Episode Title: CLP Changes and What They Mean for Commercial Operations -- A Conversation with Karin Baron and Lioba Oerter

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

This week, I had the pleasure of speaking with Lioba Oerter, Director of Expert Services with Verisk 3E Europe, and Karin Baron, Director of Hazard Communication and International Registration Strategy for us here at B&C and our consulting affiliate, The Acta Group (Acta®), about the significant changes to product classification, labeling, and packaging (CLP) in the European Union (EU). I met Lioba recently at a speaking engagement and found we have a shared belief that these CLP changes will have a profound commercial impact on product CLP globally and that with everything else going on in the world, I kind of suspect that it's a little underappreciated.

Karin and I spoke about these matters last year, and I welcomed an opportunity to consider them again with Karin and Lioba in light of the new CLP developments as of December 2024. Karin, Lioba, and I discuss the CLP changes, including those recently made, why they came to be, what they mean for commercial operations, and conclude with some tips about staying ahead of the coming storm. Now, here is my conversation with Lioba Oerter and Karin Baron.

Lioba, Karin, welcome to the studio. I've been so looking forward to this conversation. Thank you for being here.

Karin F. Baron (KFB) Thank you.

Lioba Oerter (LO): Thank you very much for the invitation. I'm very excited to have the opportunity to be part of this podcast series. Very exciting.

LLB: In that regard, Lioba, let's start with you. You are a Senior Director of 3E Europe in the Expert Service Processing Center, and you're a resident in Germany. Maybe you could give our listeners just a little background about yourself and your expertise in hazard communication.

LO: Yes, absolutely. It happens to be this year marks my 25th year of anniversary in the field of product stewardship, chemical compliance, and regulatory affairs. I began my career back then in the industry at a, I would say, typical medium-size German formulating company, where I was responsible for safety data sheet (SDS) authoring, CLP, but also dangerous goods safety advisor, workplace safety, waste management, and supply chain communication. I would say one of my key milestones in my career was preparing my former company to get ready for EU REACH [Registration, Evaluation, Authorisation, and Restriction of Chemicals], which was quite an experience that was both challenging but also rewarding.

I would say I'm a strong believer that regulatory protections can only be achieved if the people truly understand them. With that in mind, I decided in 2012 to extend my expertise beyond a single company and join the Business Compliance Services to do it for a lot of companies. Over the years and through various acquisitions, I have grown into my current role as Senior Director, leading the Expert Service Processing Center for 3E Europe, and we are supporting our customers in managing regulatory programs and ensuring product safety through our innovative authoring services.

LLB: Wonderful, and congratulations on the occasion of 25 years in. That's quite an achievement.

LO: Thank you.

LLB: Karin, I know you have been a frequent guest here in the studio, and we love having you because of your extraordinary expertise. Maybe you can just remind our listeners who may be new to the podcast what it is that you do for B&C and Acta.

KFB: Sure. Very similar backgrounds to Lioba. I've been with this organization as the Director of Hazard Communication and International Registration Strategy for over a decade. Prior to joining this group, I worked in industry as well. I was with specialty and industrial chemical manufacturing for over two decades. I will also be hitting a little over 25 years this year of experience in hazard communication, product stewardship, and regulatory. Almost all of my time in this space has been supporting not just the companies I used to work for, but now a multitude of organizations in this very complex space of hazard classification and labeling.

One of the things that I really enjoy at this time is exploring not just how the EU or the United States adopted it, but also getting deep into jurisdictional divides, where you explore not only aspects of hazard classification, but their practical application to industrial, professional, and consumer workplaces. That's one space that we've been spending quite a bit of time on, especially with this particular hazard that we're going to talk about today.

LLB: Wonderful, and almost congratulations on your anniversary, Karin. We have almost a half century of experience here on the podcast. That's extraordinary.

Lioba, I met you recently at a 3E conference, and I was attracted like a moth to light to your extensive background and expertise in supply chain communication, raw material procurements, SDS authoring, and similar topics -- and also your shared view that I have

with all of the changes that are coming about in the EU COP [Conference of the Parties, focused on climate change].

I'm thinking that people are not fully appreciating the magnitude of the tsunami coming their way and that is underway now. Just by way of very brief background for our listeners, chemical hazard communication in the EU is regulated by CLP regulation. The European Commission (EC) amended the CLP regulation to include a bunch of new hazard classes: endocrine disruptors for human health and the environment; persistent, bioaccumulative, and toxic (PBT); very persistent and very bioaccumulative, so-called vPvB; persistent, mobile, and toxic (PMT); and last but definitely not least, very persistent and very mobile (vPvM). To me, this is just a lot, and as we discussed, it just seems to me to be a very, very big deal when chemical manufacturers will need to update packaging, labeling, SDSs, REACH dossiers.

Before we get into the timing and implications of these changes, maybe you can provide some context, given your perch there in Germany, as to what the EC's goal was in making these, I think, very substantial changes.

LO: Yes, substantial, that is so true. Amendments adapting to technical progress changes of the CLP regulations, that is the typical thing. We went through that over and over again, and so the market is used to it. But in October 2020, the EC published the Chemicals Strategy for Sustainability (CSS). The so-called CSS is part of a broader umbrella, which is the European Green Deal. The main goal of the Green Deal is to protect human life, animals, plants by cutting pollution, but also making the EU climate neutral by 2050. In addition to that, the current target is 55 percent less emissions by 2030 in comparison to 1990. For the Green Deal, there needs to be the right chemistry. And so the CSS drills that down to the chemical industry and defines new EU chemical policy, which is also better protection for citizens, especially consumers, considered to be the most vulnerable part, but also boosts innovation for safe and sustainable chemicals and shifting toward chemicals and production technologies that require less energy. Also the new commission, which started last year in December, committed again to those goals.

In the new mission letters, we see some newer ideas, like they want to reduce some bureaucracy. We will see if that really happens. But they will also tighten regional CLP regulations, so there will be new data requirements, more restrictions. All those priorities work in the direction of more regulations, increased enforcement for the next few years. Important for all these numbers is to identify the critical substances. These substances of concern, they were --until the new CLP regulation -- not properly described.

That is a bit of the background to introduce four new hazard classes. The goal here now is to reliably identify the endocrine disruptors because they have this interference with the hormonal balance in humans or in the environment, which is obviously causing harm. Also, they are focusing on those substances that are PBT; these degrade poorly and accumulate in the food chain. The other hazard class covers those highly mobile substances, which don't accumulate, but due to their mobility, they can contaminate drinking water. To describe that better, there was the decision to stray away from the [United Nations] (UN) [Globally Harmonized System of Classification and Labelling of Chemicals] (GHS) and do a European own way, and so in 2023, we introduced those new hazard classes.

LLB: That's very helpful, Lioba. Thank you.

Karin, maybe the same question for you, given your perch here in the United States. What do you see as the driving force behind these changes?

KFB: It was very clearly the CSS, but I think one of the most important aspects of the introduction of some of these was to bring some continuity between the two legislations that are the most impactful to the chemical industry in the EU, and that was REACH and CLP. Prior to the introduction of CLP, including these hazard classes, the concept of PBT and the concept of vPvB was part of the REACH legislation. So companies that were subject to registration under REACH were already required under the chemical safety assessment, under the regulatory framework of REACH, to assess their chemicals and determine if -- based on the data they were generating or the data they had accumulated -- they were considered PBT or vPvB.

Then there was further disconnect between CLP and REACH when they updated Annex 2 to REACH to incorporate in the SDS requirements the endocrine disruption aspect of this. It wasn't defined consistently, and it was confusing. As someone who participated in REACH registrations, we were already aware of these things, that they didn't have a proper definition or a proper inclusion, so part of that chemical strategy was to put them where they belonged, which was in the CLP. What makes this interesting from a U.S. perspective is that these will never be part of an [Occupational Safety and Health Administration] OSHA Hazcom Standard [Hazard Communication Standard]. As Lioba mentioned, one, it's not part of the UN GHS model system. We're already aware of the disconnect between UN GHS. Lynn, you and I have spoken about that.

LLB: Many times, right.

KFB: Many times. But what makes it even more complicated for North America is that environmental hazards are not part of OSHA's Hazcom Standard because environmental hazards are addressed under a separate regulatory body in the United States -- and in Canada, for that matter. What we see is we're incorporating non-GHS elements into the CLP regulation, but even putting the United States -- put the GHS disconnect aside -- the Environmental Protection Agency (EPA) in the United States -- while they have a mechanism for assessing similar types of hazards, their approach is entirely different because it considers environmental exposure, not just criteria.

What I think is a really important piece of this that gets even more in the weeds, even more complicated, is that when EPA assesses an environmental hazard, it has its own criteria, but then it also looks at the risk of those chemicals ending up in the environment, and whether that risk is present or not determines how they address exposure or controls within that space. So we're going to see chemicals classified in the EU as PBT where EPA may never consider those chemicals to be PBT. It's going to be really interesting, complicated and interesting.

LLB: That's one word for it. I kind of freak out when I think about it, because as you've already noted, Karin, these changes are part of CLP hazard classes, and European member states are currently proposing for either specific substances or groups of substances, mandatory inclusion of these classes into the annex of CLP, which I understand is a process that's kind of unique to this regulation. How is this actually currently playing out and impacting companies, when you say that environmental hazards are addressed outside of the SDS and OSHA Hazcom framework, but not so much under CLP in Europe? To me, that causes extraordinary dissonance between two very large trading partners. How does that play out in the real world?

KFB: One of the really interesting aspects of CLP that is unique to CLP, is its Annex 6, which contains mandatory classification and labeling instructions for individual substances -- sometimes, and I'm going to put this in air quotes, "generic grouping" -- and we're going to hear more about that later as we go into this. But what you're seeing is the moment that these hazard classes were introduced into the CLP system, it provided an opportunity for a proposal to include a mandatory classification and labeling on a substance to include these hazard classes. What we're seeing now is, for example, the German state -- German competent authority -- can say, "You know what? We believe this chemical should be classified as very persistent and very accumulative, so under the new CLP hazard classes, we're going to put in a proposal to harmonize the classification and labeling of this substance into this hazard class." That has been happening, and when they do that, then the whole criteria-driven approach kind of goes out the window a little bit because now it becomes a mandatory minimum classification.

As a U.S.-based manufacturer, where one, under OSHA, we don't even have consideration for this; two, it's not part of the mandate, and three, it's unique to CLP, but it's mandatory. We create an environment where now anyone who uses that substance, or uses that substance in a mixture at various thresholds, is obligated to include it as part of the SDS and labeling requirements. So what we are seeing now is that that is happening. We see endocrine disruption being introduced on specific chemicals. We see vPvB being introduced on very specific chemicals.

But what's more disconcerting, the data -- because all of this comes down to why did the member state competent authority believe that that chemical should be classified that way? When we look at some of these, they're relying very heavily on the evaluation process under REACH to key out key pieces of information, and then we're seeing from the assessment of regulatory needs, maybe one REACH registration had some data about it, but they're using generic grouping to then suggest that a whole entire chemistry now include one of these hazard classes. So you're going to see proposals in the near future that include -- because one chemical was registered, one chemical had these data, one chemical was assessed and determined to meet the criteria based on a competent authority's weight of evidence approach -- an entire chemistry now will be obligated to be classified this way.

LLB: That strikes me as pretty radical and very impactful for entire classes of chemicals.

KFB: I would -- yes.

LLB: Lioba, let me get your take on that. I've read that as many as half of the 24,000 registered substances in the EU could be -- probably will be -- impacted by CLP. I know your clientele is global, but particularly for your EU clients, what are they bracing themselves for? What are they doing right now in light of these seismic changes?

LO: Yes, hopefully every substance manufacturer holding those REACH registrations is currently reevaluating all the data they have got on the new hazard classes to come up with an assessment whether or not the one or the other new hazard class is applicable to that specific substance. So this task is an upstream task with the REACH registrants. Yes, we have roughly 24,000 registered substances, and all need to be reevaluated. That is not an easy task, and time is running up. What Karin also said is like, what is now the case is that these new four hazard classes are on the same level as the CMRs [carcinogenic, mutagenic, or toxic for reproduction]. For those substances where we already have that, partly, in the substances of very high concern, or in the biocidal products legislation, or in the plant protection legislation, these substances, they can go directly into Annex 6, even without the

harmonized classification and labeling proposal and going through all the discussions. And that has a huge impact on everybody, down the supply chain in the end.

LLB: Exactly right. I've heard some commentators refer to it as the ripple effect. I mean, if you have chemicals that are regarded as endocrine, human health, or environmental substances, and if you are marketing a product globally, how do you manage the labeling of that chemical in Europe, where it is an endocrine disruptor, but not so much under, for example, U.S. law or Canadian law? How do you bridge that dichotomy? Either of you.

KFB: You don't.

LLB: That's right. Good luck with that.

KFB: We often hear from our clients where they have this wonderful idea of a global label and a global SDS, and I've long said, "That went out the window a decade ago." The idea that you could have one label suit every variation or iteration of UN GHS is already a pretty difficult, if not impossible, task, but to further dissect and add hazard classes that aren't part of the UN GHS model that are not -- that are controversial. I'll just say it; it's controversial, not just the idea of an endocrine disruption, but it's how you *define* endocrine disruption.

LLB: Exactly.

KFB: At the UN level, they couldn't even agree to this. So this is very CLP driven, but it is a challenge because of its deep influence globally. I mean, we can't *not* look at the EU and the EU's approach to green chemistry, the CSS, and not acknowledge this is going to be deeply influential on key trading partners. And then here, I'm not even talking about the United States and Canada. We're going to do our own thing, very clearly.

But Latin America: when you look at how Latin America is setting up its legislation right now -- Colombia, Chile -- we are seeing the influence of REACH and CLP into those regions. We are seeing a divergence in Korea. We're seeing differences in China. This just adds so many layers of complexity, and I would say to any company facing this challenge, look at the criteria, look at the data, look at the decision. Determine for yourself whether or not you believe your mixture, your substance, is actually an endocrine disruptor. Look at all of the facts; look at everything that went into that. Look at the precautionary principle, and make a decision, but put some science behind it. Don't just say, "I don't like it." That's not a good approach.

LLB: That is not a reasonable response, Karin.

KFB: Exactly, exactly. Put some science behind it. Document your decision-making. But it's okay to not agree, and it's okay to come up with a path that's applicable for the regulations to which you're subject.

LLB: What's your take on that, Lioba? How are you advising your clients with respect to endocrine disruptors?

LO: Yes, it's very complex. The thing is for the whole assessment for the new hazard classes, the guidance actually was updated last year in November, so that timing is not good here at all. This assessment is very much an expert assessment. Yes, there are test data you can use; there are computer models, but then you will need to have good experts in the way of evidence, which usually is something you will end up in some discussions and decisions, as

Karin already said. For endocrine disrupting, there is no defined test strategy to close data gaps.

And looking at CLP, then hazard classes are also relevant for self-classification. So if the substance is not REACH registered, you are very much on your own. And this is getting more and more tricky and complex because the REACH regulation itself -- the revision of which is now desperately needed -- this is still pending, because you would need information for this classification out of, for example, Sections 11 and 12 of an SDS, but those are not ready. The same is for the dossiers. They are not ready because of the pending REACH revision, which is crucial for dossiers and SDSs and everything else. So the idea of having just one label -- that is, if you want to be compliant, okay.

LLB: Karin has been saying that for a long time because clients are desperate for the one-size-fits-all approach to global product labeling, classification, and hazard communication. And that just is not a realistic outcome here.

I know in late 2024, on December 10, there were additional revisions that entered into force that impact CLP. Maybe, Karin, you can identify what those changes are and then both comment on how that is impacting an already complicated space for entities marketing in Europe.

KFB: Yes, what happened at the end of December -- and there were several changes that entered into force -- these relate more specifically to things like the label itself. There were changes that included things like the text on the label. It had to have specific characteristics: printed in black on a white background, the distance between two lines has to be 20 percent of font size, the single font has to easily legible -- and then they went even further because everybody's legislation includes, you've got to be able to read the label. I mean, that's --

LLB: That's kind of the whole point, right?

KFB: They also went further to say it couldn't have serif fonts. We already had a pretty complex labeling layout in CLP. They already had specific requirements for the images. They already had specific requirements for the size and the dimensions. These just added more to that. They also had now the reduction of some -- allowing the use of digital labels. So those -- our favorite thing -- QR [quick response] codes, and how you could address QR codes. So there were -- these changes, I felt, maybe it's just me -- you may not agree. I felt it was just quietly introduced, and then -- bam! -- it's there. I'm sure a lot of companies are still looking at that -- or they didn't even see it yet -- and not understanding the true implication. Just from our clients' perspective, the marketing implications of just being printed in black on a white background seems like a small thing, but it's actually --

LLB: No, it's huge.

KFB: Yes, those began -- they entered into force in December, and they're being implemented now.

LO: Yes, absolutely. Some of the details -- on paper, maybe if you read through it fast, they seem to be easy and clear for people, but only for those people who are working day-to-day with typography, like graphic designers or press specialists, because font size, it doesn't mean the height of the small x in that font. If you have a lot of text, that might be important. Also, this 120 percent line spacing, there are still discussions about how that is measured,

and that is like, is it baseline to baseline, or is it the font size? Even the authorities -- national authorities -- are not 100 percent sure, which is always not a good sign.

For that black on white, I also heard discussions around that if you have printed packaging or based on the paper you use for your labels, maybe you have papers that have a certain amount of recycled paper. Then white might be -- maybe it's not white, around 90/10 pure, but more a grayish white. Would that be still compliant?

There are a lot of details, and I'm pretty sure that some people have recognized that they are in trouble, because not every company sells products above five liters or more, so this is a huge -- there will be a huge impact on your corporate design, because of that black on white background. Because of the size from this line spacing, you will not be able to put in all 27 EU languages on your label. QR code -- so digital labeling -- nice idea, but it is currently just in addition to a physical label, and there are only very small parts that you can only have just in the digital labeling. I don't think that it is that useful yet, but they have promoted more the use of the fold-out labels and things like that, but those are quite expensive. All of that will have an impact on each and every company.

KFB: You brought up so many great points. That fold-out label, I cannot tell you how many times when we speak to clients, the expense is one issue, but it's also how it's attached --

LO: Absolutely.

KFB: -- and can it become ripped off? But the key thing I think you said relates to enforcement, because enforcement of CLP, at this time, is left to the individual member states. So, if member states are confused as to what they mean by at least 120 percent of the font size and how to measure that, enforcement is going to be very haphazard and very confusing for folks that are trying to comply with an entire union-based approach and not be able to ensure that Germany, and France, and Croatia are going to agree on what that means, and the interpretation of white -- can you believe we're going to have to have a conversation about what white means? This is crazy.

LO: Yes, that is crazy, but it's something I have heard in discussions, so this is ridiculous. This is kind of ridiculous, but --

LLB: What's going on in the EU right now, Lioba? Are there enforcers out there in member states with their rulers looking for the 120 percent line size? How serious is the member state community, and how resourced are they to be doing compliance checks on particularly the December 2024 changes that are in effect now, right?

KFB: No, they're being rolled in now.

LO: They will be rolled in, and I would say one has to take it seriously, but not yet, due to the transition periods. But in the end, what I can clearly see -- and that happened when the EU changed from the Dangerous Substance Directive of 1967 to CLP -- that after all the enforcement dates, the due dates, and the transition periods, then the enforcement will be there the next workday in the shops, and they will look at it, and they will be precise. This time, it is maybe not that easy. That last big switch was easy to detect: Go in the shop. If there is still an orange symbol, you know it's not compliant. This time, it's a little more to measure, but I'm pretty sure that will happen here again after the time. And there will still be things that are easy to check, so if it's not black on the white background, you're not compliant.

LLB: Yes, that's pretty obvious and easy to spot, but maybe either of you can talk about what these transition periods are, because what attracted me, Lioba, when you and I were on the podium, was you were as passionate and as concerned as I am about why is there not being more said about this? Because these changes are significant. They are definitely not trivial. With some of these more obvious labeling requirements in terms of spacing, background, color, size, they're going to be easy to detect. From an enforcement perspective, that should make people somewhat concerned. Perhaps not right now, if it's not the subject of enforcement as we speak, but it's going to be, and these process changes take a while to implement. So what is the timeframe?

KFB: I can cover that. There's two -- it's going to be very messy. We have the new hazard classes, which entered in, as Lioba mentioned, in April 2023. And we have a rolling in – phase-in, I guess -- approach. It's going to be driven by when you placed your substance on the market, or when you placed your mixture on the market. Here, when they talk about placed on the markets, one was imported, one was actually introduced. This is a very European term. It's defined in both REACH and CLP. So if you placed yourself on the market after May 1, 2025, you have until November 1, 2026, to address the new hazard classes. That's going to be the endocrine disruption, the PBT, that whole rigmarole. When you look at mixtures, if you placed your mixture on the market after May 1, 2026, you have until May 1, 2028. We have rolling deadlines that address substances and mixtures separately for the inclusion of the new hazard classes. Labeling --

LO: Can I add something to that?

KFB: Yes, please. Because I know there are deadlines before you put it on the market, which are also confusing, but yes, please.

LO: Everybody focused on what you just said, because that is what is in the paper. But there has been a clarification on the ECHA [European Chemicals Agency] page, agreed by authorities, that this "already on the market" is meant to be, it is already somewhere at some stage in the supply chain. It is not applicable for *new* quantities of substances or mixtures that were already on the market before the cutoff date. So if you are producing the next tranche after the due dates, they need to have the new hazard classes. This has come by surprise to many people, and they are now under high pressure for getting the assessments done. This is not -- I would also say, this is not the proper way to do it, but the clock is ticking very much, I would say.

KFB: You're 100 percent correct. I think this is very confusing for folks when they talk about the "placed on the market" caveats that they built into these deadlines. Because if you look at it, substances that were placed on the market before May 1 of this year, you would be subject sooner. So it is really important to understand what the intent of that is, and then it goes further into the next set of CLP changes, where the general application date for these changes is July 1, 2026.

We have a lot of deadlines coming at industry right now, but when we look at the label formatting, the changes to the label that include all the dimensions and the black-on-white issues, again, they've split it by substances and mixtures and when they were placed on the market. So it's going to just be tricky for companies to navigate the exact deadlines that they're subject to, because ultimately, depending on where you sit with that, you could be subject to some of these in 2027, or 2028, or 2029. It does create this -- we have this massive amount of change happening under CLP, where you could have deadlines from now until 2029 that you're going to have to be addressing.

LO: CLP revision, fun with transition periods.

LLB: I know, Karin, there were some changes made in late 2024 that include a more transparent process for reconciliation of the CLP notification inventory process. Maybe you can explain what this means and the potential impact it may have on notifiers and then, Lioba, please add anything that you may wish to in response to Karin's explanation.

KFB: I'm going to go back a little bit in time. When the original CLP legislation was introduced, there was this concept of notification and a creation of what became the C&L [classification and labeling] Inventory. The notification is highly subjective, where companies who were -- it didn't matter, this has nothing to do with registration. Keep in mind, this doesn't have a one-ton threshold. This had nothing to with whether you were registering a chemical. This has nothing with REACH. This is all CLP, where you notified the classification and labeling of your chemical. It created this massive inventory of classification and labeling that is highly diverse in how companies approached their notification. It kind of prompts some of the harmonization activities that we were talking about before, where we get how chemical companies notified the classification and labeling and generated this inventory.

The idea behind it is that there has to be some type of reconciliation because what you have is an inventory that shows maybe 800 people agree that this substance should be not classified. But two people -- or two notifiers -- said it *should* be classified. One of the revisions that was included was actually looking back at some of this and asking those particular folks that don't have harmonized -- or haven't reconciled, or haven't updated, and are still disconnected from the majority -- asking for some logic behind it. What this does is for -- I remember being part of industry at the time when we were rushing to get these notifications in, and we maybe -- I'm hoping chemical companies have looked at these since, have updated, have done their due diligence to ensure that they have reconciled their C&L notifications.

My thoughts are that's probably not the case, but if you're going to now be specifically asked by ECHA or by a competent authority why you are still sitting out there alone with your weird classification and labeling, you may want to take the next year -- because again, this would probably fall under that general application date of July 1, 2026. You may want to take this time now to go and verify that anything you notified hasn't been updated under maybe a harmonization activity that is now mandatory, and you're still disconnected in your notification. I think that process has probably been grossly neglected by industry, and I could be completely wrong --

LLB: No, it doesn't sound like it, Karin.

KFB: -- but I know we're working with companies now that notified over 500 classification and labeling of individual substances where I'm going to go back and reconcile, and that is a monster of a task. I just feel like people need to be aware that you're going to -- you could potentially be called out for that harmonized, that inventory, and I long since have been critical of the Inventory, because I feel like there wasn't a lot of science behind it. People were rushing to get the notifications in, and then it was just left there. To me, I see this as kind of a good and a bad, but I think more good will come from this, in that we will see some actual cleaning up of that C&L Inventory.

LO: Hopefully, hopefully. Yes, it's really needed. And yes, the Article 4 changes that are applicable from July 2026, it's really needed, so there are a lot of things there. People use it still, and if you dig into it and ask, "Yes, but why? Is there any science behind that? Are

there actual data behind why that substance is in that classification nobody else thinks it has?" I would think yes, it's a good idea to clean that up.

LLB: I'm glad you both agree on that, and I hope our listeners take that to heart, with our 50 years of CLP and hazard communication experience here. That seems like good advice. And speaking of advice, last question, looking ahead, what is expected in terms of regulatory changes in the EU? And what advice are you both offering clients, your clients, in preparing for these changes? Lioba, you want to go first?

LO: Yes. Looking ahead, there will be more to come, and they will stress test each and every European chemical legislation sooner or later, so there will be a lot of changes. Maybe not in that magnitude, like this for new hazard classes, but there will be, and so you have to keep track. I would think the biggest thing to come is still the REACH revision, because it's -- along with CLP -- the biggest legislation is driving a lot.

With the REACH revision, we are still very much in discussions, and there are still discussions around the extension of the registration obligation to certain polymers. Obviously, as I already stated, there is a need for expansion of the data requirements. There are further requirements in accordance with EU's Safe and Sustainable by Design (SSbD) concept. There shall be an introduction of non-toxic material cycles, as for the essential use concept. Everything is now pending due to the pending REACH revision. Potentially there will be a mixture assessment or allocation factor, which is also something that you have to keep an eye on. One thing that comes through REACH review, which is directly connected also to our infamous/famous new hazard classes, that will be the generic risk assessment.

The generic risk assessment, this is based on hazard classification. It triggers risk management measures, packaging requirements, restrictions, and bans. This is directly connected to a classification. We already have something similar in REACH in Annex 70. This is like, if you have a mixture containing substances that are CMR, categories 1A, 1B, and they are listed, and you have that contained in a mixture above 0.1 percent, it can no longer be supplied to the general public. It is like a full stop, and it is immediate. You don't have to go through the whole restriction process, which is long with a proposal and a lot of people discussing and going through all those stages for legislation, but it is generic. So you get that classification, you are ending up no longer selling that.

And those four new hazard classes shall go in something similar. When everything has been worked out and you have an endocrine disruptor, Category 1, you might not be longer able to sell that to the general public. In addition to that, a lot of things are currently also discussed about if we do need a third category. A lot of those things are currently -- you have consumer use, private use, everything we are doing at home, or workplace safety -- but there are now discussions around "but if we are looking at people using the chemicals for work, there is still a huge difference between an industry site or if you are a craftsman using it." And this is like, you will have -- maybe we will get to the point where we have a third category for professional users.

There is a lot upcoming, and for advice, what I always say to my clients is like "Know your product portfolio." Know what product sells best, and maybe currently is a good time to phase out slow-moving items. Know your distribution countries. Maybe it's not necessary to include all 27 national languages on a label. Just in case, maybe you have to review that as well. Communication is key. Know your key stakeholders; get them talking: your sales department, your product stewardship department, your storage department, and so on and so on. Engage early with your supply chain to get the needed information on the new hazard

classes, for example. Ask for help. Look for a service provider that can assist with SDS authoring, labeling, horizons, scanning, office content tools, and other necessary support. That would be my -- this is usually my advice to each and everybody.

LLB: No, great advice, Lioba. Karin, same question. What advice are you giving to clients?

KFB: Follow what's happening. I feel like we're seeing changes that you have time to address, but if you aren't following what's going on, for example, assessment of regulatory needs. Look at what's happening to specific generic groupings of chemistry, because even as you start to fade out one specific substance, it's not going to do you any good if an entire chemistry is being targeted. The introduction of something similar won't help you. You need to be looking at what's going on with specific targeted chemicals and whether or not they're being considered endocrine disruption or PBT.

Look at the intention for classification, and look at what member state competent authorities are proposing. Comment on the data that are being used and the weight of evidence. Verify that that scientifically makes sense. You may not win that comment, but you should at least put it out there into the public record that you looked at the data as well, and you may or may not agree with what is happening with proposals for a chemical. But one of the more interesting things we're seeing, as of last year, is during the registration period, everybody was very quick to register their chemicals, but there's a next phase, and that's the evaluation phase.

Look at what's happening to chemicals during the evaluation phase, because what we saw in 2024 is that of roughly the 270-plus chemicals that were evaluated in 2024, only 11 didn't receive some type of requirement to do additional testing. We're seeing the evaluation phase being very targeted for the introduction of data requirements, where, for example, we registered something at an Annex 8, but based on some of the chemical profiles during the evaluation phase, we are being asked to generate data that are not part of the Annex 8 data requirements, which leads you to data being generated that could be used as part of the overall ripple effect, where you're generating data that might lead you down the path of being persistent or bioaccumulative.

When you see these changes to REACH -- which we welcome -- just keep some of this in mind is that just because you registered something doesn't mean you're done. There's going to be an evaluation at some point in time, and you may be obligated to generate more data, but look at what's happening to the generic chemical categories to ensure that while you are addressing a specific problematic substance that you're not trying to substitute with a substance that's equally problematic. And that's one of the harder aspects of this.

LLB: Great advice. This has been a fascinating and very informative conversation. I want to thank Lioba and Karin. We could go on and on, as we haven't even touched upon what some of these classification and labeling changes might mean for product defense and tort liability in jurisdictions far beyond the EU. Maybe we'll save that for another conversation.

But Lioba, I want to thank you so much for joining us. I really enjoyed connecting with you again. Karin, as always, great advice. Congratulations on your joint 25-year anniversaries. Allow me to thank for joining our podcast today. Thanks so much.

KFB: Thank you.

LO: My pleasure.

LLB: My thanks again to Lioba and Karin for speaking with me today about the EU's CLP regulation and what it means for entities in the EU and globally.

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