



Episode Title: What Is the Difference between a Biostimulant and a Pesticide? -- A Conversation with Lisa R. Burchi and Sheryl Lindros Dolan

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Lynn L. Bergeson (LLB): Sounds like a lead-in to a joke, doesn't it? A pesticide walked into a bar and said, ...

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

B&C recently presented a webinar titled "Navigating the Jurisdictional Tightrope between Biopesticides, Biostimulants, and Related Emerging Technologies." The webinar explores fascinating, yet commercially vexing, jurisdictional divides between and among these agricultural chemical products. According to a recent USDA [U.S. Department of Agriculture] report, the plant biostimulant industry is expected to be at least \$2.2 billion now and up to \$5 billion by the year 2025. As big as this market is, there is, surprisingly, a great deal of confusion in markets globally regarding what exactly a biostimulant is and how it differs from a fertilizer or a pesticide, and importantly, how the U.S. Environmental Protection Agency (EPA) goes about regulating the claims made for these products.

This podcast focuses on these issues, especially as they relate to how EPA regulates biostimulants and offers some tips to stakeholders in this commercial space on how to avoid enforcement scrutiny. My guests today are my colleagues Lisa Burchi and Sheryl Dolan. Lisa is resident in California and counsel to B&C. Lisa counsels clients on chemical law and regulation and has significant experience with legal and regulatory matters specifically related to these jurisdictional issues, which most often arise in the context of an enforcement action brought by EPA headquarters or regional offices. Sheryl Dolan is B&C's Senior Regulatory Consultant. Sheryl works with a wide variety of chemical innovators to commercialize their products and works very closely with the legal team here to make this happen. Both Lisa and Sheryl are employees of B&C's consulting affiliate, The Acta Group (Acta®), with offices here in D.C.; Manchester, UK [United Kingdom]; Brussels, Belgium; and Beijing, China.

Here's my conversation with Lisa Burchi and Sheryl Dolan on biopesticides, biostimulants, and pesticides and learning the differences among these products.

Sheryl, Lisa, it's just wonderful to have you in the studio today. The topic we are about to discuss is one of my very favorites because it's just fascinating. I'm going to kick off this discussion with a very broad question. Who among the two of you can tell me the answer to the \$64,000 question here, which is, "What is the difference between a biostimulant, and a pesticide, and a fertilizer? Lisa, you want to take a shot at that one?"

Lisa R. Burchi (LRB): I can. That is the crux of all issues, because obviously the difference between being a biopesticide and being a biostimulant is the difference between requiring registration under FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act] and review by EPA, and being excluded from such registration and being allowed to market your product, maybe without as much review and restriction. But to be able to really define which is which, I think you need to focus on three items, because EPA requires a product to be registered as a pesticide, depending upon what claims are made and whether the product can or should be used as a pesticide, the composition of the product and whether there is a component within that product that would be considered an active ingredient and is used for pesticidal purposes, and then an intent by the distributor or seller that that product is going to be used as a pesticide. The trick really between the two, as we've seen lately, comes down to what kind of claims you can make and what claims are considered to be pesticidal or not.

Then the ingredient issue can also get tricky because it's unclear whether there is a finite list of substances, the presence of which at any concentration and at any function might turn a product into a pesticide, or whether there are products that can contain certain ingredients, but at concentrations low enough that don't impart pesticidal properties, or for functions that are non-pesticidal that could still be considered a biostimulant type of product, even if you contained one of those ingredients. It's the claims, and it's the ingredients. EPA's guidance, particularly on the claims front, is trying to help companies know that line and what claims would be considered pesticidal and what claims would be considered biostimulant.

Sheryl Lindros Dolan (SLD): Another footnote, just to drop off all of Lisa's excellent summary, is that it seems like there's a -- one way to break on the claims and the composition is if the product will be used on food crops or for non-food, like ornamentals and turf only, because EPA does seem to provide a little bit more elbow room for vitamin hormone products, as long as those criteria are met.

LLB: We're going to return to the claims component and intent criteria in a bit because they are super important. But I want to back up for a minute, because asking the question "What is the difference?" assumes that there is a real-world consequence to being a fertilizer, a pesticide, or a biostimulant. Along the continuum of maybe cost of doing business, how would you organize those three categories of agrichemical products?

LRB: I think that, as I already said, if you are a plant regulator or a biopesticide, then you are required to register your product with EPA. It requires a certain amount of data to be submitted and reviewed, a label that needs to be reviewed and approved by EPA. There are costs and time associated with that review. If you are a fertilizer or a biostimulant, you can avoid the EPA registration process, but it's not entirely without *any* regulation.

Fertilizers, for sure, have been regulated on a state level, and even biostimulant products, although maybe not biostimulants as a category, but some particular types of biostimulant

categories can require some activity at the state level. But in most cases, biostimulant products probably have the least regulatory oversight of the three. Those are the different categories and the different regulatory consequences and requirements that are triggered based on which category you're in.

LLB: Okay. No, that's very helpful. If I have this right, being a registered pesticide product under FIFRA is kind of the gold standard, meaning that it's the most costly and probably the most time-consuming to obtain -- and the most regulated.

It might also represent the highest price product for the downstream user or grower. Then there are fertilizers, which are not regulated by EPA at all, but rather by the states. Then at the bottom rung, there are biostimulants, which are not now regulated as pesticides, but given what we're talking about, could be, depending upon claims made, the intent, and the component in the biostimulant of the product. Do I have that right?

SLD: I don't know that I would draw a hard line between fertilizers and biostimulants because there are so many different categories of what we collectively call biostimulants that are regulated under the same program as fertilizers, depending on the state. Then, of course, you've got -- while there is a model statute offered by AAPCO [the Association of American Pesticide Control Officials] that many states have adopted as their fertilizer statute and on which their regulatory program hangs, there are differences between states about whether a soil amendment or environment hormone product has to be registered.

LLB: Got it. Okay. No, that's interesting and helpful, because where I was going is the answer to the question, "Why are we having this discussion now in 2020?" Biostimulants as a product category have been around for a long, long time, as have, of course, regulated pesticide products and fertilizers. Yet there's a lot going on in the international agrichemical community seeking to define more precisely the jurisdictional boundaries of registered pesticide products over this class of agrichemical products. I'm just wondering why now? Why here? What's going on?

SLD: Lynn, I think the discussion and focus on this issue have been around for a while, but the concern and focus have been building. I think the issues are rising now for a variety of reasons, including a need for improved agricultural efficiency, a lot of attention being given to being more productive on given acreage, or trying to find ways to manage growing crops in droughts, or high heat, or with other non-biological stressors.

Also, I think there's been better science, better understanding of these products, and that both drives innovation for new products, which then prompts review and also a better understanding of existing technologies. One situation we've seen -- if a product has been used for many years, but now how it works and the benefits that it offers are better understood, perhaps the folks who are making the product want to make more claims, and maybe those claims, in some regulators' view, might tip it over to being more of a bio -- a plant regulator, rather, and require registration. Or perhaps one company sees those additional benefits and can prove those additional benefits and wants to go forward and register the product, make those claims. Yet, other people who have those same products have not gone down that path. Then you've come up with a situation where it's regulated in one way because of claims, which is not an unusual situation for a separate product, but it can draw some more scrutiny than on those other products. Are they really dual use? And are there -- such and such registered the product, and your product has the same components, so why aren't you registered? That's creating some tensions right now.

LLB: Perhaps another explanation just is based on the size and rapid growth of the industry. I'm looking now at a December 2019 report to the President from USDA in consultation with EPA, and I think this is available on our website in connection with a couple of webinars that we have done on this subject. But I quote, the plant biostimulant industry is "[e]stimated to be at least a \$2.2 billion global market." The industry is active, growing quickly, and expected to become a \$5 billion global market by 2025. That's in four and a half years; that's huge growth.

I'm guessing where there's rapid growth, regulatory bodies almost biologically have an instinct to make sure that what's going on in that rapid growth reflects the best practices and the best science that might be available to jurisdictionally regulate products that are being used in and on food and in feed. Correct? Just the mere growth in the industry is itself a little bit of a driver for regulatory review.

SLD: Absolutely. In this day and age of everyone having a website, and promoting their products online, and all of us being glued to our screens, really successful marketing from the innovators is going to draw attention to their claims by the regulators who are glued to their screens, just like the rest of us.

LRB: I was going to say, too, even in the world of pesticides, there are different types of pesticides. Biopesticides are considered different from conventional pesticides. That area has been an area where there has also been a lot of growth. You can tell from EPA's review process, the data that they require, the PRIA [Pesticide Registration Improvement Act] fees that they demand, and the time within which they set to review certain pesticides. The biopesticides can cost less and require less data, which is something that I think companies might be interested in, too. Even in a pesticide world, there are -- industry is going toward a more biobased consideration, so the biostimulant side of the equation benefits that way as well.

LLB: Let's pivot to some -- how a regulatory body like EPA interprets the three criteria that, Lisa, you kind of kicked this discussion off with: the claims that are being made, the chemical component in the formulation itself, and the intent of the person marketing the product. Those are three very important and somewhat -- one might argue -- subjective criteria, particularly with respect to a claim, and also what is the intent? Are those three criteria, when EPA is looking at a product and trying to decide whether it's a registered pesticide product, that must be registered under FIFRA Section 3 -- or a biostimulant, that may not require FIFRA registration? Are those three factors assessed equally? Is one more important than the other with respect to the chemical component? For example, if a biostimulant formulation contains any amount of what might be considered an already registered active ingredient under FIFRA, is that necessarily controlling? How does that work?

LRB: I can start, and say that as far as registration goes, EPA's regulations state that a product needs to contain an active ingredient with no significant commercially valuable use as distributors sold other than use for a pesticide purpose. Using that language, it should be inferred that if you had an ingredient that had a significant commercially valuable use as a non-pesticide purpose, that you should be allowed to have that active ingredient in a product without it requiring FIFRA registration. The presence of a substance should not necessarily per se qualify you as a pesticide. Now, having to prove that and what its use is may not always be as equally clear in all cases. But again, as comparison to EPA in its draft guidance on plant regulators and biostimulants included a list of substances that it considers to be plant growth regulators that require pesticide registration. They didn't really hit on this issue, about what its use or intent is, and even sometimes I think what the concentrations of

those substances are, because you can tell from the way in which some of these active ingredients are registered in pesticide products, you might need a certain concentration level of that substance to impart pesticidal properties. The question would be, if you had a certain substance below a certain concentration level, would that also indicate that it's being used for a non-pesticidal purpose? That also is not addressed by EPA in its guidance as of yet.

SLD: That concept of dual use is hard. You'd like to think it could be correlated with the claims. Certainly claims for all pesticides are an important consideration jurisdictionally. In fact, EPA's 2019 guidance really makes most of the determinations, all based on the claims, and what words you use, and so forth.

But there *is* that tough issue then about what's in there, and at what concentration. EPA did list in its draft guidance some active ingredients that are -- I don't know -- Lisa, did they say they were presumptively bio -- plant regulators, or at least they're active ingredients that are in registered plant regulators? And yet, there are components in there that, if they're at a lower concentration or if there's another "use," quote, unquote, as defined by the claims that suggest that they're functioning *not* as a plant regulator.

Those, arguably, are full use and should not fall under FIFRA. But a lot of times, I think, companies are left in the difficult position of then having to prove the negative. No, we don't function as a plant regulator, and frankly, that goes beyond the limits of known science, in some cases. We don't understand at a molecular level necessarily, or at a physiological level, how exactly the effect is being achieved.

LLB: Part of the lack of clarity in this space is driven by the law itself, right? We've been talking about pesticides, which are clearly defined under FIFRA, and fertilizers, of course, are regulated by and large at the state level. While the definitions may vary, there seems to be a general consensus as to what is a fertilizer versus something other than a fertilizer, as defined under state law. But then you have these biostimulants, a class of substances *not* explicitly defined under FIFRA, and not, surprisingly, explicitly defined in EPA regulations. I suspect because of the lack of clarity in this regard -- and you've noted, both of you, in your comments today, this EPA guidance, which came out about a year ago -- a little more than a year ago -- in March 2019, entitled "Guidance for Plant Regulator Claims, Including Plant Biostimulants." Who can walk us through who developed that guidance, where it stands right now, and what we might expect to glean from reviewing it?

LRB: I can say that this guidance document was a few years in the making. It clearly was an issue on EPA's radar. I think that they were working, and perhaps struggling along with all of us in terms of having that kind of guidance about what claims and what issues relate to plant regulators versus plant biostimulants. There was a lot of work and input from industry that has been very helpful. We know EPA has also worked with state agencies and other federal agencies and done its own review of existing product claims and things of that nature. They say that all of those were components in developing this guidance.

The guidance really primarily focuses on the claims that can be used for these different categories of biostimulants to be within that sphere and then contrasts that with a list of claims that it considers to be pesticidal, to try and sort of show that divide between the two. The guidance, also -- as we just discussed earlier -- has a list of chemicals and active ingredients that it says has mode of action and are registered as pesticides. It provides a definition of biostimulants, which may in itself be helpful in terms of trying to define exactly what this category -- or what a biostimulant -- actually is.

LLB: When this came out, I know some of our clients commented on the draft guidance. Was it like “Hallelujah! Finally, we have clarity on what a biostimulant it is!” Or were the comments on the draft guidance very good and robust and elicited a number of other questions that have thrown this issue into further kind of disarray? Where do you see that debate going?

LRB: I think the comments -- as with most issues -- were a bit mixed. I do think that there is general support for this type of guidance, and the industry really welcomes it. There obviously are a lot of advantages to having guidance that clearly defines this jurisdictional line and helps companies know, for example, what kind of claims it can make for a soil amendment that keeps it as a soil amendment and that they don’t really inadvertently make a claim that they don’t intend to be pesticidal but that EPA considers to be pesticidal.

But, of course, while the guidance is helpful and wanted, I do think that there were some considerable issues raised with regard to the guidance that are hoped to be addressed by EPA when the final guidance is issued. I think that there might be some claims that can be tweaked, additional claims that might be added. As we already noted, I think there are issues about that list of active ingredients, whether it’s qualified enough or really should be included at all in this guidance. There are some significant issues that hopefully will be addressed and the guidance can be improved upon to really give industry the examples and the EPA thought process and really distinguishing between these types of products.

SLD: In looking at the guidance analogously, maybe to an earlier guidance document, PR Notice 2000-1, for treated articles, it kind of defines the safe havens, right? I mean, if language is used, and it’s noted as being an acceptable nonregulatory set of claims for at least a biostimulant of one of the categories, as opposed to a plant regulator, then it becomes more straightforward to argue, at least based on claims, that you fit in a certain bucket. Then similarly, it provides things that in EPA’s view are clearly plant regulator claims. But what happens when you come up with a new verb that isn’t in either bucket? It becomes a little bit more challenging in that case to figure out what to do. But it’s something.

LLB: Looking at where a lot of the federal Office of Pesticide Programs’ energy is devoted right now, it obviously isn’t necessarily on agricultural pesticides, or biopesticides, or even biostimulants, for that matter, because so much energy is being devoted right now to the registration of disinfectants and other chemicals that are regulated under FIFRA intended to combat the pandemic. But surely EPA recognizes this is a pressing issue? Many believe, for example, that drought and extreme temperature are responsible for declining crop yields and that biostimulants might offer a relatively expedient and efficient way of driving yield growth and inviting agricultural stability.

In that regard, as soon as EPA can kind of redirect its energies away from COVID and back to business as usual, might this commercial reality of the expedience and efficiency of these class of chemicals influence EPA’s regulation and maybe tip the scales away from heavy regulation, or not? What are your thoughts?

SLD: I think EPA would say it’s either going to fit into our jurisdiction or not. If it’s in our jurisdiction, there’s a set of requirements. If it’s a biochemical, if it’s a microbial pesticide, there’s a set of requirements applicable to biopesticides -- of which plant regulators are a category -- that apply. And if they apply, then they apply. You have to meet all those requirements. I don’t see -- once that jurisdictional determination is made -- that EPA would back off on that. That includes your range of mammalian toxicity, and environmental fate and facts, and product chemistry, and so forth that apply -- and even efficacy. Maybe not at

the federal level because it's not a public health pesticide, but certainly for California. I think if you fall into that bucket, there's perhaps a more straightforward path for what you have to do, but it's -- I don't see EPA backing off. If data are required, data are required to make that safety finding.

LLB: Just to play devil's advocate a little bit, Sheryl, or just to kind of go legal on you, this guidance that EPA came out with in March 2019 is a guidance document. Many of the issues that the agrichemical community actually faces in defining these concepts is in the context of an enforcement action. Will the guidance be interpreted as a law in a way that will provide precisely the clarity that you just alluded to? Either it is or it isn't. These claims are being made. Will it be registered -- or regulated -- as a pesticide or not? How do you square that circle? Maybe, Lisa, what are your thoughts on that?

LRB: I don't know if it will be -- I mean, they're clear to describe this as a guidance document, and there are questions raised within that guidance document as to whether they need to propose any regulations. For example, they provide a definition of *biostimulant* and ask the question whether they need to initiate a rulemaking to incorporate a biostimulant definition into the regulations. But even short of any effort to make this a formal -- any of this a formal regulation, I do think it becomes highly persuasive -- in terms of where EPA's head is at -- what OECA [EPA Office of Enforcement and Compliance Assurance] could look at in terms of claims that do or do not fit within one category or another. So it may not be law per se, and there may be a lot of claims that aren't specifically listed here that might be considered synonymous in there.

There are still gray areas, but I think it should be highly persuasive in terms of if there was any enforcement action, if you could demonstrate that a claim that is -- EPA in an enforcement action is considering pesticidal but fits more clearly into one of the non-pesticidal, biostimulant-type category claims, you would have to take the hard look at the inconsistency of EPA's -- if there are any inconsistencies between an enforcement action and this guidance, that would have to go far in resolving that toward using this guidance as a real rule of thumb.

SLD: I would hope there's a little bit of wiggle room. I mean, it's guidance, and in fact, it's draft guidance. But this is such an area in which there's evolving science that I don't think EPA's planning because of the evolving science and kind of the lack of consensus within the industry, to put it in final anytime soon. I think, again, between those two factors, that it's guidance; it's not the result of notice and comment, and that it's draft, that there will be hopefully some wiggle room to address those gray areas, but --

LLB: -- Implicit in your answer, Sheryl, is that EPA may keep it in draft for an indeterminate period of time. Does that make it kind of three degrees of separation from something that is reliable and on which the regulated community should emphatically rely as a North Star for assessing these complicated issues?

SLD: I would think and hope -- and Lisa, I invite your thoughts -- that for those things that EPA sort of said, "These are claims that are associated with a soil amendment. These are claims that are associated with a plant nutrient." That, hopefully, if a company found itself in a defensive position, it could point to that, and that would be reasonably North Star.

LRB: Absolutely, and prospectively, too, to sort of look at how EPA has divided these claims. It might not be final, and of course, there hopefully are changes. There certainly were enough comments submitted that could result in some changes or additions to the claims. But

probably there is some core here that is going to remain, and I think companies can focus on what's here and help them more than would have existed before this guidance in trying to make some claims.

Just as an example, I would just say it's interesting that there are some things that -- for example, seed germination -- that is something for which claims are made in this space. In the EPA guidance, you could make a claim that you're optimizing soil conditions for seed germination, and that's a plant nutrient claim. But if you were inducing or promoting seed germination, that's a pesticide claim. It *is* tricky. You're talking about the same activity, but the word you use and what's happening with your product to seed germination can even determine which side of the line you're on.

SLD: Those differences of verbs, I think, are supposed to hint at different modes of action, maybe. But again, that's a refinement of the science that doesn't exist in all cases.

LLB: You guys are so close, and so good at this stuff. I hope you're listening to yourselves, because the word, the tense -- the subtleties here -- are just kind of mind-boggling complicated for people who are not FIFRA nerds. My heart goes out to the regulated community in trying to find their way through this very complicated space.

Let's pivot for a minute to the old adage: there's strength in numbers here. The United States is not the only jurisdiction to be struggling with these issues. There is a lot that *has* gone on in the European Union (EU). Perhaps one of you can talk about what *is* going on in Europe, and I think there are also some regulatory initiatives elsewhere in the world, Canada, for example. Who wants to tackle that one?

LRB: I can start. Yes, the EU has been working on these issues recently and simultaneously with the United States. In the EU, there was a fertilizer regulation that did not apply to biostimulants, and there was the plant protection products (PPP) regulation, which is more akin to the U.S. FIFRA scheme for agricultural pesticides. The PPP regulation specifically excluded nutrients, but nothing else -- I mean, lots of other things, but not biostimulants. The nutrients did not include biostimulants. It was its own term. And then just last year, the EU repealed and replaced its fertilizer regulation with a new regulation, and that regulation now is intended to include plant biostimulants. It also amended the PPP regulation to specifically exclude nutrients and biostimulants. *Biostimulant* now has its own legal definition in the EU. They are addressed on an EU level, not varying member state regulations.

There are now specific criteria -- labeling requirements, category functions, a lot more specificity and conditions under which you qualify as a biostimulant. In that sense, there also has been some improvement and nationalizing it across the EU, as opposed to being more highly variable between EU member states. Most of the world really doesn't have a lot of definitions. There are still a lot of gaps in how biostimulants are regulated. You did know Canada, and they do also have their own fertilizer act, and they have requirements for fertilizers and supplements, which isn't exactly the same as biostimulants, but those supplements require registration. There are those that improve physical condition of soil or aid in plant growth or crop yields. It's different, but again, it has its own definition, has its own requirements, and in that case, requires its own version of a registration requirement.

SLD: Canada's regulating substances that are -- in addition to fertilizers but maybe somewhat undefined, given that the boundaries on all these are a little overlapping -- and they've gone forward and created at least some greater certainty for business in creating a regulatory

paradigm and maybe uniform labeling. I don't know if that's included in that, which is what I think industry generally is craving: Just greater certainty and maybe a national label, rather than -- at least in the United States -- having differing requirements between the states.

LLB: Perhaps. It sounds like there is a definition for *biostimulant* in Europe. There are similar initiatives going on elsewhere in the world, Canada among them. But at the end of the day, we are no further along the spectrum of having some model or global definition of plant biostimulant in a way that manufacturers can move seamlessly among countries and avoid the types of jurisdictional questions that this podcast is discussing, correct?

SLD: Correct, although I think with a lot of products in this space, and certainly a lot of products that are used for food use, you're going to have some kind of registration program in each jurisdiction. It's wonderful when we strive toward harmonization -- whether that's for data development, or labeling, or registration requirements -- but there are always going to be some regulatory hoops that everyone has to go through.

LLB: That's right.

SLD: Nice to minimize them.

LLB: And harmonization will always remain the unicorn that I believe it to be.

But let's -- our last topic of discussion relates to a term that I think is relevant for everyone in the regulated community. That's enforcement.

My sense is that a lot of these issues are obtaining a definitional patina in the context of FIFRA enforcement actions brought against manufacturers of products that were not thought to be required to be registered under FIFRA. But oops! EPA decides otherwise. Is there any way to obtain any type of clarity on what the results of those enforcement actions are? Because enforcement actions typically are not public. You can sometimes see through EPA press releases and other contexts how issues were resolved, but it's a uniquely unsatisfying way to define space. I know the guidance will be coming out. It *has* come out, and there will be refinements to it, but where does the enforcement piece figure into all of this in terms of adding clarity? Or does it? Maybe it's just a disincentive.

LRB: Yes, and I think, as you just said, you don't have a necessarily clear landscape as to all the enforcement cases that have been brought against products. In most cases, the situation for enforcement would be a company markets a product that *it* believes is a biostimulant. And then because of the claims that are being made, EPA makes the argument that it's *not* a biostimulant. It actually is an unregistered pesticide. But it's not always clear, as you noted, from enforcement, how things are settled -- exactly even what the claims are that EPA has alleged are problematic, how it is resolved.

And there are different EPA regions that can be involved, although that might not be as big a factor, because it does seem as if EPA headquarters -- the nucleus of information about what claims are or are not considered pesticidal -- some of them are technical issues, really aren't addressed as a regional issue, but are funneled through to headquarters. It probably would be helpful if we could see across the board, and those enforcement cases could inform even EPA in its guidance document. But I'm not sure that exists. But again, despite the gray area, what we do know is that this *is* an area of enforcement, and EPA is looking at some of these products and determining that certain claims that companies think are biostimulant-type products, EPA argues are in fact pesticide claims.

SLD: If a company is trying to get some greater certainty, there is a process that they can submit a request for a determination to EPA. For pesticide registration, of course, and for amendments and for other actions under the Pesticide Registration Improvement Extension Act, or PRIA 4, there is now a category -- M09, I think -- which, for a fee of \$2,500 and a review schedule of four to five months, a request may be made to EPA to say, "Is this regulated under FIFRA? Is this a plant regulator?"

If the company is willing to live with the answer it gets, this is an opportunity to put all your cards on the table and make a determination up front whether or not, in EPA's view, your product should be registered or not. I think EPA and industry engage in discussions about what information should be submitted, parallel to what you would normally submit for, maybe for registration, only some information, but more to what's in there, and the claims, and what's known about the mode of action, to try and navigate the regulatory determination of when something requires registration and when it does not. That's another opportunity, on a one-on-one basis, case-specific basis, to come up with a determination whether *that* engagement will -- EPA will use that to further inform its guidance would be interesting, advisable, I would argue.

LLB: It is definitely, as you suggest, Sheryl, an option. Another one is to ask us, the experts in this space, as well, because once you've asked EPA under PRIA or asked EPA, period, that creates quite an important precedent for purposes of defining the jurisdictional reach of FIFRA as to that product formulation.

For those of you considering that PRIA option, recognize that the good news is it brings finality and closure to the issue. The bad news is you might not like the answer. Like everything else in life, good news, bad news.

Listen, I want to thank you, Lisa and Sheryl, for this fascinating conversation in an area of the law and in agricultural products generally that I think we can all agree is fascinating, evolving, and pretty tricky. For those of you that have further questions, I refer you to our website, because we're on this topic. We love this topic, and it's definitely an important one.

Lisa, Sheryl, thank you so much for being here today.

SLD: Thank you, Lynn.

LRB: Thank you.

LLB: Thanks again to Lisa Burchi and Sheryl Dolan. Stay tuned to this space, as there is a lot more coming and a lot of developments in the months and years ahead. As always, please check out our website at www.lawbc.com, where you're going to find a lot more information on similar topics and find out more about what our firm offers.

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