Episode Title: Compliance Checks and REACH — 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 am Lynn Bergeson. This week, I sat down with Karin Baron, Senior Regulatory Consultant at B&C and our consulting affiliate, The Acta Group (Acta®).

Karin works extensively with the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals program, better known as REACH, which is the EU counterpart to the United States' Toxic Substances Control Act (TSCA). We discussed today REACH Article 41 "compliance checks," an innocuous-sounding component of REACH that has the potential to cause considerable business anxiety, delay, and expense if a company's REACH dossier is found to be deficient as a result of a compliance check. Karin walks us through what these checks are for, what could happen if you're caught up in one, and how best to respond if your dossier becomes ensnared in a compliance check. Now here is my conversation with Karin Baron.

Karin, thank you so much for being with us today. It's just great having you back in the studio.

Karin F. Baron (KFB): Thank you. I'm really excited to be here today.

LLB: The topic of the day, our REACH compliance check, is something about which you know much and have a lot to say. So let's get at it. First off, for the benefit of our listeners, perhaps you could explain what a REACH Article 41 compliance check is, and maybe even back up a little bit and explain the commercial content of REACH. Is it the regulatory gatekeeper for industrial chemicals in the European Union, or is it something else in your mind?

KFB: We could spend about 7,000 hours on REACH. Describing it as a regulatory gatekeeper is perfect because REACH is incredibly complex. It's newer than some of the other chemical control legislations that you're familiar with, like TSCA in the United States. It was enacted in 2007, and it's had a pretty global impact from its concept and how it's evolved. The most important thing to understand about REACH is that it is specific to EU member countries, of

which there are now 27. It involves manufacturers and importers within those 27 member states. It is an acronym, like everything in regulatory -- we love our acronyms. It stands for Registration, Evaluation, Authorization and Restriction of Chemicals.

The aspect that we're talking about today is actually the E in REACH, the evaluation. To understand it, we need to back up and talk about registration itself, essentially registration applied to, again, EU manufacturers or importers that made or imported more than one metric ton. A threshold volume was established. It is substance-specific, and the exceptions and what's out of scope -- in every piece of legislation we've ever looked at, there's always going to be a scope and an exception to the rule. There are some things that are exempt from registration, but that list is kind of small, and companies that exceeded that one metric ton did need to register. Registration, as anyone would expect, is pretty involved. The legislation details out what's expected for the registration dossier, but it is entirely based on volume.

For example, if you are in a one to ten metric ton per calendar year tonnage band, you would have a different set of data requirements to somebody in a higher tonnage band, like ten to one hundred. The key piece to registration was that companies were to work together, which is unique because, as we are familiar with how new substances and chemicals are evaluated in the U.S., under the European scheme, it was expected that companies would work together, they would compile or generate the data if necessary, and that there would be a Lead Registrant, who would submit that data package on behalf of all of the members of that same substance. So everybody was working cooperatively, in theory --

LLB: I get the "in theory" part.

KFB: Yeah, only in theory -- and that they would then develop one registration, and then all of the parties that were involved would submit co- or joint registrations where they would reference that data. As I said, that is a very high level, very quick summary of what registration was, but what we're talking about today is that next step.

After you submit that registration dossier, you get into the evaluation. A compliance check is simply an evaluation of that information. REACH also has a risk-based element associated with it, so when they're looking at this compliance check, they're looking at, did you satisfy all the data requirements we laid out and does your risk assessments and your risk management measures, are they adequate and do they make sense? That is essentially what Article 41 details.

LLB: Okay, it sounds like it's a very important component of the REACH program.

KFB: Absolutely.

LLB: And as we're about to talk about, it might have some significant commercial implications. The European Chemicals Agency, or ECHA, is the agency in the EU that implements REACH, and from my perch, it's certainly understandable why ECHA would wish to assess the compliance of each of the dossiers looking at REACH compliance obligations. But I suspect ECHA's resources don't allow it to go through an evaluation process for each and every dossier, or maybe I'm wrong.

I was looking at the standards recently and understand that ECHA selects dossiers based on both a random check, however random is defined, and also a quote, unquote "concerned-based" or "targeted basis," which is interesting because the selection of targeted dossiers

itself involves some degree of subjectivity, coming from ECHA's perspective. But do you have any insight into how dossiers are selected and what clients that you are helping to counsel through this program might be looking for to help avoid being targeted? There's probably nothing to avoid being randomly selected, I guess. I could be wrong, Karin, what do you think?

KFB: No, it does state -- and if you look through the ECHA website and you look at their procedures and you look at their questions and answers (Q&A), they definitely know that it is random, but they also state it's done in line with their strategic objectives and their regulatory strategy. So that's one point that you can evaluate, and they're looking at high tonnages. They're looking at suspected data gaps in those higher tiered bands, and they're also looking at high potential exposure. But when you look at the overall statistics, like you mentioned before, it would be nearly impossible for ECHA to commit to evaluating every single substance that's been registered. And there are over 22,000. And those 22,000 have been registered by over almost 100,000 different registrations, so it's a bit much. ECHA in 2020 did commit that by **December 31, 2023**, they would have evaluated no more than 20 percent of the total in the tonnage bands of 100 tons or more, and that by **December 2027**, they would commit to reviewing no more than 20 percent in those lower tonnage bands, less than one hundred tons. They have legislated a commitment to actually evaluate a certain percentage of these dossiers, but there is nothing in the regulation, nor in recent communications, that indicates that they will ever get to the point where they evaluate all of them.

When you talk about targeted selections, we've seen that more frequently, recently, we've seen that with nanomaterials. We've seen some decisions on compliance checks where they are targeting on specific endpoints that they're interested in learning more about, or they don't feel that that registration dossier has provided enough information about the potential effects. And nanomaterials is where you see a targeted check coming through. But then I've also seen -- and you and I were talking about this -- decisions for registration dossiers where there are only two parties involved. It's a pretty small registration, but it was targeted for a compliance check because it was suspected of not containing all the required elements, so it does feel random, but there does appear to be some logic behind it. And I went back and looked at just a couple of recent ones and then looked at some older ones. When you look at the statistics, you'll see that the substance that has the highest number of registrants is ethanol. That should not surprise anyone. There are over 600 individual entities involved in the ethanol dossier. The compliance check that was issued for ethanol dealt more with the exposure aspect of ethanol. And you could understand why that would be something of interest, because I highly doubt that there are data gaps with respect to requirements to understand the toxicity of ethanol. I think we can all agree it's been studied enough.

LLB: Oh, absolutely. It's very well studied.

KFB: I think the concern was based more on its exposure profile because there is a high degree of exposure across a wide range of professional, industrial, and consumer uses. You do see what you would expect to see, but there's also that randomness where you have these smaller two-party registrations also receiving compliance check evaluations.

LLB: Yeah, it does seem to be pretty all over the map because in the example you cite, Karin, -- the one dossier submitted by two entities -- in theory that could be a high production volume chemical. But one would think if it were, there would be many more entities involved in the dossier. In that particular instance, was that a two-person dossier of a relatively modest volumetric chemical?

KFB: That one was a fairly low, so it would have been a 100 ton or lower. That was one where I would not have flagged that one immediately for one of those higher tonnages, higher tier data gap or higher potential exposure. The comment on random and their strategic objectives does appear to be the majority of the cases, but not necessarily. Just because you're in a smaller tonnage band in a smaller dossier grouping doesn't necessarily mean you're going to not be the subject of a compliance check.

LLB: It's an interesting observation you note about nanomaterials. The dossiers are selected based on the chemical, right? So if it's titanium dioxide or carbon black -- both of which might be expected to have a higher percentage of nano applications -- are those nanomaterials being evaluated within the context of the dossier for the substance, or are there applications of a chemical that are selected independent of the dossier?

KFB: No, the dossiers are definitely substance-specific, so any compliance check would relate to the substance, not necessarily a targeted. That doesn't mean that ECHA isn't, as part of its agenda, looking at all registrations that include nano and selecting them as part of its strategy. But when it does select it, it is substance-specific.

LLB: Okay. I know ECHA claims compliance checks that it engages and focuses on eight different endpoints, some of which include genotoxicity, carcinogenicity, reprotoxicity, and so forth. In the context of these compliance checks, what exactly do these endpoints mean?

KFB: That is an excellent question. ECHA states that it is looking at specific data. And when we were talking about higher tier, higher risk, those types of elements, those endpoints tend to appear in the higher tonnage bands as required elements. Those endpoints are also strategic for ECHA as a whole, because what the entire legislation was enacted to do was to have everybody submit all the information they knew about those chemicals, have ECHA evaluate those chemicals, and then make a determination on whether those chemicals should be restricted for certain uses or certain percentages or certain marketplaces, or whether those chemicals should be subject to authorization, which is essentially eventual removal from the market.

When you get to the evaluation phase and you have an interest in certain endpoints: CMRs -- carcinogens, mutagens, reproductive toxins -- or things that are persistent or bioaccumulative in the environment, those eight endpoints are going to be critical in that evaluation to determine whether restriction and or authorization is necessary. When we're talking about a compliance check, it would make sense that if we are focused on high exposure, higher tonnage bands, higher tiers, that these endpoints are those that are critical for evaluation. If you don't have everything ECHA asked for or understood, or the quality of those data is not adequate for ECHA to make a decision, then you would receive a compliance check. In particular, there's a big focus on environmental endpoints. We've seen this with things that they determine are persistent, bioaccumulative, or toxic (PBT) or very persistent or very bioaccumulative (vPvB). And those are just things that don't behave well in the environment. They don't break down. The uptake process exceeds the removal. When you're looking at those eight, those tend to be the endpoints of focus for whether or not further evaluation and restriction or authorization might be necessary.

LLB: If you look at these endpoints, you appreciate that the review and research into the chemical is never ending, right? Not surprisingly, ECHA urges registrants voluntarily to update their dossiers after they're submitted under the REACH program to include new information. So two questions there. Number one, does that routinely happen? And number two, when it

does, is the compliance check also an assessment of whether the dossiers have been adequately updated? And if so, how would ECHA know that? You're a little bit on your own there to update, with what frequency, and what is the scope of that updating process? How would ECHA know, in any event?

KFB: We use a tool for submitting our dossiers that was designed by ECHA. It's called REACH-IT. Dossiers are developed in a very specific platform: IUCLID. I don't want to talk about it. Not my favorite.

LLB: It's challenging, I've heard.

KFB: Yes, it is, and when you submit the dossier, there are other checks that go into place. There is an alert every time a dossier is submitted, so the frequency is apparent to ECHA. The regulation in the beginning said that dossiers were to be updated with any type of information they came across without undue delay. Yes, do people update their dossiers, but that undue delay language was very open to interpretation.

LLB: Indeed, it's highly subjective.

KFB: ECHA recognized that. And in 2020, so we're talking about October 2020, ECHA clarified what it meant by "without undue delay." What ECHA stated was that they expected folks to, at least on an annual basis, look at your dossier and that if you did have a change, if it was a minor change, "undue delay" means about three months. Then if the change was more complex, and they gave several examples, they expected updates within six-, nine-, and 12-month periods. So you're starting to see the evolution of clarification, and deadlines, and a tightening of when you should submit an update.

I will tell you that each dossier includes your annual tonnage, so if you've not updated your dossier since the original submission of 2010, one, ECHA is aware of that because they can see the last time you submitted. And two, you have an obligation under REACH to ensure that the tonnage bands that you registered in are maintained, so you should be at least evaluating on an annual basis your tonnage.

Then there's a use aspect to REACH, so you should also be looking at and ensuring that the uses are in line with the market and the evolution of how these materials are being used, not only in professional and industrial, but also consumer markets. I would say that the clarification helps, especially for consultants who say, "I really do need to look at this on an annual basis, and we do need to make changes. If changes are there, I have to do it within the specified timeframe." But it is obvious to ECHA when you have not done an update in a long period of time. And there may be a valid reason why, but there is definitely some transparency there.

LLB: Got it. That's very helpful. Let's assume, as I'm sure this is the case from time to time, Karin, that your client is caught in a compliance check. Even that language that has a faint whiff of a compliance component to it. And that nomenclature may be inappropriate, but what happens next? This is surely not good news? Or maybe it's value neutral. What do you think?

KFB: It could be pretty alarming.

LLB: Okay. It is disturbing.

KFB: It is a little disturbing because the words "compliance check" do imply that you have somehow failed to provide the information you were required to provide as detailed in the regulation, which I said is very complicated. But the process for how you address a compliance check, not surprising here, is also a little bit complex. And you're not going to be facing immediate action. ECHA will always issue a compliance check to you through REACH-IT in a draft, with an opportunity for you to comment. So you're not completely caught off guard, and you're not completely without a voice. You are able to review what they are stating, and you are able to provide comments back to ECHA on that draft, but you have to do that within the first 30 days. You don't have an opportunity for extension. They will not extend it. You must provide comments back if you disagree. You may just look at it and say, "No, they're right, I need to do this."

Even if you agree, I would still highly recommend you just go ahead and say, "Yes, we agree to what you're stating." But even then, the process isn't necessarily done because ECHA also submits that same draft to the member state. They're also afforded an opportunity to submit proposals for amendments. Then again, you're afforded another opportunity to comment on what the member state authority is proposing as far as amendments go. So the process can take a bit of time. There is some back and forth. Eventually, the Member State Committee (MSC) will review all of those comments, whether or not there are any amendments. Then a decision is technically adopted when no members propose amendments or there's a unanimous agreement on those amendments, and then you receive your decision. But even then, there's an opportunity, though it's very small when you get the final decision; the final decision will include when you have to submit all of the data by. If you are still in disagreement, there's a Board of Appeals process, which is pretty involved as well.

LLB: Yeah. A couple of questions, Karin. It sounds like there's a rebuttable presumption of fault, right? You have an opportunity to challenge in that draft notice that is found in REACH-IT. It is probably a good idea always to acknowledge receipt of it, and then if you agree, as you suggest, say so. And if you don't agree, certainly make that known as well. Is there a high degree of alignment between an ECHA determination and a member state determination, or do they usually not align?

KFB: As I will say, when I've seen member states submit proposals, it's more of a refinement of what ECHA had said in the draft. It's rarely -- it's like if ECHA in their draft decision asks for some kind of specific study with specific endpoints it was looking for, the member state may comment on whether that method was appropriate. Maybe another method was more appropriate. You typically don't see disagreement. You typically just see clarification or proposals to clarify some of the requirements that ECHA is stating in the decision. For the most part, it may exist out there, but I've not seen one where a member state just outright proposed to disagree with what ECHA was saying. And you are right. You have a chance to refute or to request that ECHA reconsider, but you need to be scientific in your justification. You can't just say, "I don't like what you told me."

LLB: Stomping one's feet seldom works.

KFB: If you have a solid scientific reason why what they're asking you to complete or what they are considering deficient, then you need to include that in your comments back to them.

LLB: Sounds like there's a high degree of alignment between ECHA and a member state. What about -- I'm guessing the notice of deficiency or the compliance check alert goes to the Lead Registrant. Is there ever a case where the members of the consortia that submitted the

dossier don't agree among themselves regarding whether or not data are deficient or some additional study needs to be done? Does that happen?

KFB: Yeah, and it's interesting because, originally, the compliance check decision did go to the Lead, but in 2019, they changed that, and now the decision goes to all registrants. There may not have been as much visibility -- and it's all posted publicly, too. Don't get me wrong. Once the decision is made, you can go search to see what decisions ECHA has made. But now that all parties receive it, typically, I have not seen a lot of dissension among the co-registrants that are part of a decision. What I've seen is the good consortia that we've been part of -- and we're part of some really great groups that have been subject to some of these processes -- they do work together. And, while I failed to mention it before, ECHA does not want to receive comments from the 689-plus registrants of ethanol. ECHA wants to receive one set of consolidated comments, so the consortium does need to work together and provide one set of comments.

Typically, active stakeholders engage and develop a set of comments, and most are afforded an opportunity to work together to develop those comments. But again, you're under a tight window. You've got 30 days to get back to them, so there isn't a lot of time for parties to engage every single entity that may or may not have been part of that active development of the dossier in the beginning. I think that's one thing. And having been the recipient of the decision where we were one of the two parties, we did try very actively to engage with the Lead on, "Are you going to submit comments? Are you going to refute any of the items in the decision?" That, too, becomes a little bit frustrating in just trying to ensure that your voice is heard as well, because, when it's just you and someone else, it creates an interesting dynamic.

LLB: No, we addressed the harmonious part early on in this conversation. When you have a group of competitors, or people who are nominally aligned to achieve a shared goal, reasonable people can disagree. And there are varying degrees of engagement and varying degrees of advocacy. So I can imagine that makes for some uncomfortable competitive situations.

KFB: Absolutely. And we've seen that. It's not all roses and sunshine when it comes to some of these. We've been involved in some pretty contentious aspects in registration, but I've not been engaged in any adversarial decisions. I think when you do receive a decision, most parties consider what ECHA is saying very seriously and do try to come to consensus in their comments back.

LLB: Got it. We touched a little bit upon this, in terms of the consequences of an ECHA determination that a dossier is not compliant. It does connote additional work needs to be done or there needs to be a response within a finite period of time. And I think I heard you mention, Karin, that that is not amenable to extensions. So in other words, "We just stumbled upon this, and we're in our 21st day of the 30th day." You don't get another bite at the apple, right?

KFB: No.

LLB: And is there a penalty, or is the penalty just the required action itself? But there's no monetary fine or sanction, right?

KFB: No. You don't have to comment on the draft within 30 days. They will send you reminders. They're fairly good. We do receive a lot of notices in REACH-IT. You will see reminders that say, "Hey, this is still here, and you haven't said anything." But if you don't comment,

then you are essentially agreeing, so lack of comment is agreement. There's no way around that. So there were parties that asked for extensions, but I have not seen ECHA grant an extension. There is an expectation that you will respond, and you're alerted to that, and no response is agreement.

LLB: But let me ask you this. If the required action, if ECHA determines that -- and this is purely hypothetical -- that whatever genotoxicity study that you submitted was not up to par and you have to do another one, are the terms of the conditions with regard to the generation of a new genotox study amenable to negotiation? Or when you are acquiescing to the compliance check terms, that's the whole shooting match, not just that it was deficient, but also the terms and conditions by which the registrants now need to address the deficiency?

KFB: That's typically noted in the draft notice. There's a lot of detail in that draft decision. It will specify this endpoint was considered deficient, and it will explain the reasoning behind it. So when you comment back, if you disagree with that, that is your opportunity to either request opportunities for clarification on that particular endpoint, and it's going to be that. And I will say that there was a notice that ECHA issued recently -- in fact, I just got it in my REACH-IT box last week. It says, "We started a compliance check on your registration dossier." One of the things that they state is that no dossier updates are taken into account and that -- let's say they're assessing my dossier for a ten to 100 tonnage band. They are not going to accept if I come back and say, "Oh, wait, but I don't really sell that much. I'm going to go down to a one to ten." No information on a downgrade of a tonnage band is taken into account, and no removal.

If there were concerns with the exposure assessment, the uses, or the consumer use or the industrial use, no removal of uses are taken into account. So they're going to look at the dossier that they have on record. And any amendment to that dossier that you make after the fact are not going to be considered. So I think that communication -- I just received that in July -- was interesting because we were involved very early on on an evaluation. It was a slightly different consideration. It wasn't a compliance check; it was a testing proposal, which is an entirely different process. We commented on comments that we received in draft, and we didn't update the dossier, and ECHA, in the final decision, said something to the extent of, "You didn't update your dossier."

I feel like everybody is learning as we go a little bit with some of this stuff and that now they're saying, "In all fairness, we need to just put a stop. This is the point at which we evaluated, and we're not going to consider any amendments at this point." I think that helps, when you're involved in this process, to understand it's going to be based on what's in the dossier that you have presently provided to ECHA.

LLB: I've noticed over the many years REACH has been in existence that ECHA and REACH in general is very metrics oriented. And it seems that the number of compliance checks in 2020 is lower than in years past. It was 255 in 2020. In 2014, that number seemed to be closer to 400. Is COVID-19 to blame for this, or is ECHA easing up, or are these numbers just not correct?

KFB: The numbers are a little misleading, too, because I looked at the dossier evaluation statistics, and it does say that they have evaluated 3,000-plus substances. But I'm not entirely clear that those entries don't refer to the same substance a couple of times, and ECHA committed in 2020 to a certain percentage. So if you were to say you had over 22,000 individual registered substances, that 20 percent number is also a little misleading because you have to break those down by tonnage bands. But you would expect to see ECHA in maybe the

4,000s, and that could be a gross overestimate. But in respect to COVID, I will say that ECHA states that it did extend deadlines in registration and evaluation processes to address potential delays, so that was probably the exception to the rule. I'm sure Brexit --

LLB: -- had a little something to do with it. Just a tad.

KFB: I would definitely say that ECHA resource-wise, was heavily resourced when they were addressing the registration window. So there was a pre-registration phase from 2008. There was a registration in blocks, so there were three registration windows. The last registration window for those pre-registered substances was 2018. So I would have expected to see a slowdown, just because I'm sure that resource-wise, we don't have as many resources available now that we're past that big 2018 registration. You now lose the UK Member State and the Competent Authority associated with that.

Yeah, I'm not surprised the numbers are down. I don't know what this means in the future because ECHA had posted at the end of June revisions -- or potential or possible revisions -- they say they apply to some of the data requirements. Those revisions go into effect in **2022**. I would suspect that changes to the data requirements that go into effect **next January** would prompt ECHA to just ensure that folks are up to date and looking at these new requirements and that dossiers are being amended accordingly, or at least being reviewed, and just ensuring that you are following the latest requirements that ECHA is putting forward. Maybe there's a little downturn now, but there could be an uptick, say, in **2023**.

LLB: That seems fair. You alluded to this a bit ago, Karin, and that is the opportunity to appeal an ECHA decision to the Board of Appeals. Do you have a sense of how successful appellants have been over the years? Just looking at some of the decisions that have come across my desk, my sense is the Board of Appeals process is long, costly, and the outcomes somewhat uncertain. Is that your take?

KFB: Yes. Here's the way it works. Once your decision is in final, the only option you have is to file with the Board of Appeals. And what you typically see is that people will file because they have no other opportunity to speak. They've spoken in the draft. Maybe the comments they made weren't assessed to what they felt was sufficient, so the only option you're afforded is to go through the Board of Appeals process.

But what I have found, and not in a draft decision, we were subject to one of these where we received the decision, which was like, "What do we do?" In consulting with Legal, we did file with the Board of Appeals. At that same time, we were then given a second opportunity to speak to ECHA. During that discussion, we came to an agreement, and we then filed a motion to withdraw our appeal. So when you look at the website that talks about decisions, a lot of them are missing decision summaries. I think the reason they're missing those decision summaries is because the appeal has been withdrawn, because it may be they've come to some other agreement, right?

LLB: Accord.

KFB: Yeah, exactly. Or they've come to an agreement with ECHA, and there's no need to continue their appeal through the Board. But those that have gone through that process, the success rate, in my opinion, is fairly low.

LLB: Yeah, I'm glad you agree, because that was my take as well is that you can try, and there might be some incremental changes, but on the whole, it seemed it was a pretty uphill battle.

KFB: Yeah, it seems to me, and as you mentioned, it's not for the faint of heart. It's going to be drawn out, it's going to require counsel, and it's going to be expensive.

LLB: It's pretty serious litigation.

KFB: It is, and I think the consequences of what ECHA is asking you to do and the process of appealing through the Board of Appeals, and whether or not the data they're asking for are worth the time and effort the Board of Appeals process would take because it may not be economically feasible. It may be better to just look at what they're asking you for and seeing if you can just accommodate the data that they have asked you to provide.

LLB: And I'm guessing, too, Karin, these are pretty fact-intensive situations. In other words, maybe early on in the REACH process, there may have been more appeals as the elements of the program were being refined and explained, and there might have been a greater appetite for challenging some of these decisions. You know, REACH is a mature program now, so I'm guessing, as you suggest, you have to have a pretty incentivized entity to appeal an ECHA compliance check decision because the cost alone is a deterrent. It might just be easier to comply. But again, it's very fact-intensive.

KFB: Absolutely, yes. We underscore here the amount of data that you are required to provide and the evolution of the details within those data elements has also resulted in just layers and layers and layers of complexity. And you're right, in the beginning, when you look at some of the early registration dossiers, those at the highest tonnage band that were submitted in 2010, and you look at some of the decisions that ECHA was issuing early on, those compliance checks tend to focus more on uses and substance identity. But now, as we look at some of the decisions that have come in the last year or so, those are very targeted and very specific. The one for nanomaterials was incredibly specific and very detail-oriented. It wasn't a matter now of substance identity. It was a matter of intrinsic properties and how to evaluate them in nontraditional methods. The entire process has evolved, so you're seeing the compliance checks have evolved. And then the appeals, how do you appeal that, whether you appeal, that has evolved.

LLB: Last question, Karin; this has been a fascinating conversation. I really appreciate it. But do you have any tips for our listeners on avoiding compliance checks? And if you can't avoid them, it sounds like, because of the luck-of-the-draw syndrome, how do you prepare for one?

KFB: I think the most important thing is just to ensure that your dossier is up to date. As a co-registrant, that means you are in communication with the Lead, or the consortium that's working with the Lead, that you are evaluating and updating your information as ECHA requires within the timeframes that they specified last year. I think that's key because if you do receive a decision, it's going to be based on the information that was presented to them most recently. Having an up-to-date dossier is going to be critical in that process. Then once you receive the decision, consider what ECHA is saying, and if you do disagree, develop arguments that are sound and scientific in that comment period back, and then you provide it within the timeframe. I think that is the best path forward for this process.

LLB: In addition to the ECHA website that you mentioned, I'm sure the Acta website has a lot of really good information on REACH, as well, that our listeners may be interested in taking a look at, yes?

KFB: Yes, absolutely. We operate Only Representation in now both the United Kingdom and the European Union.

LLB: Double your pleasure, right?

KFB: We have a lot of experience in this particular aspect in registration and in handling compliance checks. Our website is full of lots of helpful details, including anything recent. I know I've talked a lot about -- there's been a lot of movement in the last year within ECHA, but those details are published on our site as we track these changes.

LLB: Great. Well, that website is www.actagroup.com, and Karin, thank you so much. I feel much better prepared and much less anxious now over a compliance check and have a much better understanding of what they are and how to prepare for them. So thank you for being here today.

KFB: Oh my pleasure. Thank you, Lynn.

LLB: My thanks again to Karin for speaking with me today about REACH compliance checks: what they are, and how best to respond to a compliance check to ensure a minimum of business disruption.

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