disrupting properties for human health with two subcategories, 1 and 2. Then they're going to add to the environmental several chapters that would address the PBT, the vPvB, the PMT, the vPvM, and endocrine-disrupting properties for the environment. It is a pretty substantial revision, with the highest impact being again on that environmental portion of CLP.

LLB: I understand conceptually what the categories are. What is a little less clear in my head and perhaps in our listeners heads, collectively, is -- the concept of endocrine disruptors is a much more focused concept and probably better understood in the EU than it is here. Is it well defined what an endocrine disruptor is? And having a new hazard class may be less impactful there than it is here. But what are endocrine disruptors? And why is this one of the classes that seems to be generating quite a lot of controversy?

KFB: That's a really good question. And you're right, endocrine disruption has been part of the EU for some time now. It was deeply embedded in REACH. It's been part of ongoing substance-specific actions where they have started to restrict substances for endocrine-disruption properties. And so the concept being introduced now into CLP is -- it's not shocking; it's just the way and the mechanism by which it's being included. But endocrine disruption, simply put, if you can really simplify it, is that it's something that alters one or more function of your endocrine system and that because of that alteration, it causes adverse effects. And those adverse effects can be in your progeny; it can be in populations or subpopulations, or intact organisms, and that's from their definitions.

It's a pretty broad definition, and they talk about what they mean by adverse effect. And here they're talking about morphology, physiology, growth, development, reproduction, the life span of an organism, how populations or subpopulations are impacted. And then they also include this concept of biologically plausible linking, meaning correlation between one or a series of processes leading to an adverse effect on endocrine activity, and then how that correlation is consistent with your existing knowledge. It's got a very broad definition, and they have the same impact for both human health and in the environment. They separated them out. But I think the problem being is that separation because -- don't get me wrong, endocrine disruption has been something that's been discussed for 20 or 30 years. It's not a new concept. It's just the thought that it's being segregated in this way, instead of incorporated into existing hazard classes. For example, under the UN model and adopted into CLP is this concept of specific target organ toxicity (STOT). And when we talk about impacts to things like central nervous system or to other systems, like immunology and things like that, we typically assign those into a STOT category. I guess what some folks are

struggling with, and myself included, is why the EU couldn't find a mechanism to incorporate this particular health outcome into existing GHS already -- language. Why not incorporate it into what they call the STOT endpoints and call it out there? Because there already existed unified ways to classify and label in substances and in mixtures when you have target organ toxicity. And maybe that, me not being like Ph.D. toxicologist that's oversimplifying it, but it just feels like it could have been added in without having to create an entirely separate chapter for it.

LLB: Yes. No, I take your point, Karin. The obvious follow-on question is, does this set a disturbing precedent for purposes of other endpoints that would be cleaved off and put into a separate hazard class, as opposed to being assimilated into the existing infrastructure that seems to get to the same point?

KFB: Exactly. I think that's where some of the concern -- and when you see some of the comments, it's not only the alignment with the UN subcommittee, it's the actual separation out of this particular endpoint and including it with its own -- it just feels excessive. It could have been addressed in guidance or in -- you could have amended the legislation to include it as part of the STOT, or even at the UN subcommittee level. They may have been already discussing why do we need a separate hazard class for this?

LLB: Well, that brings up the next constellation of hazard classes, PBTs and very persistent, very accumulative -- or bioaccumulative, excuse me. And then persistent, mobile, and toxic, and vP and vM. And I will *not* say that quickly five times. There's an awful lot going on globally with regard to PBTs in general, the most obvious classification of which are PFAS [per- and polyfluoroalkyl substances] that the world is struggling with. Do you think these hazard classes are in part derivative of the concern with classes of chemicals that are PBTs or, why these two other -- or four other, depending on how you count the hazard classes -- what's behind cleaving off of these hazards?

KFB: These are really interesting because PBT and vPvB were already part of REACH, and I said there's a close alignment between the two. So this concept of something being persistent, bioaccumulative, and toxic or being very persistent and very bioaccumulative was already part of the consideration for the chemical safety assessment and chemical safety reporting in REACH registration obligations. And to a certain extent, these have already been triggers for other regulatory activities within the EU, meaning things that are classified in these categories of PBT or vPvB are considered as part of restrictions and eventual authorizations which would result in their removal from the market. So your PFAS and things like that are all part of this discussion.

So the incorporation again of these into CLP, it's not foreign in its thinking; it just seems duplicative in its approach. Meaning when you talk about something being persistent or bioaccumulative, this was somewhat addressed in the environmental parts of UN GHS that are incorporated into the EU CLP. So there was already a consideration for things that weren't readily biodegradable, that had high bioconcentration factors or high octanol-water partition coefficients. Things that were toxic were already addressed as carcinogens, mutagens, reproductive toxins, target organ toxins. So again, calling something out as -- it's like taking properties we already have flagged, we've already classified and labeled them for those properties, and now we're going to label them again, only we're going to label them now as PBT or vPvB, I see it as being hugely confusing. It just seems confusing.

LLB: And a little redundant.

KFB: Yes, it just seems very confusing, and I might be oversimplifying it, but it did feel like we've kind of addressed it maybe in a roundabout way, and that perhaps building clarification in on when something should be classified as chronically hazardous to the environment could have been amended, because right now it's got this focus on aquatic. It's aquatic chronic, aquatic acute, but we could have added in some of these concepts. But the idea that now we have a separate category for PBT and vPvB, it just -- to me -- I think it's already going to add confusion to what is already a very confusing piece of legislation. CLP is not easy to navigate. It is one of the most difficult to navigate, and it's one of the ones that's most often misapplied. This isn't going to make it any easier.

LLB: No, this will not streamline things. No, I get that.

KFB: I find it strange.

LLB: Well, I would expect the EU Green Deal and the EU's commitment to chemical sustainability and -- those are hugely important, paradigm-shifting pieces of legislation in the EU. And I know there is a genuine commitment to get these over the goal line, as it were. And I don't see things changing a lot going forward to minimize the level of complexity and confusion with respect to CLP, but do you have any sense of what the timeline is? Will there be yet another public consultation to digest the comments that were received most recently? Or is there an imperative to get these things implemented by a time certain? Is it 2023 or 2024? What is your sense of the timeline?

KFB: My thoughts are -- right now, we're already seeing updates to CLP at a pretty regular basis. So with the ATPs, which are the adaptation and technical progress, we see amendments to CLP on a pretty consistent -- so we have the 17th ATP comes into force this December; we have the 18th ATP coming into force next November. I would expect if they're going to make this broad, sweeping change across, that it would be timed out in a way that either aligns perhaps -- and this is just a wild guess -- with an ATP, so that we see this incorporated into or it's brought in as it's an entirely separate proposal. I don't know if 2023 is the year, but it's getting closer.

The thing that kind of surprises me about it is, is when you talk to other stakeholders and you mention it, it's all kind of like in our minds, we said, "Oh, yes, I think I read something about that," but I don't feel like it's being as widely publicized as maybe it --

LLB: Hmm. Interesting.

KFB: Maybe that's just my perception, but when I've spoken to colleagues in the UK [United Kingdom] about it and said, "They're making these big changes. These are big changes to CLP," and they know that there's been discussion at the subcommittee in the disagreement with the EU. It's clearly out there, but it doesn't feel like it's been as widely publicized as it probably should be for the impact that it will have.

LLB: Right. I take your point. You know, Karin, probably way more than most people. You serve on the board of SCHC [Society for Chemical Hazard Communication]; you're in leadership positions. You know this stuff better than anybody. And so for *you* to say that this is something that is not as widely promoted as being as consequential as it probably *will* be upon implementation is troubling because what happens over there across the pond inevitably has a lot of implications over here in the United States and North America. Talk to me a little bit about, given Brexit and what happened in the UK, what about alignment with the UK's approach? Are there issues here that we should be focusing on?

KFB: Yes, there definitely already are issues with alignment with the UK. If you didn't know already, the UK left the EU. That occurred --

LLB: Breaking news!

KFB: -- at the end of December 2020. At the time, what the UK did was they basically took EU legislation -- what they called a lift and shift -- and put it into UK law. But they're behind, and the UK has made it pretty clear that they're going to move forward at their own pace. It will be, now that they are separated, it will be up to the UK competent authority, the Health and Safety Executive, to decide whether it wants to incorporate these. And it's not just the changes, these broad, sweeping hazard class inclusion changes, but also minor changes to the mandatory substance classifications in the annex. The UK has clearly taken a step back and said, "No, we don't agree with what's being done, and we're going to classify our substances differently."

I don't believe that the UK will be rushing to do this, and if they do, it wouldn't be any time soon. They're several versions behind what's happening in the EU, and they always kind of will be. And an interesting point to that, too, is also considering other REACH-like and CLP-like legislations, like in Turkey. We're going to see the same thing happening, where, as the EU moves forward, these other legislations that are based on them will be in a very reactive state and will be behind whatever the EU does. And it would be left up to the Turkish ministry or the Health and Safety Executive in the UK to decide if they want to continue down these paths. You will see in the EU and the UK some discordance. There will definitely be a lack of alignment.

LLB: Let's shift a little bit to talk about Annex II of REACH, which I know you've addressed in other podcasts, Karin. It included revisions to the safety data sheets (SDS) by adding, as best as I can tell, endocrine disrupters in Section 2.3, which is the other Classification 3, ingredients, 11 and 12. The transition period ends soon, at the end of this calendar year, December 31, 2022. How can you reconcile the Annex II revisions that I just enumerated with the proposed revisions on which the Commission has sought comments repeatedly? It seems to me, to your point previously, there's an element of redundancy here, which could invite even more confusion in an already confused law.

KFB: Yes, this will be interesting to see how these two pieces of legislation interplay with each other. Just in case folks don't understand, CLP lays down the criteria for how you classify substances and mixtures, how you label them, and then the packaging requirements, and it's both industrial and consumer. REACH, and Annex II specifically, of REACH, an entirely separate piece of legislation, lays down the SDS requirements. The SDS requirements are not within CLP. They have a lot of interplay. Don't get me wrong; there's a lot of overlap, but the content of the SDS and the requirements for what goes into the SDS are not -- they're in the REACH legislation. And so this update to Annex II, which has been around now for a couple of years and comes into force, introduced the concept of endocrine disruption on the SDS, but not on the label.

LLB: Oh, good grief.

KFB: So what you're going to see is, now you'll see that REACH will require at the end of this year that you include endocrine disruption in Section 2.3, which as you noted is Other, whereas the labeling -- the hazard statements, the precautionary statements, the pictogram, the signal words -- they're in 2.1 and 2.2. So the hazard classification section in the SDS only under Other, which has no bearing on the label, now includes the endocrine disruption,

but it also includes PBT and vPvB, because that was already part of REACH. So the consideration for those elements are now incorporated into 2.3. So if CLP is updated, they will have to reconsider how those elements are communicated on the SDS because you could potentially see, if they don't get the timing right and they don't make the changes to the SDS, 2.1 has endocrine disruption, vPvB; 2.2 is endocrine disruption; and then 2.3 is. So when we talk about redundancy, this is going to become messy. It's going to be messy, so they'll have to work on how do we then amend the SDS so that we have a proper designation in the proper sections to not create more confusion on these properties and address them appropriately? And Sections 11 and 12 are the toxicology and ecotox, and they created entirely separate sections for endocrine disruption in Section 11 and Section 12. There's new sections to address those hazards. They'll somehow have to be reincorporated in, or they'll leave them, I don't know. But again, it's kind of a strange -- and maybe the intent in the beginning was that they would align this all together, that they would issue the CLP and then they would, but they don't make sense the way that they're proposing now. You've got the SDS legislation comes into effect the end of this year, and we haven't even gotten to whether or not this amendment to CLP will occur in the next two to three years. It'll be interesting to watch.

LLB: I hope our listeners are beginning to picture the lack of alignment here with SDS requirements, packaging and labeling requirements, and the lack of clarity and the possibility of enormous confusion, not just on the part of the regulated community and complying with these requirements, but also those that are in a position to rely upon the information and labeling and packaging and the SDSs in ways that will further inform hazard communication, which is nominally what this is all about.

KFB: Right.

LLB: Speaking of which, here in the United States, OSHA and HazCom are our provisions and the federal government authorities for addressing hazard communication with respect to chemicals. How does OSHA and HazCom figure into all of this? For many of our clients, international shipment of goods, chemicals, materials, and mixtures is, of course, the norm.

KFB: Right.

LLB: How do you navigate this space, given the fact that HazCom and OSHA are quite different with regard to these types of hazards?

KFB: Absolutely. I'm shaking my head, if you can't see me.

LLB: Oh, I see you, Karin.

KFB: I think first it's important to point out that OSHA's GHS adaptation is the HazCom standard from 2012. It is based on Revision 3 of GHS. We're in Revision 9, and I would expect Revision 10 next year. We're -- one of the things that's unique about OSHA's implementation is that they, rightly so, they excluded the environmental part completely. It is not OSHA's jurisdiction to deal in environmental legislation. That is up to EPA, so OSHA did not incorporate any of these environmental aspects into the HazCom standard. It's allowed if you wish to include it, but it's not required.

And that's true with Canada as well, so Canada is in the same boat. What we see is if we now have CLP adding an intense focus on environmental, concept of PBT, endocrine disruption in the environment, vP, vM, all of these complex things into their environmental

section, then our part of the UN model, it really will have no impact on OSHA. They probably won't even bat an eye about it. But as an international company, there's a lot to consider here, especially considering that it's entirely optional, but it's not part of the UN model. It creates some really complex business discussions on -- it's one thing to incorporate the UN adaptation for environmental into a GHS-type SDS and label that you're using in OSHA and shipping overseas. It's another to then add entirely separate elements that are not part of either. So now you have this consideration of do you really want to label your chemical in the United States as PBT for shipment to Europe?

That adds a lot of discomfort, I'm sure, on the side of many companies within the United States, again, my biggest concern not being that we address these hazards. These are very important hazards. My fear is that it's convoluted in its definition, and it's confusing, and will it be misapplied? And now you're creating a miscommunication on whether or not it's appropriate to classify that particular substance within these unique categories that the EU is picking up. I do see a lot of complex business discussions on supply chain and regulatory obligations. Who has the obligation to provide the SDS that complies with these complex elements if you're a U.S.-based company shipping overseas? It's going to be interesting.

LLB: And to your point, it's difficult to begin difficult communications and internal discussions regarding labeling, packaging, and SDS hazard communication representations when these changes in and of themselves are not well understood or even necessarily well publicized. And not -- there's no criticism with the Commission because CLP changes and amendments to the law are regular and routine. But you noted earlier that you're a little bit surprised at the lack of fanfare here. People should be jumping up and down and waving a little bit, which is one of the reasons why we're having this podcast. People need to begin to think through the implications of this, not next year, and not when they're implemented, but now, assuming, of course, you must navigate the global space of sharing your products around the world.

Let's pivot to just what are the consequences of potential noncompliance going forward. Let's assume these changes are implemented. And even if these changes are not, noncompliance with CLP generally is consequential. So maybe you can walk us through what some of those consequences are, both administratively and in the form of fines and sanctions, but also commercially. What might be some of the implications of noncompliance?

KFB: With any EU regulation, it is at this time the Member State Competent Authority that's responsible for ensuring that its -- that each member state complies. That's true for REACH; that's true for CLP. I think historically what we've seen is it really will depend on the activities at the member state and whether they have the stomach to undertake. And this is going to be even trickier than I think people appreciate because, say you classify or you review your substance and you determine it doesn't meet PBT criteria and you don't classify and label it as a PBT. And then there's a similar commercial product that exists on the market where that individual made a classification decision and *did* classify it as PBT. Who's right? Who's wrong? Unpacking that, and actually going back and determining if one was right or one was wrong or both are correct.

Historically, I've not seen a lot of MSCAs wanting to undertake that. Typically what you find is somebody has applied the labeling, but they've applied it incorrectly. Those are things that you typically see member states questioning. And some of it has to do with just -- very simplistic elements within CLP, like the pictograms have to be a certain size and the text has to be of a specific size. And if you have -- you're supposed to have this many

precautionary statements, and you're supposed to have these particular elements on your label. Those are the easy things for a competent authority to question. And I think a few years back -- and I think you and I talked about this -- they did -- I would call it an audit, but that's probably not the right word. But they did pull -- they pulled a bunch of things off of shelves and they did do a review. And they found that the large majority of folks at that time were not applying CLP correctly, and the resources the member states have to enforce are member state specific. And while they may come back to you and say you need to fix it, I'm largely unaware -- and again, I could be completely wrong -- of financial retribution for a misapplication, because I think most of the time when people misapply, it's not done in a malicious way.

LLB: Oh sure, it's inadvertent.

KFB: Yes, it's a completely difficult piece of legislation to navigate as it is. But questioning whether somebody classified a substance correctly, unless there's a mandatory list and you've misclassified, it's very difficult to sort through that. And even in the United States, when we look at OSHA and then the enforcement and the compliance directives, it takes a whole separate charge to go back and actually determine that somebody classified something wrong. So I think if you see something, it would just mostly be on those elements that are already there, that somebody -- their pictogram isn't the right size. They don't have the proper number of precautionary statements. They're missing an e-mail address, or something very simplistic. But this will be interesting to watch and see what happens as it moves forward.

LLB: It's definitely more complex. It's quite easy to assess your compliance against an observable independent standard. The pictogram needs to be on this label, and it needs to be in these dimensions, and so on and so forth. But there's a good deal of subjectivity thought, and it's just much more robust when you think in terms of hazard classes that are brand spanking new. So that's why I think we're having this discussion giving all of our listeners kind of a heads up that this is in the works, and we need to be focused on it now, not later.

KFB: I think records are going to be a big part of this, too. Like, if you're ever asked, being able to document how you came to the conclusions you came to are going to be a big part of navigating this. And I think companies should be looking at these properties now and preparing for what the implication is from a product perspective, because I don't see this as being a good thing on your product to be marked as an endocrine disruptor and a PBT or a PMT and that perhaps ensuring that if you're looking at these and you determine that that criteria is not met by your particular substance or your mixture, that you have the right records that show how you came to that conclusion. And that's going to be a big part of this.

LLB: That's a good segue into my last question, Karin, and that is, in addition to the tip that you just gave us, which is be thinking about these changes and be thinking about ways to corroborate and document the decisions that you made and why you made them, do you have other tips for our listeners to help just stay on top of this fast-changing area?

KFB: I think tracking what happens next is going to be big. I see a lot of companies not implement early enough, because they'll give you hopefully a generous implementation period. But I still am aware of companies that haven't made the changes to the SDS that are coming into force at the end of December. This will take a significant amount of time to implement. Systems -- and we always talk about systems because a lot of companies rely on systems to do their hazard determination. Building the right system and ensuring that the system understands and is programmed appropriately to address these hazard classes is going to be

a big part of this, and then ensuring that somebody -- that there's hands on, a human person, is reviewing it to make sure it makes sense. Because the last thing I think companies need to be dealing with is struggling to meet an implementation deadline and then finding that now all of a sudden, products that they never would have considered PBT are being classified by their system as PBT. So ensuring that you do have a second set of trained individuals evaluating the output from the system before you start labeling product and shipping it marked with some of these hazard classes. That's a problem, I think. So that would also be my advice.

And then just track what's happening within the EU, because I see this as being a complex, very complex implementation. I would hope that they did a phase-in like they did with the original CLP, which was over five years. You had the 2010 deadline for substances and then the 2015 for mixtures -- that they think about something similar, especially with the introduction of new hazard classes. And they have a long sell-through period, because all of us are painfully aware relabeling is a nightmare, so that things that were placed on the market -- and that means imported as well -- that they are kind of time stamped and are allowed to remain on shelves -- because keep in mind, CLP is consumer, not just industrial -- that they're allowed to remain on shelves for an extended period so that we don't have to undertake relabeling activities. Tracking this, tracking the deadlines, ensuring your systems understand and that you have a person who's physically looking at these will be huge when and if this finally does get implemented.

LLB: I'm going to add two more to your list, Karin, which was excellent. That is, subscribe to our REACH blog, because we keep track of this stuff, among the four other blogs that we maintain. And Karin has written pretty extensively on these highly consequential proposed changes through our Firm Clients and Friends memoranda. I know you did one relatively recently, Karin. For those listeners who don't know, look at our website or subscribe to our complimentary memoranda. Please consider doing so, because Karin, you are the best on this stuff, hands down. Thank you so much for sharing your knowledge and your expertise in this area and preparing us for a brave new world out there, with new hazard classes under the CLP regulation.

KFB: Thank you, Lynn.

LLB: Always a pleasure, Karin. Thank you so much.

KFB: Thank you. Have a good day.

LLB: Thanks again to Karin Baron for speaking with me today about the ever-changing CLP regulation, proposed changes to it that are now being considered, and a few of the many reasons why the changes are controversial and likely to make the space even more confusing than it already is.

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