Episode Title: GHS Update -- A Conversation with Karin Baron

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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 welcome back to the studio Karin F. Baron, Senior Regulatory Consultant at B&C and our consulting affiliate, The Acta Group (Acta®). As many listeners know, Karin is an internationally recognized expert on hazard communication, risk assessment, the regulation of food contact materials, and the Globally Harmonized System of Classification and Labeling of Chemicals, otherwise known as GHS. Karin's expertise in hazard communication and GHS was recently recognized as Karin was elected to the Board of Directors of the Society for Chemical Hazard Communication, an organization Karin has held leadership positions in for years. Our conversation focuses on the truly seismic changes underway in South and Central America, in the European Union (EU) and United Kingdom (UK), and in Asia with regard to the adoption of the GHS and safety data sheet (SDS) implications of these actions. These initiatives have a profound effect on the movement of goods and materials internationally, and the unwary may find themselves in a world of trouble by not keeping up. Karin's special talent in this space is directed at helping her clients avoid bad commercial decisions and bad things from happening from them. Now, here is my conversation with Karin Baron.

Karin, I can't tell you how excited I am to have you back in the studio. You are a definite crowd pleaser.

Karin F. Baron (KFB): Thank you very much. I'm happy to be here. I feel like I haven't been here for a while, so it's good to be back.

LLB: Well, let's get started. As the principal author of the GHS Update in our fabulous, and detailed, and much-read 2022 Forecast, you know, perhaps better than anyone, that there is just a tremendous amount of change in global GHS regulation. Perhaps countries are making up for lost time? Maybe in the 2020, 2021 timeframe, given delays occasioned by the

pandemic. But maybe you could just give our listeners a global snapshot, if you will, of the status of GHS before we do a drill-down on Latin America, Asia, and the EU-UK specifics.

KFB: Sure, happy to do so. Anytime we talk about GHS, we need to start at the United Nations (UN) level. The UN establishes the model which all other countries then look to. In 2021, the UN published revision nine (Rev 9), so consider as we talk this morning at the UN level, we're in Rev 9. In addition, the UN subcommittee, even through all of COVID and its travel restrictions, remains quite active and meets biannually. We do have a UN subcommittee meeting in July coming up in Geneva. The agenda items are those that we have seen historically, but it's worth mentioning because these agenda items do inform later revisions to GHS.

A couple of the agenda items I think are interesting from a perspective of not only a hazard communication specialist, but just the ongoing environment and regulatory, include discussions on nanomaterials -- which we'll talk about a little bit more when we talk about the EU -- also a continued focus on how to use non-animal methods for health hazard determination. This has been an ongoing topic, not only in chemical regulation but in hazard communication as well.

LLB: I did not know that, Karin.

KFB: Yes. When you look at some of the later revisions of GHS, they're starting to consider how do you take those non-animal method results and apply them to the criteria that exist in the separate chapters, especially like Skin Corrosion was one that faced a lot of attention. I believe that's in Rev 8. And then in Rev 9 they started talking about eye. How do you use the in vitro eye results for classification and labeling that were used as part of registration programs like the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation in the EU. The also -- always controversial -- topic of a possible list, and where this comes from is the idea that GHS is a criteria-based approach, so it's left up to the individual to use the criteria to determine the classification of a specific substance. As we have seen, everybody reviews that information a little differently, so we do have a lot of variability from substance to substance and from country to country. The UN has had a long, ongoing discussion on what a possible list at the UN level would look like, meaning that a substance like titanium dioxide, one of my favorite controversial classification labeling topics, if the UN were to review the overwhelming amount of data that's available and make a determination of how they would recommend classifying it, has been on the table and the agenda at the subcommittee for some time now.

LLB: Hmm. Okay.

KFB: And then always in play are reviews and various amendments, refinements, things like that. I would expect to see, as always at the UN, the proposed changes. The next update to the actual GHS would not be expected until next year. This is a biannual update. But from a global snapshot, what we have happening right now is we do have multiple countries that are transitioning from either an existing GHS to a more updated version, or, as we'll see, we have multiple countries that are actually finally implementing GHS, so expect this to be a very transitionary period, for example, Australia.

Australia is currently in a two-year transition from Rev 3 to Rev 7. That transition period ends this year in December, so keep that in the back of your mind. There's a lot of transition periods ending this year. New Zealand -- which for me was a welcomed update -- they had one of the oldest versions of GHS. It was an interesting thing.

LLB: They're finally getting with the program, I take it.

KFB: Yes. It's like they were with the program very early on, but then that program changed a lot. So they -- right? Now they have updated to Rev 7 again, like Australia, and because it was such a big change, they're in a four-year transition, so we wouldn't expect to see enforcement until **2025**. We do have multiple drafts of regulation, and both pending and new, and then we continue to see and we -- I don't see it going away, just a lot of variability between how countries approach GHS and not just the classification and labeling aspect, but also the SDS aspect. We're going to see and talk a little bit about some of that.

And this includes everything from, if they pick up a certain revision, did they establish all of the building blocks? We see things like environmental is a big variation between country to country. We're seeing, as you know, the UN is in Rev 9, but a lot of the countries are proposing to go to Rev 7, and it's typically not -- it's only done that way because at the time the country started to propose the legislative change, Rev 7 would have been the most recent or the second most recent version. Because legislation takes so long to get implemented, you're going to see a continued lag, and that also creates a lot of variability. But we're also seeing a trend to add things that are not part of GHS. The United States is also guilty of that, and we are seeing that in other countries as well. So that's kind of a big global snapshot.

LLB: My takeaway is always just the exquisite irony of the "globally harmonized" part. I know that's the aspiration and the goal, but it's not the reality, which brings us to our conversation.

Let's focus maybe first on South and Central America, because I know you noted in the update and our Forecast, Karin, just a whole lot going on in Chile. In December, for example, under Decree 57 of 2019, Chile implemented GHS, and I understand the Chilean Ministry of Health recently issued its updated list of official substances for GHS classification, which includes some 4,000 substances. Now as I understand it, any company that now manufactures and distributes industrial-use substances in Chile, since February of this year, must ensure its SDS and workplace labels are GHS compliant. What version? Don't know. And whether there are significant changes from what was recommended, I don't know. But maybe you can comment on what the state of play is in Chile.

KFB: Yes, Chile's GHS implementation is really interesting, and it brings to mind a trend that we're going to talk about also in Colombia, where a country is -- one, it has a key trading partner that's heavily influencing its approach. So when we talk a little bit about what Chile is proposing, you're going to see that its key trading partners with the EU are going to heavily influence its decision-making to create some alignment between that trading partner. The way that Chile decided to implement GHS was to do so within a REACH-inspired type scheme. And when we talk about REACH, we're talking about the Registration, Evaluation, Authorization and Restriction of Chemicals, which is a very daunting piece of EU legislation that has had a wide dispersive influence around the world. In its implementation of REACH, Chile opted to include Rev 7 of GHS. So it's kind of a complementary REACH slash CLP [Classification, Labeling and Packaging regulation] approach, and that's why you're seeing the list -- the 4,000 substances included in that mandatory list -- because that's almost exactly what the EU did with CLP and an annex that includes a mandatory list of substances, which means if you are manufacturing or importing that substance or mixtures containing that substance, this is the minimum required classification.

But in addition to that minimum required classification, they're including a registration obligation, which -- this is actually a departure from the EU, because what they're saying is,

"If you have a substance, say, on that list or meets the criteria -- so don't think you're off the hook if your substance isn't on the list." You have something that meets the criteria of being hazardous or is classified based on that list, and you import or manufacture it in Chile at greater than a metric ton. You also will have a registration obligation, and this is a departure because in the EU, the REACH piece of legislation said that if you manufactured or imported at greater than a ton, regardless of its hazard, it had to be registered. This is a slight shift in Chile, but they also included notification obligations, so if you have substances and mixtures at specified concentration limits, you may not have a registration obligation, but you'll have a notification obligation.

There's a lot happening. This is a lot going on in a country that previously didn't have a very robust scheme. Now they've implemented a registration scheme, a notification scheme, a classification labeling scheme, so trying to navigate that and figure out when your obligation begins is then further differentiated by your use. Now, as you mentioned, if your use is industrial, your substances have to comply by 2024. If your substances are in mixtures, you have until 2027. If you have a non-industrial use, your substances have until 2025 and your substances in mixtures have until 2029, so there's a lot to unpack in Chile.

LLB: Boy, I'll say.

KFB: I know.

LLB: Well, Karin, let me ask you a couple questions. Number one, if I understand what you're saying correctly, they've kind of bootstrapped on a registration requirement to GHS implementation. And number two -- and actually probably in reverse order -- is it unusual for a country to adapt its GHS practices to align with a trading partner? I mean, are those matchups common?

LLB: I will say that, while we don't see it as much here, the United States and Canada did align, as much as possible, the classification and labeling aspects of their two different pieces of legislation, so that is not entirely uncommon. Where this becomes a little bit more tricky to navigate is the fact that they added on this registration obligation, but instead of taking REACH the way that the EU implemented REACH and saying, "We're going to do something similar," they added a layer of complexity by embedding this classification aspect that drives whether or not you have a registration aspect.

I personally appreciate some of that because I do believe an incredible amount of data was provided to the EU for substances that had relatively zero hazard according to the hazard determination process, and here Chile is saying, "We don't really want to see any of that. That's already been done with our trading partner. We're really only interested in looking at the things that we consider hazardous based on the criteria that we've established or based on the list that we've published." And that alignment then helps people who are working in and out of those two trading partners to understand their obligations. Because as we see, as a regulatory support group, when a U.S. entity, for example, tries to provide a chemical to, say, the EU, the differences between what TSCA expects in the United States and what REACH expects in the EU are so very different. A lot of companies, especially new companies, really struggle to place new materials on the market because there is such a vast difference between those two pieces of legislation, and the regulatory burden being so different, it's difficult to navigate. In some ways I see this as a benefit, a way of Chile saying, "We really want to trade with the EU, so we're going to use a complementary piece of legislation to do that."

LLB: Well, no. Put in that context, Karin, that makes a lot of sense. What is surprising to me -- and I'm not nearly as close to this stuff as you are -- is that seemingly this pretty remarkable and complex -- and as you noted, difficult to unpack -- system seemed to come out of nowhere with regard to Chile. But I suspect this has been building over the years and maybe just sprang into action, and now between 2022 and 2027, you can expect a lot of changes for companies wishing to export product into that country.

LLB: Yes, I think what we're going to see is Latin America has incredibly altered the face of trading over the next several years, and companies in the United States need to prepare themselves for how to address where they had very little obligation before. Now, they may not have the obligation because roles in supply chain become very complicated when we talk about manufacturers and importers, but their customers in country are now going to be facing obligations, and they're going to rely very heavily on their U.S. counterparts to assist them in meeting some of these obligations. You're going to see companies facing challenges in a region they didn't typically have that many challenges in.

LLB: Well, exactly why we're having this conversation, because I don't think a lot of our clients appreciate that markets that had been relatively uncomplicated have become more complicated, and their compliance obligations and their customers' expectations have changed and are changing quite a lot.

Well, maybe we can move into another South American country, Brazil, which to my eye also seems to be in great flux. Brazil continues to propose adoption of the seventh revised edition of the UN GHS Purple Book. As I understand it, the proposal is to consolidate the technical standards from four separate parts into one: GHS terminology, classification, labeling, and SDS criteria. What is the practical effect of this change? Is it similar and as seismic as what's going on in Chile, or is that a more predictable transition to a slightly different system?

LLB: Yes, it's definitely the latter. One thing I will mention for Latin America just generally is they will implement a piece of legislation and it may not have a lot of detail in it, and then they'll follow that up with a technical standard. And in the United States, we look at this as guidance, and sometimes it's not mandatory, sometimes it is. It is always mandatory when you're looking at this in Latin America perspective, so when Chile says they're going to change a technical standard, they are going to revise legislation. But in this change, it actually makes a lot of sense to me, because right now, if you wish to acquire a technical standard in Chile, that's a purchase. It is something you do have to buy on their website. Some of the older versions of the technical standard are available to the public, but anything new has to be purchased. So instead of purchasing --

LLB: Are they translated?

KFB: Yes. Yes they are. That's one benefit. They are translated. Not always, but yes, you usually can find translated versions of them.

LLB: Good. That's good.

KFB: But what you'll find is instead of having to purchase four technical standards or try to figure out which technical standard you needed because you're interested in a certain aspect -- the SDS, or the label, or the criteria -- now it's going to be consolidated into one. I doubt the price is going to make any difference, but I think from a practical perspective, having only one standard makes it much easier to navigate. And then from a Rev 4, where Brazil now is,

to Rev 7, there are some changes there. But Brazil had a very straightforward GHS approach. They did not have any variability. They didn't add their own unique elements. They pretty much took the UN model, so it's just Brazil keeping up with the UN to go to Rev 7. It's just understanding the changes between Rev 4 to Rev 7 for Brazil, so it's not -- from the GHS perspective -- it's actually, I think, a welcome change for especially folks that saw the UN adopting some physical hazard classes that aren't in Rev 4 now being included. But they did not tie in any type of chemical control within that GHS; they never had that, so one thing (as we talk about emerging legislation) is that my understanding is that Brazil is now looking to be part of the Organization for Economic Cooperation and Development (OECD). In doing so, it will need to push forward with some type of chemical control legislation, but I don't see that having any impact on GHS like we saw in Chile.

LLB: Okay. Now it's, I guess, comforting. At least it's predictable.

KFB: Right.

LLB: Let's move on to Colombia, where Resolution 773, as I understand it, provides a couple of year transition period to implement GHS Revision number 6, which ends in April of next year, 2023 -- for substances and diluted solutions and mixtures -- concludes a year after that in April 2024. Is there any practical impact of this approach and the two-year transition for folks exporting to Colombia?

LLB: The GHS is fairly reasonable. As you noted, Lynn, Colombia did split its GHS: 2023 substances, 2024 mixtures. That's pretty standard practice, appreciating that classification of substances is the first step. And then once you've obtained a classification of a substance, you can then derive a mixture that contains substances. That's fairly normal at the Rev 6, though it's slightly off from what others in the region have done, but it's a fairly straightforward GHS implementation. Where, again, it's taking a left turn is Colombia has added on a REACH-inspired approach as well, so once you derive that GHS classification, if you've determined it's hazardous and, again, there's no mention of a list here, so we don't have a list of 4,000 that we have to look to. It's an individual criteria-based approach. If you've determined that your mixture or your substance is hazardous and you are importing or manufacturing it at quantities of greater than 100 kilograms -- and we took a double take on that because typically we see a one-ton threshold, but this is a 100-kilogram threshold -- you will have a registration obligation.

But that to me is where this goes very differently from what we're seeing in countries like the EU and Chile, because they list a ton of exemptions to that registration. And that registration feels more like inventory gathering, information gathering, and less burden. It's more of a Colombia trying to get an idea of how many hazardous substances are in their market at greater than 100 kilograms.

LLB: Oh, I see.

LLB: Because they excluded a lot of things that have been historically problematic. I'll give you a perfect example. Polymers are completely excluded from this obligation. And they didn't say, "Polymers are excepted, but --," there's no but, just exempted. So even monomers of polymers, the things that make up the polymers, are exempted. They also exempted substances of unknown or variable composition, which I thought was a very interesting take because --

LLB: That's so specific.

KFB: That *is* so specific, right? I mean that we're talking about some major commodity items, like think about all your petroleum distillate chemistry. That's all exempted from this. It's not exempted from the GHS, but it's exempted from this registration obligation. But in addition to the registration obligation, it looks like they're possibly developing an inventory because they have an annual update requirement.

LLB: That's exactly what it sounds like--.

KFB: It does --

LLB: -- a predicate to an inventory-type approach. Otherwise, the diversity and number of these exemptions really doesn't make sense.

LLB: Exactly. And then what you're seeing is the Ministry discussing, establishing a priority chemical. They'll look to see how many hazardous chemicals are coming in and then start to establish a list of priority chemicals, where further risk assessment and management measures and potential restrictions will start to take place. You're seeing the building of a framework in Colombia that's just a little bit different than what we saw in Chile, and the deadline for registration is right after the GHS deadlines, so that's a 2025 deadline.

Once you finish your GHS obligation, you're not done. In Colombia, you also have to then consider if you manufacture import volumes of those hazardous materials above 100 kilograms, and then you'll start to see them building out a framework. This looks different; it feels different to me than what Chile has proposed.

LLB: Oh no. Very, very different. Very interesting how these regional variations influence kind of their approach to governance. And speaking of that, looking across the entire region there, I noticed a mix of UN GHS editions in play -- Argentina, 5; Brazil, as we talked about, 7; Chile, 7; Colombia, 6; Ecuador, 1; and Mexico, 5. Given the variations, these *must* cause some transactional disarray. Can you describe for our listeners, Karin, what might be -- what type of transactional challenges would you expect to see as a result of these different GHS editions in play?

LLB: I think when you look at how a country implements GHS, you always have to look at its scope and its intent. And for a country like Mexico, for example, Mexico's GHS or the NOM [Norma Oficial Mexicana] that writes to the GHS, the standard that they use is specific for industrial workers. But if you are making biocides, or foods or drugs, or cosmetics, or agricultural products, you have an entirely separate set of technical standards you're obligated to follow. Just a word of caution: There has been and always exists within these regions specialty areas with variations on control and standards that the GHS that they've implemented may or may not be part of, so you do need to ensure that you're aligning with the regulatory requirements for that region -- looking at what's in scope, what's not in scope -- and then appreciating that there are definitely pieces of legislation that may have existed or are being implemented now. In an area that had little regulatory oversight, you're now seeing quite a bit of oversight being developed. There is definitely increased movement for stringent controls on what's being allowed to be brought in and then how you communicate the material that you're bringing in. Your agricultural product that you also use as an industrial product could have two separate sets of technical standards that you're obligated to comply with in a lot of these countries, so it is becoming a more complex space to navigate.

LLB: Oh, yes, I'll say. It's the understatement of the century.

LLB: But no more so than I view -- we have managed and dealt with this across the globe. We dealt with it in Europe; we dealt with it in the Asia-Pacific region, so I don't see this as any more tedious. It's just appreciating that you can't always expect that the way you label or the way that you address something in the United States is going to be identical in, say, Argentina, so you do need to work with agents in the country. The other difficult piece about Latin America is finding English translations, and there are not a lot of available English translations, so having someone who speaks the language and the importance of translation here is key. Because we've learned time and time again just in dealing in things like China, knowing someone who speaks the language in a technical way, not just a straight-up translation, because sometimes there is, "Did they mean "and" or "or" here?" It can mean a very different thing, so having someone who's technical looking at translations is critical in navigating the space.

LLB: Let's stay on Asia and maybe focus on South Korea, because I know there are several -- to use your language, Karin -- troubling issues or at least somewhat disturbing relating to the mandatory review of MSDSs [material safety data sheet] and the ever-thorny issue of confidential business information (CBI). And what is the process there? What are these issues, and why are they so challenging?

LLB: In 2021, in January 2021, there were amendments made to the MSDS requirements under the Ministry in Korea. It's known as KOSHA -- K-OSHA (Korea Occupational Safety and Health Agency)-- very creative on our part, right?

LLB: It's memorable.

KFB: What's troubling is that -- well, first, they're still using the term MSDS, but that's a pet peeve on my part -- is that the Ministry of -- I think it's Employment and Labor, so it's not the same ministry that oversees the K-REACH [Korean REACH]. This is an entirely separate part of requirements for Korea -- is asking to have, for you as a manufacturer-importer to provide an MSDS, a copy of that MSDS for them to review. Included in that review process is, if you wish to claim any aspect of the formula, so say you have a mixture that contains two components and you don't wish to disclose one of those components because it's considered confidential, the ministry requires substantiation in a separate submission for them to determine whether it's a valid claim. This is not new, this idea of substantiation of claiming hazardous -- and I repeat: this applies only to hazardous -- has existed in other frameworks: Canada, for one. EU is another -- where if you do have something that under the Korean GHS implementation meets the definition of hazardous and you do not wish to disclose that on the SDS or the MSDS, you do need to provide to the Ministry a -- it's a pretty intense package of detail to be able to maintain that claim of confidentiality.

LLB: That's important.

KFB: Right. And it doesn't apply if your material is not hazardous. But again, how you determine hazard varies from country to country. Korea does have a mandatory list of substances that they have deemed hazardous. In alignment with that, you also have under K-REACH them reviewing new substances as part of the old registration scheme and now reviewing existing substances under the revised registration scheme, so there's going to be amendments made to the classification and labeling. It's going to be a very evolving process.

But if you had materials that were already on the market prior to this January 2021 date, they did make it a rolling process for the submission of the MSDS. I think that was partly

done because I think we all appreciate that there are tens of thousands of MSDSs out there, so the Ministry understood that it wasn't able to review everything. The rolling deadlines applied based on tonnage and started this year with the 1,000 tons or greater, and then next year it's the 100 to 1,000, and then the next year it's 10 to 100, so you see that, but where this gets complicated is, say, as a U.S. company, I have something in the United States that I have claimed as a trade secret. Our trade secret provisions on our SDSs are very generous -- and I wish to then introduce this product to the market in Korea.

Prior to that introduction, if I wish to maintain that confidentiality, I must submit that information, or I have to provide it to my importers because they would have the obligation to provide that MSDS. You as a foreign manufacturer can deploy the Only Representative [OR] -- it's the same function as registration, right? They -- under this K-OSHA requirement -- you can also have an OR, who can act on your behalf for that submission process, but it does require -- you can't just say, "Oh, it's confidential. We don't want to tell anyone."

LLB: Right, you have to substantiate it because it's hazardous, right?

KFB: Yes. And substantiation includes proof that you've never disclosed that somewhere else. If your company is a global company and you provided that ingredient and fully disclosed it in the EU, then your substantiation claim is invalid. If you can demonstrate that you have not disclosed it to anyone else, you then have to provide an economic value behind maintaining it as CBI. How much investment did your company make in, say, [research and development] R&D, or how much commercial value is there to you with your competitors? Then you have to provide measures that you currently use to keep it confidential, and they were asking our clients for things like screenshots of their security on their systems, which --

LLB: Really?

KFB: Yes. I found that very -- I know our client was very troubled by that aspect, because nobody wants to provide screenshots of your security. So we worked --

LLB: -- Well, it's kind of counterintuitive, right?

KFB: Exactly. We worked with the Ministry on "Would you accept our standard non-disclosure agreement template? And here's the process that they use to maintain their confidentiality." And we were able to navigate some of that. In the end, the Ministry will provide an approval number, but that approval number has an expiration date. So even after you go through this entire process, you're only given so much time with --

LLB: What was the timeframe? Was it like a year?

KFB: Five years. It's five years.

LLB: Okay, well, that's better.

KFB: And then you can reapply, but the burden falls to you to reapply.

LLB: Are you notified before the CBI falls off, or do you have to implement your own internal system to make sure that at the five-year mark you re-up?

LLB: Korea has been very good about notification, so you would be notified, either by your OR, or if you're in the country, I'm sure you'll receive notification that you're -- it's near the time of when you need to reapply.

LLB: I was going to ask, Karin, are these CBI substantiations and cooperations relatively painless? I think you've answered the question, like no.

KFB: No.

LLB: They were painful.

LLB: It took a lot of time, I will say, the one that I worked on. The client had a stellar history of maintaining -- for most that we work with, being able to demonstrate that you've never disclosed that material, even as a salesperson inadvertently disclosed it to a customer. You really have to be able to prove, no, we never did that. The only way someone, say, an EHS [environmental, health, and safety] professional needed it, was through a non-disclosure agreement, so this client that we worked with had all of that proof, but it still took several months and several revisions to the MSDS to get the Ministry to accept it.

LLB: Very interesting, oh, and very helpful for listeners to understand these challenges in Korea.

Well, moving from Asia quickly to the EU, I understand that the inclusion of certain non-GHS elements in the SDS is posing some problems. Can you elaborate on that, Karin?

LLB: Sure. In the EU, as we talked about before, you have two pieces of legislation that impact hazard communication. REACH actually contains the content that's required on the SDS, and CLP contains the annex and mandatory classifications, the criteria, the labeling, the packaging requirements, so two very robust pieces of legislation. In 2020, the Commission issued amendments to Annex 2 of REACH, where the SDS template and content is laid out. And that -- the changes that they implemented into Annex 2 -- enter into force later this year, so in December, the end of December 2022.

They include, as you mentioned, elements that are not part of CLP, so criteria or endpoints that were not considered either in the EU classification labeling and packaging regs or at the UN level. I'll give you a good example. In Section 1, you now have to note whether your product is a nanoform. We are seeing a heavy weight being placed on nanomaterials, as the EU defines them, and communication to downstream users that your material is a nanoform. That's one big change.

The second big change is the inclusion of endocrine disruptors in the hazard sections of Section 2. There's now a new criteria requirement to include in Section 2.3 -- which was typically reserved for Other -- now you must include details about endocrine disruption, and it's either at the substance level, or if that endocrine disruptor is in a mixture at 0.1 percent or greater. You're now seeing the endocrine disruptors that the EU has been focused on for some time now being incorporated into the SDS. And then in addition to including it in Section 2.3, disclosing it in concentrations above 0.1 percent in Section 3, then you're seeing new subheaders in Section 11, which is Tox, and in Section 12, which is Ecotox, that talk about the health and environmental aspects of endocrine disruption. There's new subheaders, which -- any time you mess with header or subheader language -- anyone using software would need to have software updates. So that in itself is going to make it very easy for someone in that country that you're selling those materials to or placing those materials on the market, either the competent authority or the customer. If they don't note those

changes to the subheader language, they'll know that your SDS is not up to date. So that's always a caution.

LLB: Oh, for sure. The other thing that strikes me is you now have a relatively mature regulatory governance program that is requiring the elicitation of whether a chemical is an endocrine disruptor. So that's going to have, I think, pretty far-reaching implications in other jurisdictions, far beyond the EU.

LLB: And the EU has been very active in this space under the other acronyms of REACH, the restriction and authorization aspect, where they have been under substances of very high concern, they have been labeling substances with endocrine disruption. You're going to see a trickle down, especially with key trading partners. You talked about with Chile, who knows how this then impacts how hazard communication, SDSs, things like that, now contain these details? Those are big changes.

And then they also made some changes in Section 14, which is transportation. And it's mainly, like I said, you've got to watch out for where they revised headers and subheaders because the terminology that they use in those sections, those are requirements. Verification that you're in alignment with the way that the subheaders have either been renumbered or revised is going to be a big part of what I see companies striving towards the next six months to comply with that December 31 deadline.

LLB: One more question on the EU. The European Chemicals Agency (ECHA) recently published the 18th ATP [Adaptation to Technical Progress] to the CLP. Why don't you explain the implications of this update to our listeners? And how should impacted parties prepare themselves for that change?

LLB: Yes, the ATPs are interesting process-wise because what happens with CLP is, as we talked about, there is a mandatory annex to CLP. It's huge. It's a lot of substances that hold the mandatory classification and labeling that the EU has either harmonized or was existent before CLP came on board. You have this huge list of substances, and some of those substances actually have specific concentration limits for when they're present in mixtures. This is viewed as the minimum classification and labeling for anyone who is placing these products on the market that contain these substances or these substances and mixtures.

The 18th ATP contains changes to that annex. In this case they have added 39 new entries, so we have the addition of new substances to the list, and then we have revisions to 17 entries. Any time you see a publication to the ATP like this, like the 18th ATP, you're seeing an amendment to CLP that does require a review to ensure that if you are formulating or you are actually manufacturing the substances, that you have the proper classification and labeling as it's been revised or added in some cases to the annex.

What's interesting about this is it shouldn't be a surprise to anyone about these entries because a lot of these were part of opinions that were being developed several years back. In most cases, the opinions were adopted in the 2020 timeframe, and you're given until 2023. If you had been tracking these materials as they have been discussed through the entire harmonization process, you would have known at least from 2020 that this was going to happen, and you have from now until 2023 to ensure that you have amended your SDS, your labels, accordingly to the classification labeling. In some respects, it's not unexpected, but --

LLB: Yes, it's more predictable.

KFB: It is. It is because the process is very involved, and it does take several years before it actually then ends up being part of the annex and now required.

LLB: Oh, that's helpful, Karin. Well, we can't talk about the EU without talking about the UK, right?

LLB: No, of course not.

LLB: Ever since Brexit. But it invites its own set of unique issues. Maybe you can explain to our listeners how the UK is approaching classification and labeling generally. I suspect, as has been the case certainly with UK REACH and EU REACH, there are a handful of issues derivative of the UK doing things differently from the EU. But can you elaborate a bit on that?

KFB: Yes, definitely. When the end of the transition period -- by the way, if you didn't know, the UK left the EU.

LLB: Right. News flash.

KFB: And with that came the genesis of what we refer to now as GB CLP, sometimes UK CLP, but I think we're trying to train ourselves to say GB because GB implies the actual countries involved: England, Scotland, and Wales. We'll have geography lessons. It doesn't involve the entire United Kingdom, but only Great Britain, so England, Scotland, and Wales. And we have a new sheriff in town because we have the Health and Safety Executive (HSE) now being responsible for GB CLP.

What happened was after the exit, anything that existed in the EU right up to December 31 2020 was retained in GB CLP, so that was the good news. We retained what we had, but now under the HSE, we have what's known as a mandatory C&L (classification and labeling) or the GB [Mandatory Classification List] MCL process, which is similar to what the EU does with the harmonization process. It allows the HSE, in conjunction with other parties, to decide how to address classification and labeling, so they can either adopt what the EU is doing, or has done -- because we're behind now. They can amend any way they see fit.

A good example, looking at that 18th ATP, which we know enters into force in the EU in November 2023, is to see how the GB is proposing to adopt those same substances. So what -- I picked out a couple, just to point out where we are going to see some variability. In most cases, they may just take exactly what the EU has done and incorporate it into the GB MCL, which right now is an Excel spreadsheet on the HSE website, so go track that down. It's a little different. It's not as sophisticated as the ECHA website, but the agency website does have an Excel spreadsheet that contains the mandatory classification and labeling under the GB CLP.

LLB: You make it sound so rational, Karin.

KFB: It's not. Really. I mean --.

LLB: -- It is not.

KFB: It is troubling because you have now a departure from -- it's just going to make it more confusing. It will be confusing. You also have timing issues because you're looking at the

EU implementing the 18th ATP in November 2023. The GB CLP is clearly lagging behind, so you're going to get variability in when these things get adopted, if they get adopted, and how they get adopted. That's going to create confusion on SDS and label content, no doubt.

LLB: All right. Well, as we wind up our conversation -- we could go on for hours, Karin, because actually I find this very interesting, and the way you presented it is so understandable. But I know as soon as I leave your company and start looking at this on my own, it becomes less comprehensible. So thank you for being so clear, but looking at the remainder of the year, what should our listeners be watching for?

KFB: Definitely a big year of transition. Like I mentioned in the beginning, Australia is in a transitionary period. EU SDS requirements are in a transitionary period, so be aware of your deadlines. We also have that nagging feeling that at some point in time, both Health Canada and OSHA (U.S. Occupational Safety and Health Administration) are expected to issue revisions to our existing hazardous products regulation and hazardous communication legislation. When that's going to happen -- I would not expect it until very late this year, maybe early next year -- but that has a major impact on the United States and Canada. I'm hoping that they are able to work out the timing of that because they've both proposed very different changes. I feel like Health Canada's was very straightforward. We're going to take our existing, and we're going to update to Rev 7. The U.S. approach was a little different, a bit controversial. It resulted in a lot of comments.

LLB: I remember that.

KFB: I feel like that means OSHA has a lot more to review from the comment periods and from the public hearing to determine how they're going to update from what we now have, which is a variation of Rev 3, to what they were proposing, which was a variation on a Rev 7 slash 8. So that to me is going to be a -- that's going to have a major impact when and if those two pieces of legislation actually happen.

Then continuing to watch Latin America. We definitely -- I would expect to see Brazil move forward with their one technical standard. Then you have now transition periods opened in Chile and Colombia, and that's -- how you determine the classification and labeling of your substances and mixtures in that region -- have a big part to play in any potential registration obligations for manufacturers and importers. You're seeing not just your typical "What goes on my label?" "What goes on my safety data sheet?" but now this interchange of "Am I now facing an obligation for a chemical registration?" -- which is very different. I think that for the rest of this year is going to be a big part of what consumes companies' interest.

LLB: Well, Karin, how can listeners stay on top of all of these changes? I know the firm's 2022 Forecast outlined and announced many of the changes that you've discussed today. And through that document -- which is available on our website at www.lawbc.com -- you can at least link to some of the initiatives that were front and center in November and December, when we prepared that mammoth document. But are there other initiatives in which you are engaged in your new position as Board Member of the Society for Chemical Hazard Communication? Are there forthcoming webinars on some of these initiatives? And I know you write and speak frequently on these, but what can our listeners focus in on?

LLB: The Society of Chemical Hazard Communication is a great place to start, and we do offer an annual meeting. That annual meeting does include training. GHS is usually a key part of not only the training, but the annual meeting agenda. A lot of times OSHA will speak at the meeting. Health Canada will speak at that meeting, so it's a really great place to start. But

again, that meeting's in September, so trying to keep on top of a lot of this is incredibly challenging. I would look to the UN if you're new to this, *especially* if you're new to this. Understanding what's happening at the UN really is paramount to diving in and dissecting how each country takes what the UN model provides and adopts it into their own legislation. Be very cognizant of the fact that the word "harmonized" is a bit of a misnomer here.

LLB: You're being kind, Karin.

KFB: There is some consistency in that. Like even where you have this harmonization, you do have the same pictograms being used. You do have the same hazard statements being used. It's understanding that there is a lot of layer here, and your software may not be up to date. Appreciate that while you're struggling to understand GHS, your software provider may not be technically competent or technically fluid enough or efficient enough to understand how some of these changes impact, so you might be generating an MSDS that you believe is compliant with the requirements of the ministry in South Korea. But don't be surprised when you submit that that you get feedback. I've heard that time and time again. So just, for your own sake, as a hazard communicator, it is really important to understand the regulation yourself and not 100 percent rely on what your tools are providing you. Then look to your -- you can look to the UN for updates, look to firms like B&C and Acta, because we do try very rigorously to maintain -- if something is happening, we try to put it out there on our website, to talk about it on podcasts like this. These tools are available and out there for everyone.

LLB: Excellent advice, Karin. Just great conversation. I am just in awe of your command of the space and keeping up with these many, many changes. You make a very complex area rational and understandable. And my thanks to you for being with us today.

KFB: My pleasure. Thank you, Lynn.

LLB: My thanks again to Karin Baron for speaking with me today about the ever-changing world of GHS. Despite its name, the Globally Harmonized System of Classification and Labeling of Chemicals is anything but. And Karin's mastery of this highly nuanced subject matter is impressive and helpful.

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