



## Episode Title: Changes to Safety Data Sheets in the EU and What It Might Mean for U.S. Businesses -- 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, P.C. (B&C<sup>®</sup>) a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I'm Lynn Bergeson.

This week I sat down with my colleague Karin Baron, a Senior Regulatory Consultant here at B&C and at our affiliated consultancy, The Acta Group, to discuss the really important European Union's (EU) Commission (EC) Regulation. It was implemented last June with regard to the completion of safety data sheets (SDS). Now, as listeners know, SDSs are important commercial documents that identify the hazards identified with a particular product as it makes its way in commerce. This is an EU rule. Karin explains why the regulation has really important implications for U.S. businesses. Now, here's my conversation with Karin Baron.

Karin, I am delighted to welcome you back to our podcast. You are a repeat offender and a much sought after presenter on issues like the one we're going to talk about.

**Karin F. Baron (KFB):** Oh, thanks, Lynn. It's good to be here.

**LLB:** Great. Let's dive right in. As I understand it, Annex II of EU's REACH [Registration, Evaluation, Authorization and Restriction of Chemicals] regulation was amended last July by a Commission regulation. Again, I'm not the expert you are, Karin, but it seems to set out the requirements for the completion of all important SDSs. The regulation is commonly referred to as the Commission Regulation. It went into effect in July, and it applies as of January 1, 2021. Could you tell our listeners what Annex II is, what the Commission Regulation does, and why we are talking about it here on this program?

**KFB:** Sure. I think it's important to understand, as we've talked about before, that REACH, which is a vastly complex piece of legislation, stands for the Registration, Evaluation, Authorization, and Restriction of Chemicals. [It] contains elements that folks may not realize, particularly with communication in the supply chain. As part of the REACH

regulation, Annex II actually sets out all of the requirements for the content of the SDS, which is kind of unique because for most companies in most countries and most legislation dealing with hazard communication (HazCom), you typically find the SDS either as a separate piece of legislation or incorporated into HazCom criteria. But in Europe, REACH contains these criteria, so any change to that, any amendment to those requirements, does have fundamentally a pretty significant impact on the communication supply chain.

**LLB:** Maybe you can outline a little bit about the specific changes that would appear to require, to my read of the Commission Regulation, pretty significant changes to SDSs. Maybe as a preliminary matter, to what entities does the REACH Annex II regulation apply?

**KFB:** Annex II says that the SDS is the responsibility of the supplier and that “the supplier shall provide the recipient” an SDS when it’s classified. But then it goes further to lay down what it means by “classified.” And it refers to several different elements, one of them being the classification, labeling, and packaging of substances and mixtures, commonly referred to as CLP. CLP holds all of the hazard criteria elements for labeling content and hazard determination. If you’re classified under CLP, you’re obligated to then produce an SDS. If you’re a PBT (persistent, bioaccumulative, or toxic substance), you’re required to generate an SDS. If you’re a vPvB (very persistent or very bioaccumulative), you’re subject to SDS requirements and further communication. Then substances under REACH that are subject to authorization -- typically, these are going to be your bad actors: your carcinogens, your mutagens, your reproductive toxins in certain categories of hazard -- are also subject to these requirements, so it’s pretty extensive.

If you think about CLP itself, it’s about 1,500 pages of legislation. It’s very large in its concept, and the SDS itself in the EU is probably pretty much one of the more complex SDSs. It is still your typical 16 sections, but one of the unique elements that the EU did was they incorporate this concept of subsectioning. What you’ll see is that there are mandatory 16 section headers, and unlike the United States, where we do have a 16-section SDS, all of the sections within the EU are required, including all of the subsections. One of the minor -- it seems minor -- but one of the changes that they made was to Section 12, which in the United States is a nonmandatory element, but in Europe it’s included, and this is ecological information. But they changed -- they made is just annoying enough to -- because they changed the content in that section by adding a new subsection, but then they messed up the numbering sequence. It seems like a minor change, but for someone who has an SDS that has Subsection 12.1 through 12.6, and now you’ve added a new element, and it renumbers the sequencing, it’s changed, and it’s a visual difference. Because of that, you’re going to see that -- it’s going to be obvious who is complying with this element and who’s still behind because of the changes to the subsectioning.

**LLB:** Okay then. The term “minor” and “safety data sheet changes” don’t belong in the same paragraph because --

**KFB:** -- Rarely.

**LLB:** -- Every change is kind of a big deal. But before we get into some of the substantive changes that I think are causing some controversy, maybe you can tell us a little bit about the phase-in. It was effective, or it applies, as of January 1, 2021. You just articulated, Karin, the broad categories of chemicals that it applies to: CMRs [carcinogenic, mutagenic or reprotoxic], and vPvBs, and PBTs and all the other alphabet soup that goes into the mix. But if you’re in the EU, it sounds like you’re pretty much probably going to be covered, and

perhaps it's best to think of it that way. But what does that mean as of January 2021? Is there a phase-in period here?

**KFB:** It's interesting because the way that the legislation is written, Article 2 states that noncompliance can continue until December 31, 2022. But then right underneath it, it says in Article 3 that it shall apply from January 1, 2021. Some mixed signaling, I believe, on this, but my take on it is that if you are already on the market, if you are already classifying and providing an SDS that was compliant with the previous Annex II, that you have until December 31, 2022, to adopt these changes. But I will state that if you had not created a data sheet, or you have a new product or a hazardous substance or mixture and you are placing it on the market in the EU now, I would read that to mean you have to comply with this, these provisions of Annex II, because you -- obviously, you didn't have something there that you can continue with, but it's really not clear because it does say noncompliant. It's not 100 percent clear, but I would read you have until the end of 2022.

**LLB:** Okay. That's comforting for people that have products on the market now. There's that sell-through provision, and you don't have to worry about addressing everything as of two months ago, correct?

**KFB:** Right, exactly.

**LLB:** Okay. One further point of clarification. How does this EU Commission Regulation affect, if it does, the 6th and 7th revisions of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)?

**KFB:** As I mentioned before, it's interesting the interplay between these two pieces because you have CLP, which contains all of the GHS hazard criteria and the specific list of substances that are classified under the EU provisions. In 2019, in the 12th adaptation to technical progress, CLP was revised to amend the 6th and 7th revision of GHS. But you can't amend one and not the other. There does have to be subsequent consideration to the SDS content when you make a change to CLP because they are intertwined. Whereas CLP deals specifically with the labeling, and the packaging, and the criteria for how hazards are defined, REACH lays out the registration obligations and the supply chain communication and specifically the SDS content. They do have to maintain some kind of consistency with each other. What you're seeing is that interplay coming to force where you have a change to CLP and now you do need to amend, you *do* need to amend. And there were other changes to CLP that we'll talk about. But this is where you do see the connection between the two.

**LLB:** Got it. Okay. Now let's push on to some of the substantive changes that, at least from my non-expert eye, I found very interesting and possibly quite influential with regard to how chemical hazards are identified, not just in the EU but potentially here in the States. I've heard quite a lot about the inclusion of something called the Unique Formula Identifier, otherwise known as UFI, rhymes with goofy, but it isn't. What is this, and what does it really mean in the real world?

**KFB:** UFI doesn't really roll off the tongue.

**LLB:** No, it really doesn't, Karin.

**KFB:** As we talked about just a minute ago, this is one of those interplays between CLP and REACH. Annex VIII of CLP lays down the criteria for poison centers. Think of poison centers similar to our poison control here in the United States. The UFI is part of these

poison center obligations for hazardous mixtures that are placed on the market. Not to get into a tremendous amount of detail, because it is incredibly laborious in its task, but the idea was that when a hazardous mixture is placed on the market, and there is an emergency response, and someone does call a poison center in a member state, there was very little visibility as to what the actual contents of those mixtures were. Part of the goal with the UFI was to have folks notify the poison centers in the various member states and for them to generate this unique alphanumeric 16-digit code that could be located on the label. Then when a caller did call in to a poison center, they could provide this UFI identifier and be given clarity, from the poison center's perspective, as to what exactly was in that hazardous mixture.

It's very complex. At some point in time, each member state had different processes for how you notified. It's starting to come into more of an alignment, and one notification instead of 27 is part of the goal. But essentially what they did in this Commission Regulation was to provide the location for the UFI code on the SDS because those that supply, just to industry use -- so if I have a mixture that I place in the market, but it's only for industrial use, I actually don't have an obligation to put the UFI on the label. They gave them in this Commission Regulation, this change to Annex II, a location for the UFI in the SDS, and that now belongs in Section 1.

**LLB:** All right. Well, that's helpful. It's confusing, but it's helpful.

One of the two, I think, really major changes that, again, to my eye, seemed very consequential in this Commission Regulation is that it requires the specification of, quote, unquote, "nanofoms" of chemicals. Number one, is this an accurate read of the regulation, Karin? And under what circumstances must that terminology be used?

**KFB:** Yes. This is pretty significant because what we're seeing is the nanofom inclusion in the SDS is actually a reaction to changes to REACH and part of the registration. Registration of all substances placed on the market -- and that means either manufactured or imported -- began in 2010 if you manufactured or imported more than one metric ton per year. That process completed around 2018, but is obviously still ongoing for new importers or manufacturers that exceed the threshold.

But what happened is during that process, this concept of nanofoms was taking place, and certain substances are required to indicate now in your registration whether or not that substance is available in a nanofom. And there are specific definitions that they laid out. Typically, you're looking at size ranges between one nanometer to 100 nanometers. There are a lot of other criteria. I don't want to simplify it too much, but just appreciate that a lot of commonly used chemicals in the marketplace do exist in a nanofom. There was an acknowledgment of this at the REACH registration level. What you're seeing now is that further supply chain communication of the hazards that *could* be associated with a nanofom and a location of where they expect to see that information in an SDS.

There are substantial revisions to various sections of the SDS that now incorporate the disclosure that your substance is available (and placed on the market) in a nanofom. You're right in pointing it out, because it wasn't something that was previously -- we were aware of it, but now there's a specific legal obligation to disclose it and to disclose it in specific sections. It is significant if you are placing nanofoms on the market in the EU.

**LLB:** And that includes exports of products manufactured in the United States and shipped to the EU, right?

**KFB:** Especially if you're the importer of record. Yes. The way that the legislation reads is that -- it's a little complicated, but the person, the individual placing it on the market -- and that at times means the importer -- is the one who's obligated to provide that. But even more simplistic, the REACH legislation says, "the supplier shall provide the recipient." So that could be very broadly interpreted. Now, most folks don't interpret it to be a non-U.S. manufacturer who is not the -- um, a non-EU manufacturer -- who is not actually the importer. But I would say if you *are* the non-EU manufacturer and you're aware of the fact that you're shipping it to somebody who is importing it, you *do* have some obligation to let them know that it is nanoform.

**LLB:** Which is a very interesting change to me, because this is a specific requirement that is strictly size dependent, right? Because you can have a nanoform of a substance or a mixture and not necessarily enhance its hazard potential, correct?

**KFB:** Absolutely. Yes.

**LLB:** This is a requirement to compel that disclosure, independent of its relationship to what an SDS is intended to communicate, which is the fundamental hazard properties of a substance.

**KFB:** And I think what you're seeing is the precautionary principle in play.

**LLB:** In spades!

**KFB:** Yes, exactly. Because not only is it now obligation to communicate, you're also -- if you registered a substance that is available in a nanoform, you have to indicate that as part of your registration dossier. What we're seeing come out of this is ECHA [the European Chemicals Agency], in evaluating those registration dossiers, is asking for extensive data to demonstrate that the nanoform of that substance is not hazardous. This just kind of further goes with that precautionary principle in that it really doesn't matter whether or not you consider it not hazardous. If it's available in nanoform, you have to indicate as such.

**LLB:** Yes, it's troubling to me at several levels, because size is not supposed to matter. And if size *does* matter, it's because it imparts a particular hazard property that should -- an exporter would be required to disclose it on a safety sheet because that's what the SDS is all about. But this is divorced from that and just somewhat prejudicial to substances, mixtures, chemicals that have some nanoform component to it, and that's why I find it both somewhat controversial and clearly a big deal if you're exporting, or once it's brought into the United States, it would be on an EU-originated SDS. To me, that could really change the conversation about describing the hazard potential of a chemical substance globally.

**KFB:** I would agree. I would agree, very much so. Every SDS legislation that you see lays out intent based on a hazard determination process. But as you're pointing out here, what they're indicating is that there's an inherent hazard with a nanoform. That is a bit disingenuous in the assumption that, just because it is available in a small size, that it *is* hazardous and requires communication elements like an SDS.

**LLB:** Yes, it could be very prejudicial, so I wanted to make sure our listeners were aware of that. Another super important aspect of the regulation is relating to the chemical substance's endocrine-disrupting properties. This is super relevant to me. I was reading over the weekend Shanna Swan's new book that just hit newsstands near you called *Count Down*. Swan calculated in her book, based on her research, that from 1973 to 2001, the sperm count of average men in Western countries has fallen by some 59%. Now, putting aside whether

that is accurate or not, because we're not here to talk about that, it suggests to me that endocrine-disrupting substances will be a much more significant factor or the endocrine disrupting potential of a substance could well be a more significant factor in the United States going forward.

It's been a pretty big deal in the EU for a number of years now. But the fact that now entities are required to state in an SDS whether a chemical substance has an endocrine-disrupting property is important.

Two questions for you, Karin. First, when does a chemical substance have an endocrine-disrupting property? And second, is there any type of volume threshold above which this requirement applies with regard to mixtures?

**KFB:** Yes, absolutely. As you mentioned, endocrine-disrupting properties have been a focus of the EC for some time now. We've seen them slowly start to develop over the last several years, if not decades, the definition of what they consider endocrine disrupting -- and it's not just one thing. I think that's the most important thing. It's not a simple thing. Whereas you look at some of the hazard criteria: if it destroys living tissue, it's corrosive. Endocrine-disrupting properties are several things, and you put together the way the criteria lay out, it's a weight of evidence. You're not just looking at -- does it just do one thing? It's, does it do several different things? And if it does several different things, then it's considered to possess endocrine-disrupting properties, and the criteria are about two pages long. There was a lot of detail and thought put out into this.

The inclusion of this now is just -- it's a reconciliation between all of the work the EC has done in defining endocrine disruption, an acknowledgment that that definition doesn't necessarily lie anywhere within CLP, though I would argue it probably should have been added *to* CLP rather than as its own kind of stand-alone. But what you're seeing is, if you meet -- for example, if you disrupt the, alter the function of the endocrine system or you have adverse effects in your progeny, and some of the effects that you had mentioned, both positive and negative effects, all of these things are kind of put side by side. Then if the overall weight of evidence demonstrates it, then you are expected to disclose the substance that possesses endocrine-disrupting properties. You're supposed to describe it in the various sections of the SDS.

And as you asked, with respect to that substance in your mixture, if it's present at 0.1% or greater, then you're expected to describe that as well. What you're seeing is typically 0.1% in mixtures is left to the more serious hazard classes. Things like known human carcinogens are usually -- you're usually expected to indicate that they're in your mixture at 0.1%: known reproductive toxins, known mutagens. Then putting a 0.1% threshold and then specifically providing criteria that are pages long indicates that this is something that we do have to start to evaluate. And then as you and I were talking before, we're also seeing an indication that once you've defined something with endocrine-disrupting properties, there is a swift move to either restrict those in mixtures in commerce, in circulation, or to authorize those, which is an even more tedious process. But the reality is there is a move to remove these things from mixtures and substances that can be placed on the market in not just industrial, but consumer applications.

**LLB:** That's -- kind of backing up a bit -- apart from the granularity of the provisions you're addressing, Karin, the big take-home here is when you have to describe chemicals and mixtures a particular way in one jurisdiction, it absolutely has an impact on how that chemical and/or mixture is profiled throughout the world. If only we *could*

compartmentalize, but that's not the nature of the global chemical market. The description of a chemical in Europe and its import in the United States or elsewhere on the world is a consequential act, and that's why we're having this conversation. It's not like this is occurring across the pond; we don't have to worry about it. Quite the contrary.

One final change that I wanted to talk some about is the requirement relating to sensitizers. I know sensitizers is a pretty broad term, and it's also a feature, a characteristic, of a lot of chemicals because they are known to be sensitive based on any number of criteria, which I know you will share with us. Question here is that, as I understand it, there is a special treatment under the Commission Regulation with respect to sensitizers. Number one, is that true? And second, how are sensitizers regulated under the Commission Regulation?

**KFB:** Sensitizers are, as you noted, simply something that causes an allergic response on your skin, so anything that you have an allergic response to when it's placed in contact with your skin or more seriously causes respiratory hypersensitivity of your airways, which is -- could be anything from an asthmatic reaction or something more severe -- and sensitizers have always kind of had special treatment. I think any time you revise a regulation, it just brings these issues to light, and people read things a little bit more carefully or review things a little bit more clearly. But what they've done here with sensitizers is essentially, there is an ingredient disclosure obligation.

Say I have a mixture, and my mixture is not considered hazardous, but my mixture contains a sensitizer. What they've done is state that if I have a sensitizer at concentration below the normal threshold -- the normal threshold for classification is usually 0.1 for a pretty severe or not so serious skin sensitizer. If I have it at a lower concentration, I'm still obligated to disclose that ingredient, and there are also some labeling obligations. But it goes even further into it is -- you can have sensitizers in your mixture at concentrations below 0.005% and still have an obligation to disclose that. I think that catches people off guard, because we typically think with sensitizers, there's a very clear threshold: 0.1, and we don't have to worry about it. It's not at 0.1. But what this says is certain level of skin sensitization, there's an acknowledgment that 0.1 may not be protective enough. With more serious sensitizers, ones that definitely have been demonstrated to cause sensitization in humans, they want to see it disclosed at concentrations at times that are incredibly low. Just because your mixture calculations in your software cut you off at 0.1 does not necessarily mean you've complied with the ingredient disclosure obligations. I think it's important that people understand what those rules state and whether or not they're subject to them.

**LLB:** And I'm guessing, Karin, there isn't some handy dandy list of those sensitizers that fall at or below the 0.005%, right? Is this more of a self-implementing determination?

**KFB:** It's interesting because what they've done is, if -- under CLP, so again, this is a tie-back to that CLP legislation -- Europe has a very robust list of substances that they have mandatory classifications for that are in the CLP regulation. Certain substances within that list have their own mixture concentration classification criteria. The example I cited there was actually specific to BIT, which is a well-known, well-established preservative that does cause sensitization. There is a written concentration limit already in the legislation that says if it's in your mixture at 0.05% and greater, you have to disclose it. What these provisions state is that, at 0.05 and above, I have to call it a sensitizer. But say I have it in there at 0.04. I no longer have to classify it as a sensitizer, but under Annex II of REACH, I have to look at one-tenth of that specific concentration limit before I'm allowed to not include that in my Section 3 ingredient disclosure. That's where I get the 0.005 because it's a reduction -- a further reduction -- for you to consider. So that's one place to look, is look to see whether or

not it's already included in the Annex, to see if it's classified as a sensitizer because that means it's already known to the EC as being a sensitizer. But then the criteria are laid out -- again in CLP, not in REACH -- as to how you define. If you define it as what they call a subcategory 1A, then the ingredient disclosure is 0.01%. And if it's in a subcategory 1B, it's 0.1%. It's important to look at those criteria and determine whether your substance -- or mixture that contains that substance -- meets the criteria of a sensitizer. And then work your way out to see whether or not you need to disclose it.

**LLB:** I am so glad, Karin, you are on our staff. This is kind of mind-numbingly complicated.

**KFB:** Yes.

**LLB:** Which raises an important question. Which government agency in the EU is tasked with enforcing what would be regarded as SDS instances of noncompliance or violations, ECHA? Or member states? Or both? Or who's minding the store on this?

**KFB:** Yes, this has always been a really interesting question because historically, it's been the member state. The EC lays down the rules. Each member state is responsible for enforcement. But what we're starting to see, at least trending on other elements of REACH, is a push for ECHA to be more involved in this aspect of compliance. And as I've always stated, anything that has a written document attached to it, like an SDS or a label, is such an easy thing for someone to cite.

**LLB:** Yes.

**KFB:** It's a very obvious thing for someone to look at. And when they make big changes to subsection headers and include elements like endocrine disruption -- even if you don't have it, it's still a required subheader. It really shows that you are not in compliance. Some member states are going to be more active in this space, and we've seen that historically in the past with extended SDSs. There was a big push for folks to have extended SDSs, where they were obligated, and we did see member states actually out and enforcing that action. I do expect to see, not this year, not next year, but I would sometime in 2023, 2024, a push to ensure that folks are complying with these provisions. It would -- it could be at the member state, like it normally is, or we could see ECHA gaining -- it's been pushing to gaining more authority in the area of compliance. And this is an aspect of REACH, so it could be very well part of the REACH compliance documentation.

**LLB:** As you say, Karin, when you have a document an entity is required to complete according to code and specifications that are laid out in some meaningful context as it is here in Annex II, it is what we call fish in a barrel time with regard to potential noncompliance, because it's much easier to discern noncompliance when you have a document that is to be completed according to a known standard.

**KFB:** Absolutely.

**LLB:** What are the consequences of noncompliance? Are these big deal violations or slap on the wrist type instances?

**KFB:** What I've seen in Europe is a little bit different than what we typically see in the United States when it comes to enforcement. Most of it is just bring yourself into compliance as soon as possible. I've not seen, and I doubt you will see, a push for any type of monetary discussion on this. But I don't know; that could change. I know some member states are



definitely -- this is a target area for them, and they're more aggressive. It is pretty much in your best interest to bring yourself into compliance as soon as possible if you are asked. But definitely when you're asked, the worst thing you can do is be adversarial with the member state that's looking for this documentation. Most of them are very cooperative in ensuring -- they just want it to be compliant. That's the point -- the take-home message.

**LLB:** Right. I'm guessing, too, whether it's compliant or not, all of these changes could invite a degree of commercial competition as to how one defines their product, whether it's an endocrine disrupter component associated with it, or is it in a nanoform, or is it a sensitizer? There are all issues that invite competitive issues and potential confusion in the marketplace, when you're dealing with the same chemical but defined and attributed different hazard properties from different manufacturers or importers. I see a lot of potential mischief down the road until the dust settles, as it were, with the true implementation of all of these new changes.

**KFB:** Yes, I could definitely say that. We're seeing a lot of changes being enacted in SDS legislation, a lot of notices of proposed rulemaking. Any time there is this discussion, it's an opportunity for industry to revisit.

**LLB:** Yes. Yes.

**KFB:** The timing of that revisit will inevitably create disconnect. It could absolutely, in the case of someone who has an EU obligation, an obligation to inform about a nanoform or an endocrine-disrupting property, where that obligation does not exist in another part of the world, like the United States or Canada, because it's not part or it's not considered in the criteria -- though I would argue it is. It's interesting to see how companies go about reconciling that, and then how they address that, across multiple jurisdictions.

**LLB:** I was just going to ask you about that, because to some extent, all of these issues invite potentially, trade headaches. The descriptors of a chemical hazard are not symmetrical in the United States and the EU, so what do you see there, given the potential for some pretty significant inconsistencies between our two governments?

**KFB:** I know the first and the most major one that comes to my mind is that under Annex II of REACH and the CLP criteria, environmental hazard is a big focus. Endocrine-disrupting properties can affect not only humans, but there are indicators that it does have an environmental impact, where environmental hazards were excluded from the U.S. HazCom standard because -- we've talked about this before -- it's not part of OSHA's [Occupational Safety and Health Administration] jurisdiction, but inclusion of elements like toxicity and persistence and bioaccumulative potential, things like that that are non-mandatory in the United States but are mandatory in the EU, definitely create some disconnect. Now in the United States, you're absolutely allowed to include them, but as you've talked about, that may bring some competitive disadvantages if you're calling out properties that are inherently not considered good.

**LLB:** Yes, they're not commercially desirable, right?

**KFB:** No, no. I do see that you have opportunities to revisit and to figure out the best approaches, but I do believe -- and I will tell you, I do this as a HazCom person. I will look at a company's European SDS and their U.S. SDS side by side because I want to see the full picture of what's happening with those substances. And I don't want to be blinded by the legislation's inclusion or exclusion of certain things because as a hazard communicator, you

want to ensure you know the most about the materials you're using and that you're including that because the end game is just that you're -- it's a hazard determination process, and you're providing information for the downstream users so that they are better informed on how to manage the hazards.

**LLB:** Yes, that's what it's all about. As we wind up here, Karin, what are the two or three points you want our listeners to take home based on this podcast?

**KFB:** I would say for one, you definitely need to look at the Commission Regulation. You definitely need to consider the revisions to the subsections because that's inherently a change and an obvious change. I would consider the endocrine-disrupting property criteria and the weight of evidence to be evaluating and establishing whether or not your substances or your mixtures containing those substances meet those properties.

Clarification on nanoform – and I look at this as both an opportunity, but an interesting opportunity -- is that, if you have data on your nanoform, even though you are required to disclose that you are presenting a nanoform to the market, use the data to explain the hazards associated with that. I think that affords you an opportunity to use the data that you've generated and the information that you know about it to discuss whether or not, even though it is in a nanoform, that it is or is not hazardous. I think those are some of the big take-homes, but most importantly, just appreciate that there is a change in the SDS. If you use an authoring platform, that change may not have been applied to your platform yet, so you do need to be actively seeking those changes through your platform, whoever you're getting your platform from, and then ensuring that you are on the road to compliance, if not already thinking about how to come into compliance with these changes.

**LLB:** Excellent. And I'm guessing, Karin, you have written about this topic and many others having to do with GHS and HazCom -- being the HazCom person that you are -- and available on our website, yes?

**KFB:** Yes, absolutely.

**LLB:** And I would imagine, too, for readers or listeners who wish to read up on this, you might also check ECHA's website because I'm pretty sure we hyperlink to it in some of our writings on our lawbc.com website. But if there's anything else, Karin, that you wish to direct listeners to, please do so.

**KFB:** Yes, I would just caution you that this is not all located in a one-stop shop.

**LLB:** Yes, sadly. Just to make everyone's lives perfectly miserable.

**KFB:** Yes, you really do have to kind of navigate in and out of the various things because they may talk about endocrine-disrupting properties, but you won't find it in REACH. You're going to have to go look somewhere else to get those criteria. And then they may mention CLP, but you're going to have to go look at CLP, and not every version of CLP is available in the same hyperlink. So don't get frustrated. Definitely there. It just takes a little bit of navigating to locate everything.

**LLB:** Don't get frustrated. Call Karin. Right, Karin? I am so glad you have sorted this out. This was a hugely illuminating conversation, and I wish to thank you for joining us today.

**KFB:** My pleasure.

**LLB:** My thanks again to Karin for speaking with me today about the EU regulation relating to the completion of SDSs and why these really important changes are important for U.S. businesses.

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