Episode Title: Update on European Union Chemical Management Issues -- A Conversation with EPPA's Meglena Mihova

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

This week, I sat down with Meglena Mihova, managing partner of EPPA, the Brussels-based premier consultancy on matters involving key business sectors, including chemicals and chemical regulation. Meglena is an expert on all things involving the European Chemicals Agency, known as ECHA, and the complex relationships between and among ECHA, EU [European Union] member states, the European Commission, and other stakeholders. Meglena chairs the Environment Committee of the American Chamber of Commerce EU, which is the leading U.S. business representation body in the European Union.

We cover a lot of territory in this discussion, including amendments to REACH [the Registration, Evaluation, Authorization and Restriction of Chemicals], the EU Green Deal, the Chemicals Strategy for Sustainability under the Green Deal, and the regulation of PFAS [per- and polyfluoroalkyl substances] and microplastics. Now here is my conversation with Meglena Mihova.

Meglena, thank you so much for joining us today. I've been so excited about chatting with you. Maybe you could tell our listeners about what's going on in Brussels right now. Are things opening up? Are you back in the office?

Meglena Mihova (MM): Thank you very much for having me. First of all, it's a real pleasure. I'm actually back to the office, but Brussels is still working the lockdown situation, the partial lockdown, when actually the major part of the regulatory developments are still quite actively running and consultations are open. But actually the institutions are closed, which makes the interaction fairly difficult. But yes, indeed, telework is still mandatory in Brussels, and Commission officials are coming back to transfer the data to the office.

LLB: I'm glad you and your family are well. Let's begin. There is so much going on in the European Union that I honestly don't know where to begin. Maybe we can kick things off with a discussion about the EU's Registration, Evaluation, Authorization, and Restriction of Chemicals program, otherwise known as REACH, as our listeners know. On this side of the pond, the chemical community continues to be very interested in changes to REACH that will almost certainly impact the chemical community globally. And I know the Inception Impact Assessment was published a bit ago, and the comment period closed very recently, on June 1. Can you walk our listeners through that very important undertaking?

MM: Sure. It has been announced, this targeted revision of REACH. However, in my view, that will be a pretty big, substantial revision. Even the [European] Commission services, they actually acknowledge that they see this as one big chance to improve the system. During the evaluation and actual exercise that was done back in 2018, a couple of recommendations have been made.

The first one was basically related to hazard and hazard assessment. Clearly, the initial design of REACH registration was not meant to identify very specific hazard aspects, especially for new hazards, like neurotoxicity, immunotoxicity, and endocrine disruption. The information required afterwards for the evaluation and assessment for potential endocrine disruptor properties, for example, was not really very useful for the authorities. One aspect, as a consequence, will be to review the registration information and to reinforce some of the provisions to include, for example, environmental impact and exposure. On the other hand, the registrants basically were submitting the information per substance because that was the initial intention of REACH. Substances were registered as such. However, the interest has moved more to the combined effect of chemicals, and obviously that was not necessarily taken into account in the way REACH was designed.

There was some other criticism about the communication, supply chain, etc., but I think that the most impactful, especially for the U.S. and international global industrial community, would be the changes that are supposed to be made to the authorization and restriction processes. The authorization was basically one of the, I would say challenging but quite successful, part of REACH, where authorizations have to be submitted for very insignificant quantities of chemicals, but some very positive outcome and developments, especially the way companies can argue basically safe use or proper control of risk. That was accepted from a regulatory point of view as a basis for authorization. Some good practices, in terms of authorization, substitution plan, or socioeconomic analysis have been developed, but that has been considered as being too slow and too heavy and burdensome for the authorities. The delays were not obviously very helpful for industry either. There is a big question mark whether to keep the authorization process at all or not.

At the same time, we have the restriction, which we know actually as being a very targeted and refined regulatory tool, to change completely the shape and the design. We are certainly going to discuss it later on as a major development. We are facing now very broad restrictions on a huge scope of, in some cases, thousands of substances. In this catch-all approach, it is very difficult obviously for the authorities to prove the risk. And that was actually in the beginning, the starting point. Is the burden really being on the authorities to document an acceptable level of risk before proposing a restriction? That has been found very difficult, and the authorities are lacking resources, so that will be absolutely reshuffled to actually lead to more dramatic catch-all and ban big groups of substances and moving more into the derogation-specific approach for users, where industry absolutely needs to continue the use of the substance.

LLB: That's a lot, Meglena. You had me at substantial revision there. A couple of questions, the first of which goes to the temporal element. How long might this process be, and what would be, in your estimate, a reasonable timeline before which these changes would actually go into effect? Because any one of what you just discussed could have a very significant impact on global chemical management, to be blunt.

MM: Yes. The discussions have started already, and the preparation will be relatively long because, as you rightly mentioned, the Inception Impact Assessment was published with the possibility to comment, which finished the 1st of June. The Commission actually asked as well [ECHA] to support for the preparation of the impact assessment. Basically, the Commission is also planning to launch a couple of studies on all these different aspects. The new factors into that equation, for example, the mixture assessment factor, is something that the Commission is planning to introduce to assess risk of exposure of several substances and the combined effect. They have to test all of that and see how it will work.

There are other new elements for which individual studies will be launched and the possibility obviously for stakeholders to provide comments and participate in various workshops. That will be running this year.

There will be an open consultation that is planned for the beginning of next year around different policy options that will be presented. After that, comments will be taken into account, with the aim at this stage to finalize the impact assessment around the summer of 2022, and the proposal to be issued at the end of next year.

Now, this is very optimistic about the substantial revision, because whatever the Commission's intention is, the proposal will be afterwards sent to the Parliament and the Council in the normal standard procedure, and they have freedom to amend it. So in the current context of the Parliament, I would just anticipate that there will be a lot of controversy and interest to go and revisit many other parts of the regulation.

LLB: No doubt. And I'm guessing ECHA head Bjorn Hansen is quite enthusiastic about driving these changes, yes?

MM: Absolutely. Actually, with the knowledge and experience that has been gathered over the years, I think that's become the center of the knowledge, but also the driver of many processes that would trigger certainly acceleration of substance bans. For example, the restrictions right now, obviously ECHA can be mandated by the Commission to initiate major restrictions, and they do so. They actually start the theme in a different way so that they can handle research and support the preparation of dossiers.

LLB: Just a couple of more questions because this is just so important. You had mentioned that ECHA might now be focusing under REACH on the *combined* effect of chemical exposures from disparate sources. For many, many years, we've been hearing one chemical, one registration. How might that process be undertaken? Is there a recognized methodological approach upon which stakeholders agree in terms of assessing, calibrating, and defining what a combined effect of a chemical exposure might be?

MM: Absolutely not. This is why, actually, the study that the Commission is planning will be quite critical there, but it is a complex topic. Also, not all substances are very simple; we have also complex substances there. And then, what is the definition of mixture when it comes to complex substances? Where is the borderline in how you really assess this effect? That said, we had back in 2014 already, when Denmark proposed the restriction, a couple of

phthalates. Right back then, they refused to acknowledge that there was a risk, but judging whether there was a risk or not, they actually took into account the combined effect of the four phthalates.

So this idea, the political concept of moving forward in that direction is clear, but the train has left the station there. However, the devil will be in the details, and how to elaborate the criteria will be absolutely critical and key. I would only say it's very important for industry to participate and give their view in those studies so at the end we end up with something which is workable and meaningful. Obviously, the registration requirements will be amended as well, and more information will be requested. More documentation, as I mentioned, about the environmental footprint and information on hazards of concern and so on that have not been necessarily part of the registration process so far.

LLB: One final question I had is within the context of -- it might have been discussed more in the inception impact assessment -- but I know chemical substitution is an important component, not just of REACH revisions, but also the chemical sustainability initiative. How is substitution being considered in these various processes? How is it being incentivized? Are there specific concepts being tossed about or particular mechanisms that would incentivize the substitution of chemicals that are thought to be risky and might have alternatives that are considered more sustainable?

MM: This is actually the key focus of the chemical legislation, I would say, is the substitution and the existence of alternatives. We can see already now that the risk element -- which was the driver for the chemical assessment until now -- for example, we can continue using the substance in your application if you prove control of risk. This concept is moving a little bit away from the practice, and we see more and more the question that was asked first was actually are there alternatives? And this is the entire mentality and the approach of the Green Deal and the toxic-free environment. Regardless whether you control the risk and whether your use is safe, if you can actually use nonhazardous substances, that would be the political and policy preference.

Therefore, the key critical discussion is happening around is alternative out there, and we have a lot of conflicts between different stakeholders and parties about the existence or not of alternatives. But actually, the alternative assessments should be always done around a couple of factors, which is the technical availability, basically, what is the alternative that would perform with the same level and meeting the technical characteristics and the reliability requirements, and whether this alternative will be economically viable, meaning actually being at the right price and supplied in quantities sufficient to meet the market demand? And that discussion is a little bit diluted.

We see that in, for example, the current discussion on microplastic restriction. The simple statement that a company has an alternative is sufficient for ECHA to question a big survey coming from industry, which is representing, for example, over 50 percent of the production in a given sector. This is not really the way we should go from a regulatory perspective, and I have a very critical view on this latest development.

Otherwise, when we are talking about the stick and the carrot, actually on the carrot side of the story with the Green Deal, we see as well a couple of positive developments in the willingness of the Commission to provide different funds that will be available, especially on the horizon, for research and development. There is also a special instrument for small and medium enterprises, where actually funds will be available, especially for the cluster chemicals going into the current cluster, thanks to a bad economy and natural resources, to

stimulate innovative solutions and toxic-free chemicals that are actually also easy to recycle, reuse, and so on. On that side, there will be certainly good developments. However, the restriction on the substances that are involved is probably marching with a different speed compared to the investments that will be allowed to be made.

LLB: It's such a complicated calculus of what is in fact a suitable, preferable, sustainable alternative. I'm guessing that calculus is premised on all the factors that you mentioned -- cost, reliability, bandwidth -- to provide a suitable capacity for that substance, and then all the lifecycle assessment considerations that go into choosing an alternative that is in fact not a regrettable one. That's been an issue here in U.S. chemicals policy for quite a while. How do you go about calibrating the acceptability of a sustainable alternative, particularly when it's new and there's very little track record upon which to base some of these difficult and very important criteria? I'm sure we will learn a lot from the exercise going on in the EU.

Can you talk a little bit about developments in the substances of very high concern, the so-called SVHC category? I understand there are initiatives ongoing in that category as well, which is a very important category. These are the chemicals that are often prioritized with regard to both regulation and restriction, but also targeting them for substitution. So what is going on over there?

MM: This is a very important category because it's basically the waiting list of the substances that will be subject to a ban in the future. It has been used also as a reference point for many of the sector-specific legislation, for example, the RoHS [Restriction of Hazardous Substances] directive referring to electronic products obviously links directly to the candidate list and the REACH authorization on this. The way that list will evolve will have an impact internationally, but also on sector-specific legislation as well.

In the beginning, REACH has been really focusing on substances with known hazard to confirm that hazard. That's why we have seen in the very early stages of the candidate list a lot of carcinogens, mutagens, and so on, where we have actually completed classification. The trend now is to move away and to explore more unknown areas. One of the consequences, which is actually linked to the desire to review as well the different hazard classes on the CLP [Classification, Labeling, and Packaging regulation of chemical substances and mixtures] and to actually introduce endocrine disruptors as one of the new hazard classes will have a cascading effect on the Substances of [Very] High Concern list, because for the moment, we have either substances going from hazards CMRs [carcinogenic, mutagenic, or toxic for reproduction] and so on -- or we have the mechanism of equivalence of concern. Even though, for example, you take a skin sensitizer that is classified as such, this doesn't mean automatically that the substance will be eligible as an SVHC. It has to actually prove that that substance will cause the same effect as a carcinogen, for example, or mutagen. That has been quite difficult for the authorities, and even very knowledgeable member states like Sweden, because they have been challenged in this process by the European Commission rejecting some of the proposals because they are unable to prove this equivalence of the concern.

To simplify or streamline properly the approach, now the intention of the authorities is to have a clear-cut hazardous process, which will make this mechanism much more automatic. There are also new hazard interests, which are, for example, vis-à-vis the persistent, mobile, and toxic (PMT) substances and very persistent, very mobile substances, which is also something that is in the new interest for restrictions. All of that, we expect to happen around actually 2022, where all these new classes will be created.

LLB: Wow. That's fast approaching.

MM: Yes, it is. Especially some of those persistent and mobile [substances] hide behind that group of thousands of substances. PFAS is certainly one of the biggest restriction files.

LLB: Oh, yes, which we're going to get to momentarily. That's a huge topic. But before we do, I want to linger a minute on the EU Green Deal because it's a *big* deal. Announced in December 2019, seeks a zero carbon target by 2050, and importantly for our conversation, Meglena, it includes the Chemicals Strategy for Sustainability. Could you walk us through some of the key elements of that strategy and explain what pieces are being operationalized this year and next?

MM: Sure. The Green Deal, as you said, is a big deal. Absolutely. When it came late in 2019, this policy was perceived as being ambitious. At the same time, in March last year, everything was in lockdown, and probably industry tended to believe that the regulatory agenda and calendar would be put on pause, and things were not going to develop with the same speed as initially expected.

Quite surprisingly, there was a total disconnect with the pandemic situation and the little influence that it had on the timing and dynamic of the policy and the regulatory activities of the institutions. Surprisingly, already in March last year, the Commission issued the European Climate Law. That was actually, as one of the politicians says, is the law of the laws, which actually sets the frame for the EU climate regulation for the next 30 years.

LLB: Wow.

MM: That was actually in March. In March, we had also the new Circular Economy Action Plan that came, followed in October by the Chemicals Strategy for Sustainability. That was a difficult situation, I would say, because the interaction on very complex projects like that, complex ideas, which would require much more brainstorming and innovative thinking, was quite difficult. Although the consultations were launched, I think that industry had a difficult time to be reactive and provide meaningful input, at least in the beginning.

LLB: Yes. Is there a lot of controversy over that? This was a time of tremendous social upheaval, with the pandemic closures and everything shut down right around the time all of these things were coming out. That strikes me as being somewhat paradoxical.

MM: It is, but not everybody sitting behind a computer can run consultations online. The problem is that, for example, in some of those packages that have been issued out of the Green Deal, you would need to make a decent impact assessment of the economic implications. The Commission has been working on a package that is called Fit for 55, which is referring to the reduction of emissions by at least 55 percent by 2030. It has been conceived to be issued now in June; it will be in July, planned for the 14th of July, which is a big, very ambitious package with the revision of the emissions trading scheme to cover new sectors like aviation and maritime. We will have also the new, quite impactful for U.S. business, the Carbon Border Adjustment Mechanism that will be part of this package. Certainly the revision of the Renewable Energy Directive, the revision of the Energy Efficiency Directive, and so on. We are expecting a very big package to come, now in July. All the consultations in this process were happening under partial total lockdown, which is quite a challenge, especially when you would need to measure the economic implications around that.

LLB: As we mentioned just a moment ago, it sounds like a major focus of much of the activity with respect to chemicals, the Chemicals Strategy for Sustainability and some of the REACH revisions focus on per- and polyfluoroalkyl substances, otherwise known as PFAS. I understand the Chemicals Strategy is in large part designed to achieve a speedy phaseout (assuming speedy and regulatory change can be used in the same sentence), but a speedy phaseout of non-essential uses of these chemicals. Can you help our listeners understand what exactly that means and what might we be seeing in terms of operationalizing some of these phaseouts?

MM: Sure. The big major package of restrictions is coming with the so-called PFAS restriction, and there are two interesting compounds. Behind this abbreviation, there are around 5,000 different chemicals that are used in many different sectors. We see now a couple of member states that are working for almost a year to prepare the dossier, not only to try to identify the risks associated with the substances, but also to understand the uses, and to understand the supply chains, and also to try to figure out where essential uses would be present and therefore to grant some derogation or extended period for transitioning.

The Netherlands, for example, is working on medical devices, pharmaceuticals, waste, and recycling aspects. Germany is focusing on chrome plating, consumer mixtures, and transport. Sweden is working on textiles, cosmetics, and so on. And Norway, surprisingly, PFAS have been included as well. PFAS is also quite an impactful, important part of that group of chemicals. All these countries are working together to try to scope the restriction proposal, and the intention is next year to submit a formal proposal, but there will be consultations running also in the second half of this year.

The concern that the PFAS group is raising is really the PBTs [persistent, bioaccumulative, and toxic substances], or the environmental concern, the persistence, but adding to that as a secondary concern as well, mobility and bioaccumulation. Referring back to this new type of trendy hazard, that will be the future focus going forward.

One interesting element in that restriction is the fact that in the definition, it does refer to nonessential uses. Nonessential and essential is something that is also relatively new in terms of concept, or at least the way the authorities would like to use that concept under REACH. We know that "essential uses" has been introduced as a concept already under the international agreements to determine the way hazardous substances can still be allowed to be used under very specific conditions. Those conditions are very much linked to the fact that the use is essential to, for example, health or safety, but another parameter related to that is also the fact that alternatives do not exist. This is quite complicated to prove upfront, especially when you want to define your restriction, focusing on non-essential uses.

That ends up with a lot of philosophical debates within institutions, but also among the stakeholders. What is essential, and who can define what is essential? Is it the sector? Is it the substance? Is it the substance function? The Commission, they're planning at that stage to have a much more focused and pragmatic approach to it, to say, "We would like to come up with some workable criteria to reduce and simplify the requirements for derogations." This is the approach for the moment, and the intention is to use it under REACH restriction and authorization.

So if a substance is identified as essential, then the authorization process and the requirements will be lighter. Or if you need to get the derogation on the REACH restrictions, that process will be lighter as well. When it comes to sector-specific legislation,

there is still a question mark whether that concept will be cascaded at that level. But for the moment, the PFAS restriction will be the first test case for it.

LLB: That's a relatively sensible way to proceed. You mentioned -- and we have a similar number here -- some 5,000 chemicals that might fall into that bucket. Are they being prioritized? Is it based on carbon chain length? Are there categories of PFAS? How do you go about addressing a class of chemicals that includes so many members?

MM: This is the key critical starting point. The scope of the PFAS restriction is not yet defined. There is an approach on how to categorize the different groups there, but, for example, mentioning PFAS, that has been included very late. It's still a question mark whether it will be in the final scope of the restriction, and this is the job now of the five member states: to define the scope of what is behind this group and what should be included, and the similarity and the impacts, the structure, but also the impacts, the environmental impact, is also the driving aspect of the authorization and grouping. Going forward, we'll see much more grouping of substances from being an identification of substances of high concern to restrictions. We'll see that also in the future, with endocrine disruptors, with persistent and mobile groups of substances, where ECHA is in the driver's seat to try to map very early in the process of analyzing the registration dossiers, how to group the chemicals in a way that specific common ground of structure, hazard elements could be useful for grouping in the future. But it's a big, big debate and big question mark.

LLB: Likewise here in the United States. I think our listeners should be mindful of the initiatives under way in the European Union because they seem to be jumpstarted in a way that could prove to be very influential and perhaps prejudicial, depending upon one's perspective, with regard to how the same issues are going to be addressed and *are* being addressed here in the United States, largely under TSCA [the Toxic Substances Control Act]. Are there activities under way, Meglena, specifically under REACH, that focus on perhaps broad scope restrictions? We talked a little bit about PFAS. I know microplastics are a very major focus of attention in the European Union, and perhaps other categories. What can you tell us?

MM: Yes, microplastic is actually the first big restriction file. It's quite a precedent because when we're talking about PFAS, at least we can identify some kind of a group of substances with chemically similar structure. When it comes to microplastics, it's basically a polymer with specific size and a solid polymer. That caught in a surprise a lot of the industry sectors that questioned in the very first stage, what is the problem with microplastics? Because they have been, for example, authorized to be used in specific legislation for many years by cosmetics, and cosmetics, is focusing on assessing the human health impacts and exposure, not necessarily the environmental implications.

This is the new trend. Environmental focus is really the big policy trend and regulatory trend where we will see these big restrictions coming. On the microplastic, of course, it's also the first restriction dossier where we don't have a clear list of substances. Industry was pushing very hard in the beginning to get one, but obviously it is difficult to rationalize a list of substances also because of the requirement of solubility. So only solid polymers are in the scope. Some of the chemicals during their use, however, may actually become liquid and lose their, let's say, characteristics that can qualify them as microplastic.

The scope issue is so complex that it took two to three years even for big international companies to define if they're using or producing chemicals, polymers that would respond to this definition. And another precedent with this file is that in the beginning of this year, ECHA committees have issued their opinion, and now the dossier is with the Commission

services. They're supposed to come up with a proposal for amending Annex XVII, a restriction under REACH, and introduce the restriction of microplastics, so that would happen before the summer.

But the Commission is, for the first time, in a situation where ECHA committees do not give a clear-cut recommendation on the risk management options. So SEAC, the Committee for Socio-Economic Analysis, would take one use, and they would say, "Look, if you prioritize a ban of microplastic, then probably an immediate phaseout without too long a transition period will be the best. However, if you prioritize, for example, circular economy as a policy objective, you may actually want to give derogation because you're using a model, for example, the interim material that is also considered as microplastic, 90 percent of the central material is coming from recycled tires."

How do you go about it if you kill that model? It's a very successful model for circularity, for circular economy. And we have other examples like that in the opinion where ECHA is saying to the Commission and to the member states, depending only on your policy priorities, different options could be the best regulatory one. And it will be quite interesting to see what the Commission will do in that context.

LLB: Will that delay the process? It seems to interject an element -- being agnostic with regard to which way to go without an ECHA recommendation -- it strikes me as being an element that could invite a good degree of delay to allow stakeholders to sort out what is the best way to go, or maybe there would be multiple ways to go. That does strike me as a new approach from ECHA.

MM: It is a precedent indeed. That exercise within ECHA has been slightly delayed, and extra counsel, extra time have been given to the committees to consider and come up with their final opinions. However, for such a big file, we have not really experienced so far major delays. The Commission has, legally speaking, three months to come up with a proposal. There is a lot of political willingness to proceed without a lot of delays, but there are a lot of legal uncertainties around the definition. I guess the legal service will have to work quite hard on that as well.

That said, once the proposal is issued, the REACH committee composed of member state representatives, they all have to vote on it, and they don't have a legal deadline. It will depend very much at the end stage of the procedure whether the member states would like to have a deep dive into the file and to understand the implications as well for industry and the need actually to have a much more sophisticated approach to risk management.

The problem that I see coming for that file, and that will certainly be multiplied in the other dossiers with significant restrictions, is that the scope is growing. However, there is an absolute reticence from the authorities to go for derogations or longer transitional periods, which do reflect the reality of the different sectors. And for me, the success of this Chemicals Strategy and going forward with big restrictions is very much linked to this possibility and adaptability of the risk management measures. And this is not just to give a green light to industry to do nothing. Industry does innovate, and the pressure on substitution is there; it's coming from big consumer demands, from societal demands.

LLB: Exactly.

MM: But it should not come at the cost of innovation, and industry can obviously find substitutes if sufficient time is granted. This is something that for the moment is not really fully

integrated into the thinking of the decision makers, and that will be a very important test case going forward.

LLB: I agree. Let's zoom back for a minute and focus on a gentleman we've already mentioned, and that is the European Chemicals Agency head, Bjorn Hansen, who was on our program a number of months ago. Are there discernible changes in style under Mr. Hansen's leadership, operational changes or changes in policy? My strong suspicion, Meglena, is yes and yes. But maybe you can give us a little insight into Bjorn's operating style.

MM: Yes, I would say absolutely. We have a very experienced official with a background through the Commission, the Directorate General for Environment [DG ENV] head of REACH before. I think that he has a lot of experience, a lot of knowledge, and he has a different ambition for ECHA, I think. If you remember, in the very early stages of REACH, the previous head of ECHA, Mr. Dancet, he was trying to retain or frame NGOs' [non-governmental organization] willingness to push for, for example, adding a lot of substances on the candidate list. And that was the pressure back then with this so-called Substitute It Now, a list to be added to automatically.

I remember that ECHA was very politely assessing the list of chemicals proposed and politely declining this irrational, politicized push to get more impact on the various regulatory tools. I would say we see now a different style of ECHA. I think that we are many years later, where a lot of knowledge has been accumulated and where ECHA is becoming the center of this excellence and knowledge. And I think that Bjorn Hansen has the right momentum now when REACH is revised, but also the sector-specific legislation and a lot of the sector-specific legislations are up for revision as well.

Where there is a serious question mark, what is the added value of having, let's say, a sector-specific stream of assessing substances and banning chemicals, when in addition to that, REACH exists? He is calling for -- and I think that makes sense to a large extent -- it's coming from one substance, one assessment, which is also one of the narratives of the Chemicals Strategy, which means that basically if you assess the hazard, it should be in one central place. In some cases, the risk assessment can be done at the ECHA level and then potentially take back the risk management discussions, for example, derogations you are going to grant, how long actually you give industry to transition into the sector-specific legislation.

But he sees that, and I think that not only from ECHA's point of view, but from the Commission's point of view, there is now a much more clear view on the lack of efficiency of having the big REACH umbrella substance ban, a mechanism with a lot of ambitions and knowledge and machinery behind it, and the sector-specific nitty-gritty assessments; you take electronics, you take toys, you take cosmetics, and so on. Each of them have their own mechanisms, so there is a point there, but that would actually take ECHA to a different place, absorbing a lot of these competencies. I think that this is also a very ambitious plan. That can make sense, provided ECHA is reformed as well and sufficient resources are allocated. As we have seen, the benefit as well of the ECHA process is that they do respect timelines, which is not necessarily the case, especially on the RoHS exemptions. We know that this has been quite pathetic in the past. Some of the exemption requests were running for many years; the companies started disappearing. But then the problem is, if ECHA is able, from a purely competence and knowledge point of view, to accumulate all this knowledge in assessment, do they have the sufficient resources to continue respecting the deadlines? And this is a big question mark.

The workers protection legislation has transferred the risk assessment to ECHA. However, ECHA came back saying, "Okay, but we can do only five substances per year." That obviously is a problem. I think that, yes, a much more political, much more ambitious ECHA, probably being at the right place at the right time, probably playing a very critical role in the redesign, not only of REACH, but also of the sector-specific legislation. But the question mark would be the implementation and whether it will continue delivering with the same level of competence and excellence.

LLB: It does sound like a fundamental kind of reshifting of the centralized focus of ECHA as being kind of the central repository of the risk assessment capabilities and functionality, and leaving to the sector-specific initiatives, derogations, exceptions, timing, and implementation measures. Is that basically what might be going on now? It has some appeal in terms of eliminating potential redundancies and expediting initiatives, but I'm guessing that that shift to having a more muscular, robust ECHA in some centralized capacities might be somewhat controversial.

MM: This is certainly an issue, especially for the sector-specific legislation that does involve already other agencies. Another concept that I mentioned, the one substance, one assessment suggests that there is a coordinated way of discussing hazards, but also to a certain point, the risk assessment. ECHA has declared very clearly that it doesn't mean that it is equal to one substance, one agency.

What the Commission is trying to do right now is to try to get different agencies to work together under the joint mandate on chemicals which are subject to assessment for various applications. There are a couple of pilot cases like that. For example, there was a recent mandate of the Directorate-General for Health and Food Safety (DG SANTE), which was going to the European Food Safety Authority (EFSA) and ECHA when it comes to phthalates, because they haven't actually prioritized for scrutiny. And on one hand, there is the food contact material use, which is under the competence of EFSA. But on the other hand, we have a lot of consumer exposure from other sources. And this is under REACH and then under ECHA.

Does it make sense to have two agencies working on those streams and coming up with completely different incoherent conclusions? Definitely not. So they have tried now to issue this joint mandate. Is that easy? Absolutely not, but it certainly requires a lot of coordination and alignment among the agencies. But going forward, there is even a stronger push to say, "Well, probably the Commission will have to reflect on amending the legislation and to clearly assign the responsibilities instead of trying to get this coordination running." It will be easier, obviously, to remove where we don't have, for example, a specific agency that is assigned to remove the current system and replace it. The Commission, for example, is also envisaging for cosmetics, where we have currently a special scientific committee running the risk assessment to potentially move that to ECHA as well.

We'll see, but it's a very interesting moment to pause and actually reflect on the architecture of the future regulatory landscape in Europe. It sounds quite abstract, and it does not really appeal to companies to engage in the discussion, and it is so critical for the future.

LLB: Absolutely. We began this discussion with just how many initiatives are under way in the European Union. This is an astonishing array of very seismic changes that could bode very favorably for all stakeholders, depending upon the resolution. But it certainly is a call to arms, as it were, for U.S. businesses and others to participate, understand, and help move these initiatives forward in a way that aligns with everyone's specific perspective.

Before I let you go, Meglena, you've been so generous with your time. I'd like to ask you if there's any place that our listeners could go to find a little more information on some or all of these initiatives.

MM: I would definitely recommend visiting the website where we list our different courses and trainings, at the European Training Institute (ETI), especially to enable industry to engage in a more meaningful way in different consultation formats, especially when it comes to impact assessments, which basically means that you will be able to provide meaningful input to REACH and COP, and how other major pieces of legislation will be redesigned. Feel free to check our website and to reach out for further questions.

LLB: That would be at EPPA's website, and look for European Training Institute, correct?

MM: Yes.

LLB: Meglena, I want to thank you. You covered an awful lot of territory in a very short period of time. I am truly astonished at the depth and potential (not to be punny here) "reach" of some of these changes under way. They're both substantive, process, administrative, and they will almost certainly bode very significantly on similar developments ongoing here in the United States.

I want to thank you for being with us today and being so generous with your time. Please give my regards to all of your colleagues there in Brussels, and I hope to literally see you soon. Take care. Thank you so much.

MM: Thank you very much, Lynn.

LLB: My thanks again to Meglena Mihova for speaking with me today about the enormous regulatory changes afoot in the European Union, many of which can be expected to influence chemical management here in the United States and elsewhere around the world.

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