# Episode Title: Let's Talk about Europe's Plastics Implementing Measure -- A Conversation with Scott Burya, Ph.D.

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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 Dr. Scott Burya, a Regulatory Chemist with Bergeson & Campbell and with our affiliated firm, The Acta Group. Scott works extensively in the food contact area and other areas involving Federal Food, Drug, and Cosmetic Act regulatory issues. We discuss how U.S. regulatory professionals working in the all-important food contact space can leverage a European Union (EU) measure applicable to plastic food contact materials and articles. The Plastics Implementing Measure, or PIM, as it has been known to be called, includes, among other features, a list of more than 1,000 chemical substances and specific migration levels. Scott describes the EU measure, its strengths and perceived deficits, and discusses how U.S. regulatory professionals in this space can leverage the PIM and the specific migration limits (SML) and other regulatory context here in the United States and elsewhere. Now here is my discussion with Scott Burya.

**LLB:** Scott, welcome to the studio. It's wonderful to have you here today, and I'm looking forward to our conversation.

**Scott J. Burya (SJB):** Thank you, Lynn. Thank you for having me.

**LLB:** Sure thing. It goes without saying that the U.S. Food and Drug Administration (FDA) is pretty twitchy about the chemicals it allows in food packaging, and for good reason, right? I mean, people want to be very careful about eating foods that don't share some of the chemical components of the materials in which they are wrapped, right?

**SJB:** Right. Yes. That's one of the guiding principles behind regulation of food contact substances in the United States and elsewhere. A key point is packaging that ensures that there aren't substances migrating into foods, so that's the guiding principle. And then when additional information becomes known about substances used in packaging, then the

regulators have additional questions regarding how much is potentially migrating, and then how hazardous, and is it safe? That's really what the conversation's about.

**LLB:** Well, happily for us, since you arrived here at Bergeson & Campbell, you've been doing a lot of food contact work. And I think the purpose of our conversation today is to talk about this measure that pertains to the regulation in the EU of plastic food contact materials in articles. Based on our prior exchanges, I know it's called the Plastics Implementing Measure or PIM. It went into effect in EU member states in 2011 and then promptly replaced all existing regulations and directives pertinent to plastic food contact materials. Wondering if you can tell our listeners about why this EU measure is the subject of our conversation today and maybe just briefly go over the scope of the regulation. For example, what types of materials and what parts of the supply chain does it cover?

**SJB:** I thought this was a wonderful topic to talk about just because I feel it's an essential read for certainly regulatory professionals in the EU that are working with plastics, which is the scope of the regulation, but also for professionals in other regions and also for other types of food contact materials not inclusive of plastics. If you're a regulatory professional in the United States, working for a manufacturer of paperboard or coatings, there's something in this regulation for you to learn something from.

I guess you asked about the background and the scope. The PIM is a specific measure for plastic materials, and it's a subregulation under the EU framework regulation. The framework regulation is kind of the general food contact regulation in the EU. It's got the general requirements for food contact substances, things such as substances that shouldn't migrate to food in levels that would be harmful to human health. It's kind of the general scoping regulation. And then under that regulation, it's required that there are specific measures, and the PIM is one of those specific measures. The focus is specifically on plastics.

In the framework, it was actually outlined that there should be 17 different specific measures. One is plastics, but then there should be specific measures for plastics, adhesives, coatings, etc. There's a list of 17. And since the inception of the framework, there's only been a few actual specific measures in the EU. The PIM is one of five. If you're working even in the EU, there are a few specific measures to reference, but this is really the key one that's just so expansive and complete that it's, as I said before, it's an essential read for anybody working in the food contact space.

**LLB:** Got it. What, Scott, would you regard are some of the key aspects of this plastics regulation?

**SJB:** Sure. At the heart of the PIM, it's a positive list, so substances that *can* be used in plastics. Along with the listing of these substances is really a key piece of information that is the specific migration limit, or SML as it's abbreviated. This SML is an acceptable -- permissible exposure limit (PEL) for the specific monomer or additive. If you scroll through the list of substances on the positive list in the PIM, you'll see that some have high SMLs, and then some are actually listed in the PIM with an abbreviation ND, which is non-detect.

You can get a feeling for the hazards associated with various different monomers and additives used in plastics based on these SMLs. If you have a very high SML, that means that it's been authorized and assessed by the regulatory authorities in Europe to be fairly safe or benign, whereas monomers or additives listed in the PIM with a non-detect SML, that means these substances have higher hazards and should be potentially not used in as

high concentration in food contact materials as other substances. That's -- the concept of SML is really a key aspect of the regulation.

Additionally, I guess, included in the regulation are migration testing guidance. So, as I explain, there's this huge list of approved substances and approved levels. But then the regulation also outlines how to test your different food contact plastics, and it's called a migration test. You take your plastic and you immerse it in a solvent. You can actually test in food if you're willing to go to those lengths. But because of the complexity of a food matrix, that often makes your testing much more complicated. The PIM includes a list of different food-simulating solvents that you can use in place of food, such as water or ethanol, that will extract, well, potentially extract substances out of the plastic. And then you can analytically measure the individual substances and then compare with your SMLs. It includes the extensive guidance for testing. It also includes details on how to prepare -- it's called Declaration of Compliance Documents, which is essentially just communication letters between suppliers and customers and communicating details, such as what types of materials are in the plastics and what different regulations are associated with them, and a whole host of other things that I think we'll get into later in the talk.

**LLB:** Two questions. One is, you said this is a positive list. There are some 1,000 chemical substances with SMLs associated with each. Is that to say that if a chemical substance is not listed on the positive list, it presumptively cannot be used in food packaging? Or is there some other inference to be drawn from that positive list?

**SJB:** That is correct. The positive list, if you're in the EU and manufacturing plastics, your substances need to be listed on the positive list.

**LLB:** Got it. And my second question relates to what you said about how this is -- it seems to be self-implementing. In other words, if you are a manufacturer of a food contact material, you can basically certify that you are within the limits of the SMLs set forth on the positive list of the PIM and you're good to go? Or is there a regulatory action there?

**SJB:** Yes, you are correct in the first instance. It is self-implementing, and it's a public list of substances and approved limits, and that's one of the strengths of the regulation is that it does list all these different monomers and additives and then different formulations for contact plastics. You can put these together in different concentrations. You can use any assortment of them, and then, to self-certify, I guess that the product is acceptable for use in the EU, you would simply do a migration test. You could do the migration testing in-house or, as is commonly done, you would get a third-party testing facility to test for the SMLs for individual substances that you've used in formulating the product. And an additional requirement is something called an overall migration limit (OML). An OML is simply a limit on the total amount of material that migrates from your coating. It's not specific to an individual chemical or chemicals.

**LLB:** Understood. From what I'm hearing, it sounds remarkably efficient. You have this list, you have testing guidance. People certify that they are within or beyond that limit, and life goes on. But I understand, based on what I've read, that the PIM to some extent is a bit of a mixed bag. What are, in your view, Scott, some of the regulation's strengths and perceived weaknesses as defined by chemical stakeholders?

**SJB:** Sure. I guess we touched on the strengths of just the expansiveness and comprehensiveness of the regulation, and how it's public. These aren't proprietary, approved levels for

substances. This is for everybody. I think that's one of the biggest strengths is that it kind of creates a level playing field in the EU for food contact plastics. I think that's a good thing.

As somebody not working for a specific chemical company, I guess, that can be viewed as a disadvantage if you are developing a new monomer and you're interested in keeping that monomer proprietary or IP [intellectual property] to yourself, that's not a possibility under this regulation. I guess that could be viewed as a drawback. Whereas in the United States with the FDA food contact notification system, a system whereby individual manufacturers of contact substances apply for approval from FDA and then that's a proprietary approval for a specific manufacturer for a specific material. And that's also typically not done at the monomer or starting material level. That's typically done more at the -- it's closer to the article, the food contact article. It's a very different scheme, and I guess that could be seen as a drawback for some entrants in the European market.

**LLB:** Got it. It sounds like there are probably more upsides than downsides. The transparency aspect, in particular, I can imagine is very comforting. And unlike our system here, where the actual limits may not be as openly known, they are over there under the PIM program.

I guess I'm interested in how much information is known about the derivation of these SMLs. Is the actual analysis on how the numbers were derived part of the regulation? Or how much do stakeholders actually know beyond the specific value set out in the regulation?

**SJB:** Yes, that's a very good question. The PIM is not a -- it's not a new regulation. It's very much been built on decades and decades of authorizations or approvals in legacy regulations. I guess if you were interested in a specific substance and the derivation of the SML, you could read back through the decades and potentially come to a conclusion on how a specific SML was derived. What might be more helpful, to answer your question, is that there is a process by which new chemical substances are authorized, and that -- to essentially get new substances listed on the positive list. And that involves submission of information to the member state by a manufacturer of a plastic material in Europe. That information is reviewed by the European Food Safety Authority (EFSA). And then EFSA, given time to complete its review, will assess the new substance and any information provided in the submission dossier and will derive an SML. You can look at the authorization of newer substances and through this public -- EFSA publishes these -- they're called scientific opinions -- online for new materials, and they will walk you through in those dossiers -- or in those opinions -- how SMLs are derived.

**LLB:** Okay. If you're not on the positive list and wish to add a substance, a monomer or whatever, you submit a request to your member state authority, which in turn feeds it into EFSA and then it's reviewed. And the entire calculus is part of that scientific opinion, right? I would imagine there might be some give and take between the submitter and EFSA if you don't agree on the risk calculation derivative set forth in the scientific opinion. Is that correct?

**SJB:** Yes. There is a back-and-forth between the submitter and EFSA. EFSA will come back with their preliminary opinion before it goes public. And then I believe you can work with the authority to determine the SML. And I guess going back to the derivation of SML, this really is -- it's a risk assessment. As a submitter, you would want to find point of departure information, hazard data for the substance of interest. And you would provide that in your submission to your member state. And essentially, before it's reviewed by EFSA, you would want to have a good feeling of what your SML would be based on the hazard data you would provide.

**LLB:** Right. Because an adverse determination could pretty much make a new market for this chemical in the food context base for plastic somewhat more problematic, right? If you didn't know what the answer was before you submit the application.

**SJB:** I would say yes and no. I guess one of the advantages to having a SML is that if you had a new monomer, it might have moderate -- it might have a moderate SML, not too high, not too low. But then depending on how you formulated it or incorporated it into an article, that can take -- it can be incorporated in a variety of different ways, at very low concentration or very high concentration.

There could be various curing conditions for your article, whereby you don't see migration out of that specific plastic. Even in that case, even if you had a low SML, if you didn't detect the new chemical substance migrating out of the article, you're still okay. It's not that you need to get the highest SML possible. It's that the SML should be reflective of the hazard of the substance, which is based on your toxicology, your hazard data. And then the other side of that is that, with more hazardous substances, you just need to have a lower migration. It's not the end of the world if you have a low SML. I would say that industry certainly frowns upon substances that are listed in the PIM with a non-detect migration limit.

**LLB:** Oh, yes. That is not great news.

**SJB:** And those would be potentially slated for removal from the supply chain.

**LLB:** There you go.

**SJB:** But it depends. And I think going back to the different types of products, again, if you have these very inert products, it's arguable that, even if you have a non-detect SML, you don't have a regulatory compliance issue. Maybe it's more of a public perception issue at that point.

**LLB:** Right. You're correct, Scott, that this list is built upon decades of prior art. It's an iterative process, and the list is probably always growing. Do you have a sense of how many new substances are added on an annual basis? Is it one or two, or dozens, or hundreds, or what's the metric there?

**SJB:** It doesn't grow very quickly. Yes, as you said, it's built on these legacy regulations, and the majority of the substances have been brought in from previous regulations -- I would say maybe 10 to 20 new substances might be added each year, perhaps less.

**LLB:** Got it. Okay. Let's pivot to another new definition, and one to my eye, anyway, that seems to be somewhat debated: is the regulation of non-intentionally added substances (NIAS). While this has been used for years generally to describe impurities, my sense is that it has a slightly different connotation now. What is it? Why is it controversial? And what guidance is provided in the regulation for non-intentionally added substances?

**SJB:** Yes, NIAS. Whenever, I guess, the PIM is brought up, closely thereafter, a conversation about NIAS, I think, follows. NIAS -- it's defined actually in the PIM. It can mean an impurity in a substance or a reaction intermediate formed during the production process, or a decomposition or reaction product. NIAS is impurities and degradation products, as defined in the PIM.

Yes, it's a topic everybody wants to talk about in Europe, because I guess from my perspective, it's kind of a potential gap in the simplicity and beauty of the PIM. The PIM -- it's this black-and-white listing of substances, right? If you use these five substances, you have these SMLs and you comply with them, your compliance activities are done. NIAS is the impurities or degradation products that could potentially be present in your material. It opens this Pandora's box of possibilities. These impurities may or may not be listed in the PIM separately. The PIM actually excludes NIAS. It defines NIAS in the regulation, but then it says that NIAS *can* be present in your food contact plastic. So it's --

I should also say that the PIM, it defines its scope very well. This introductory text in the regulation where it tells you what's in and what's out. For example, NIAS can be included in your substance but not authorized. It also says that the scope of the PIM doesn't include solvents. The solvents used in the manufacture of plastics aren't specifically listed in the PIM. And it provides a rationale that solvents are expected to be removed. The PIM also doesn't include listing of catalysts and aids to polymerization. It's very cut and dry in the introductory text of what it does do and what it doesn't do. I think that's helpful for industry because it gives a list of a thousand substances. It's already a complex regulation in itself. And then it very well defines what's excluded from the regulation. NIAS falls in this gray area where it's allowed to be included in plastics, but it's in these substances that aren't necessarily authorized.

**LLB:** But is there any type of toxicological evaluation of the NIAS? Because it's clear that it's not part of the PIM, but it does seem to be part of the package. And if some of that NIAS were to migrate out, even though it's an impurity, or a reaction intermediate, or degradation byproduct, is there any way that that is assessed from a toxicological perspective to make sure that your SML is X, but if that NIAS is along for the ride, that can't be a good thing in some instances.

**SJB:** Right, yes. And this is essentially covered by the framework regulation, as I mentioned earlier, the overarching general regulatory scheme. In the framework, it says that all materials used in the manufacture of food contact substances must not endanger human health, essentially. It says it very plainly and broadly. That's really -- the standard is in the framework. That covers everything, right? That covers the monomers in the PIM, and it also covers impurities, degradation products, etc. Certainly NIAS needs to be addressed in your regulatory scheme. And then it's -- what's lacking is clear guidance on how to do that. And that's not included in the PIM at the moment.

**LLB:** Got it. The two really do need to be read together.

**SJB:** Yes, yes. The framework and the specific migration -- the specific measures, absolutely.

**LLB:** In addition to the inclusion of additional substances added annually to the positive list, are there other changes in the PIM or in the framework that you would expect to be seeing sooner rather than later? Or are they simply added in the normal course of business, as it were?

**SJB:** The strengths of the PIM --I've got so many of them here. Another strength of the PIM is that it's regularly updated. I've just counted, it's been updated 14 times since 2011, so it's more than once a year, the PIM. That includes addition of substances to the positive list and also revisions to the introductory text and the regulatory text that's in the document. This is truly a working document that's updated almost -- more than annually. It was most recently updated in September 2020, not too long ago.

Some new changes or amendments that came in that 2020 amendment include addition of new food contact materials. There were some amendments regarding metal impurities, such as lead and mercury and other substances of concern. That's what the -- the substances of concern, the guidance in the PIM is updated, I'd say, very regularly, which is responding to public advocacy groups and new scientific findings for substances of concern. Where a problem is identified, the PIM will be revised or amended to address substances of concern.

One of the big changes, and one of the reasons for having this discussion today that happened in September, is there's new migration testing guidance for repeat-use plastics. The previous guidance had been that when you have a repeat-use plastic, you need to measure migration three times. And it was kind of written that way. Now, the new amendment states that the specific migration in the second test shall not exceed the level observed in the first test, and that the specific migration in the third test shall not exceed the level observed in the second test. Essentially for these repeat-use plastics, you can't have increasing migration. It's an important revision to the migration testing guidance.

**LLB:** Thank you for adding that, Scott. For people in this space, it's an important nuance. Let bring this a little bit back to home. Given your perch in Washington, doing as much work as you do as a chemist in this space, food contact materials, direct and indirect food contact, what can regulatory professionals working outside of the EU, meaning those of us here in the United States, leverage with this approach to plastic food contact materials? I'm sure there are advocacy opportunities and scientific lessons to be drawn from the positive list in the PIM. But what's your sense of leveraging that advocacy in the EU?

**SJB:** I would say this is an essential read for anybody working in the food contact space, as I said before, specifically new product development. If you're a regulatory professional reviewing new product formulations for plastics, or coatings, for adhesives, etc., this regulation includes a long list of publicly evaluated substances. You may not be in the EU, and you may not be working specifically on plastics, but I don't think there's a better public listing of substances at hand to evaluate new products.

Say a formulation chemist comes to you with a question of "Which of these two monomers should we use? They have similar product characteristics, similar cost from a regulatory perspective." If you had to pick, the PIM can potentially give you answers on which might be a better monomer to choose. That's one thing.

When you're conducting risk assessments of existing products, FDA has some commercial PEL information, but not all in one place, and it's not as easy to access as in the PIM. It's a great reference tool for just product reviews.

And then I'd say the third thing it might be helpful for is -- it also includes explanatory text, specifically, I guess, I would say regarding solvents. In the FDA regulations, they have what I guess you could call specific measures for different product types. There's a regulation for coatings, and there's a regulation for plastics, and there's a regulation for colorants. They're much more limited in each of their scopes, and their legacy regulations aren't updated as often as the PIM are. They're not *as* helpful.

But there's a lot of gaps. And what I would say that the PIM does -- it includes explanatory text for things like solvents, where it says, "Solvents are expected to be removed on cure." It's something -- it's a place you can point to in your risk assessments to establish how certain types of substances are addressed. Whereas if you look in FDA regulations, you would be hard pressed to find similar type explanatory text for things such as solvents,

things such as catalysts. The regulation provides a lot of context for food contact -- regulation of food contact substances, just in general.

**LLB:** No, it sounds pretty -- I'm guessing it's all easy to find online on the EFSA website? Is that where one looks?

**SJB:** You can very easily find the regulation by just searching Commission Regulation EU 10/2011. And you can find it in something like ten or 12 different languages because this is an EU document, so whichever language you like to read it in, you can. And they're all official translations. It's a very comprehensive document that a lot of people can learn something from.

**LLB:** Just out of curiosity, Scott, do you see FDA regulation moving in this kind of direction of being specific, transparent and, much more, I guess, granular with regard to these chemicals and what the SMLs are? Any opportunities for some symmetry there?

**SJB:** Yes, I would say the FDA -- it's a very different regulatory scheme, given their different approval process. The food contact notification process, which came into existence, I believe, in the early 2000s, it's a different beast altogether, with the proprietary nature of the submissions. I see them as two separate schemes. You could almost compare FDA's legacy regulations in 21 C.F.R. for specific materials as somewhat related, but even then, you don't have the specific migration -- the public SML numbers that you have in the PIM. I would say they're vastly different.

FDA does have the concept of overall migration limits; they call it an end test, and they outline migration testing. But it's not chemical-specific migration testing. It's just you do the migration test, and you weigh whatever solids came out of your extraction, and you either are under it and comply or you're over it and you need to do a reformulation. FDA is certainly not as granular -- the transparency for the FDA scheme could be improved. I think you would phrase it that way. It's just two different mindsets.

**LLB:** Yes. Probably hard to compare them. But what it sounds like, Scott, is like the PIM and the website that you noted, the Commission for this 2011 regulation is -- just provides a wealth of information of which stakeholders in this space and regulatory experts and lawyers here in the United States should be aware. If we wanted to expand upon any takeaways here, please do so now. Also maybe let our listeners know where more information on this topic in general might be found.

**SJB:** Sure. Yes, I guess, as I said before, it's an essential read for regulatory professionals in the food contact space, generally. There's something for everyone here. I feel like I'm selling this product.

**LLB:** You're educating listeners, like me, who had no earthly idea this existed before.

**SJB:** Right. What it does is -- the food contact space is somewhat fragmented. I would say just historically because of where concern was raised. Some materials, maybe there was concern raised for them. FDA developed specific regulations for them, and they were developed piecemeal. Even to this day, as I was saying earlier, as far as specific measures in the EU, they're not complete. There's a lot of space in this -- there's just a lot of -- I don't want to say unregulated, because in the EU, everything's covered under the framework, but there's not specific guidance for certain materials.

Take the example for printing inks in the EU. There's no EU-level regulation for printing inks, but there is a member state regulation. This regulation, called the Swiss ordinance, that was just developed in Switzerland, covers printing, for example, and similarly for paper and paperboard in Europe, there is no specific measure for that at the EU level. But there's a German regulation for that. There's lack of cohesion between regulations of different materials. And I think what people want, or what industry wants, is this level playing field where you can look up a regulation if you're in Europe and point to that one, and say, "Oh, we're manufacturing *X*, and here are the regulations for it."

You have that for plastics in Europe. It's been done very well. And for other types of materials like coatings in Europe, you don't have that. And in that case, this is just kind of like a beacon, you know, a lighthouse. This is what your -- these are rules that are for plastics, but it's very much applicable for other types of food contact materials, because it's the same -- a similar application. And if you're using the same chemicals, it's very relevant for your risk assessments.

I think it can fill the gap for other types of materials. And certainly in Europe, I think eventually this will be referenced for other types of materials just because of the comprehensiveness and completeness of the regulation. I just think it's a wonderful read, and it should be helpful for you and your regulatory reviews and new product development.

**LLB:** Great. Scott, I want to thank you for bringing the PIM to our listeners' attention. Its utility sounds pretty much endless, its transparency welcome, and its specificity an important -- potential assets for regulatory professionals in this space. Thank you so much for educating us today and for talking with us about European regulations in the space and how we might use them here in the United States.

**SJB:** Thank you for having me, Lynn.

**LLB:** My pleasure. Thanks again to Scott Burya for speaking with me today about the EU plastics implementing measure and its potential utility and regulatory risk assessment context here in the United States and elsewhere.

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