Episode Title: TSCA Section 4 and Consortia Formation -- A Conversation with Heather Blankinship and Richard Engler, 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 Heather Blankinship, Senior Manager with B&C® Consortium Management (BCCM), a Bergeson & Campbell affiliate, and Richard Engler, B&C's Director of Chemistry, to discuss chemical testing under the Toxic Substances Control Act (TSCA). Since Congress amended TSCA in 2016, [the U.S. Environmental Protection Agency] EPA has been slowly ratcheting up required chemical testing under TSCA Section 4. Congress gave EPA expanding testing authority under the 2016 amendments, and EPA is exercising its new authority to compel chemical data production. These test orders authorize EPA to demand the production of new test data by the manufacturers and sometimes processors of the chemical substance at issue. Transactionally, this means competitors in the marketplace band together to generate the data EPA seeks.

We discuss the reality of quickly forming these consortia and the business and scientific challenges consortia managers face in complying with these federally enforceable test orders. It's not as easy as you may think. Now, here is my conversation with Heather Blankinship and Dr. Rich Engler.

Well, Rich, welcome back to the studio. And Heather, I'd like to welcome you to our studio and thank you so much for participating in this podcast.

Richard E. Engler (REE): Always a pleasure to be here.

Heather J. Blankinship (HJB): Great to be here.

LLB: Let's begin with providing our listeners with a very brief overview of TSCA Section 4. I think a few key questions are: What does Section 4 authorize EPA to do? Why has chemical testing largely been, in my view, anyway, largely a nonevent before the 2016 Lautenberg

amendments? And what did Congress do for the last five years since the Lautenberg amendments were enacted to kind of correct the situation? So, Rich, you want to help our listeners out?

REE: Prior to the enactment of the Lautenberg amendments, TSCA included testing authority. EPA could -- either by rule or by agreement, enforceable consent agreement -- could obligate manufacturers, importers, or processors of a substance to generate data, and it was typically done by rule. Occasionally, there were enforceable consent agreements. The challenge for EPA to do the rulemaking is that EPA had to have a basis to conclude that the substance may present an unreasonable risk before it could obligate the data. It was sort of a catch-22. If you didn't have the data, how did it know this substance may present an unreasonable risk?

One of the more successful Section 4 rulemakings as part of Lautenberg was the high-production volume chemicals, where EPA, simply based on the production volume and the opportunity for a substance to offer exposures for -- at least as large if they are high exposure or large releases, use that as a basis to obligate testing with the rule. Because of this criticism, this sort of catch-22 criticism, in Lautenberg, EPA was given additional authority to order testing, so using an order to obligate manufacturers, importers, or processors to perform testing for any of the various specific evaluations, so evaluation under Section 5, risk evaluation under Section 6, implementation of an order or a Section 6 rule. EPA has to make a statement of its need and explain why it's not -- why choosing an order instead of a rule or an agreement. And EPA must use tier testing. EPA does have new authority, and EPA has relatively recently finally flexed that authority.

LLB: That seems like a good thing to do. Heather, you manage lots of chemical consortia as Senior Manager at BCCM. Can you tell our listeners what it is you do in general?

HJB: Sure. We identify parties that have common interests, that wish to work together on issues, whether it be a substance or a group of substances. Typically, we broker that discussion upfront with those individuals to see if there's interest in forming a consortium. And we provide a forum where those groups, those parties can collaborate. We help mitigate antitrust risks. We help them to share resources, to bring their diverse, different perspectives to an issue. We can interact with EPA on behalf of that group of stakeholders. Many times, that's a stronger position than individually attempting to address issues and concerns with EPA.

We have our connection to The Acta Group and B&C, so we can bring in technical and legal resources to assist the members as needed. The great benefit is that they get to share the cost of that by being in a consortium. We don't make decisions for the consortium. We help them make decisions; we help them make informed decisions. We are there to help carry out whatever the decisions are that they make.

LLB: Maybe you can help our listeners who might now be thinking, "Wait a minute, developing data on a chemical substance's toxicological and environmental fate properties seems logically like something chemical innovators or manufacturers of so-called legacy chemicals would have done prior to commercialization or being in commerce for many years, as is the case with a variety of so-called legacy chemicals." Is that not the case, Rich? Why is EPA seeking data in the first place?

REE: It's all about data gaps. You need information. You need both hazard information and exposure information to evaluate whether a particular condition of use may or may not be an

unreasonable risk. And as EPA has with new chemicals for many, many years, EPA relies upon analogs and models to establish a hazard end point, a point of departure, as they call it, and then compare that to a predicted release or exposure, whether it's a workplace exposure, or general population exposure, or drinking water exposure, and then determine to do a calculation to see if that particular exposure represents an unreasonable risk or not. If -- in the absence of data, EPA relies upon, especially for hazard data, EPA relies upon analogs, they read across from data that they have for a similar substance to fill that data gap. And then they use their models, in particular, ChemSTEER and E-FAST, to predict the exposures. And so those are predictions. They are generally fairly conservative, but they aren't -- they're based on a data set and not anything specific for the substance. If you make a conservative assumption and you don't find an unreasonable risk, it's unreasonable to conclude that that particular substance under that particular condition of use is not an unreasonable risk.

If it's borderline, then there's a need for data, and in that case, either EPA or the submitter might generate data, whether it's hazard or exposure data, to fill those data gaps.

LLB: So perhaps this is a question for both of you. In your mind, given the 2016 amendments to TSCA, is the industrial chemical community receptive to receiving and responding to these mandatory test orders? Have you seen an uptick in what might be considered voluntary testing with the hope of heading off receiving a mandatory test order? How are people responding to EPA's new authority, given the passage of five years now?

REE: Our clients are generally not opposed to doing testing. It's really a question of is there a need, and how will that testing inform a decision? We've certainly seen, with new chemicals, that, for instance, EPA might, based on modeling, might set a very low surface water concentration limit and then require testing. But it's not clear that the testing will change the outcome because EPA already expects it to be very toxic to fish. In a way, it's like why kill fish to prove that it kills fish? In those circumstances, the manufacturer might be -- might question the need for data, but in many cases, it's -- they're happy to generate the data, as long as EPA has the need and that that information will be used to inform the outcome.

LLB: What do you think, Heather?

HJB: I also think that there's potentially a good incentive for doing testing, because in the absence of data, as Rich suggested, EPA will either use read-across and/or make fairly conservative assumptions where there's no viable read-across. If your substance does not exhibit the health effect or the toxicological effect that EPA suspects, then it's in your interest to generate data to prove that it doesn't. I also think that there's a difference between new chemicals and existing chemicals. With a new chemical, it takes a while for you to establish that there is true market demand, it's commercially viable. Perhaps at the beginning of that journey, so to speak, in commercializing a product, you may not have as much of an interest in making a significant financial investment upfront to do a lot of testing. But I think it does make sense over time, as that product becomes used across a wider range of uses, conditions of use, more volume is into the market. That's where the risk begins to go up. Exposure increases, so it makes more sense to generate that data over time, so to speak, rather than right up front.

LLB: Yes. You raise a good point between existing chemicals, where they might have been used for years and years and years where EPA has demonstrated, or at least has tried to demonstrate, a need for the data -- for any number of reasons that we'll get into -- versus

new chemicals that might be willing to accept the very conservative risk assumptions that go along with using the assumptions as a surrogate for actual data. I think the considerations with regard to testing are quite different for existing chemical manufacturers versus new chemical manufacturers. Rich, you were going to say something. What were you going to add?

REE: Yes, I was going to say that in many other countries, you see this reflected in tonnage bands. At low tonnage bands, there's some testing required, but it's relatively low-tier testing. And then as you cross into higher tonnage bands, you get to progressively more expensive and higher tier testing. There's exactly this anticipation of larger or greater chances for releases and exposures leads to greater need for data generation.

LLB: You raise a really good point, which is a couple of points. Number one, what types of data do the testing orders seem to demand? TSCA was amended, now going on five years ago, and to my mind, there hasn't been a lot of new test orders up until fairly recently, and the new testing orders seem to be now much more focused on very specific data needs that EPA in its review of, say, for example, the high-priority chemical substances for which risk evaluations are underway. EPA has identified -- and made a pretty good case -- that these data are necessary, but what are these data? Are they long-term toxicological studies, or something a little less aggressive when it comes to the cost? What chemical stakeholders are tapped to generate these data?

REE: Heather, do you want to take a shot at that?

HJB: The most recent test orders that we've seen have both environmental as well as health information that's been requested or ordered. There are, for example, *in vitro* dermal absorption study is one of the more expensive studies that's required, as well as some environmental studies for those substances. Not all the substances required the environmental studies. I think it depended on which ones already had existing data.

But then there's also a pretty significant exposure component to it as well. There's a dermal hand wipe sampling study that's required, as well as occupational inhalation exposure studies. It really kind of cuts across a lot of different areas, but none of them seem to be long term, so to speak, type studies. They're typically -- in fact, the deadlines that EPA has provided for the *in vitro* dermal absorption study is the one that's the furthest out, and it's 12 months from the issuance of the test order.

REE: That's reflective of the fact that there are a number of long-term studies for most of these substances, so that wasn't really a data gap that EPA was trying to fill. EPA was largely trying to fill the data gap for exposure, for worker exposure in particular. And so that's why we're seeing the inhalation and dermal wipe sampling testing. The *in vitro* absorption -- this is an interesting one that we've been discussing. It's going back to the point about what's EPA going to do with the data? So as a worst-case assumption, EPA would assume 100 percent dermal absorption.

A dermal absorption study would only reduce that amount by demonstrating that the substance is not absorbed dermally. EPA's obligating this study apparently in industry's benefit, but it's putting the obligation on industry; it's not giving industry the option to say, "Oh yes, you know what? This is our substance. We expect this isn't going to be dermally absorbed. Let's demonstrate that to EPA, to show that it's not 100 percent, it's 20 or ten or whatever the fraction might be." But EPA is putting this rather expensive study that requires the generation of a radioactive -- radiolabeled -- substance to do this *in vitro* testing.

I question, what's the point? Why does EPA need this data if it's worst case, if 100 percent absorption without this data is the worst case and EPA can proceed with the risk assessment of that worst case? That's something I think that, as a recipient of that order, I'd appreciate more explanation from EPA.

LLB: Recipients of these orders presumably have an opportunity to express their concerns with or scientific questions about the utility and actual need for the data, right?

REE: It's an order, right? The order is final upon -- so you can, I guess you can ask EPA, "Hey, what's going on?" We're certainly in discussion with EPA on a number of things on these substances, but there's not a clear, formal mechanism. There's not the discussion that you would get in, for instance, in notice and comment. And they're -- we're not aware of significant engagement between EPA and the order recipients because at least the test order consortium that we're managing was created in response to the test orders, not prior to it. That communication is -- we don't have a record of that. We weren't privy to that. Where was -- did it happen? It might have. It's really not clear.

HJB: Yes. I think more of our discussions have been along the lines of how are we going to do this? It concerns the test methodologies. I should mention, too, that it's not just manufacturers and importers that are subject to these test orders. There are also downstream processors of the material as well. What we find is that a lot of times processors aren't as tuned in to some of the TSCA stuff because they don't manufacture chemicals. They're primarily users of chemicals, and so, even the ability for those processors to take on board these requirements and understand how to carry them out in their workplaces -- and, as you know, many workplaces are very diverse -- and so these test methods have been developed and applied in situations where they really may not be applicable. For example, there really is no way for dermal absorption to occur or inhalation exposure. We've been sorting out, trying to figure out, where might we be able to achieve test waivers and things of that nature? More so than, do we really need this data?

LLB: That leads to another question I had, which is, how have these testing orders been received by stakeholders? On the one hand, TSCA has long been thought to be a kind of chemical manufacturer law. In other words, if you're tuned into TSCA, you're a big player in the industrial chemical community. The issuance of a Section 4 test order is going to be less surprising than a downstream user or purchaser of a chemical that perhaps has been less attuned, as you suggest, Heather, to the existence of EPA's authority to compel testing data, let alone actually receiving a love letter from EPA or seeing it in the *Federal Register*. I can imagine that there are a wide range of responses to receiving, or being subject to, a Section 4 test order, and that's one of the issues I think you probably grapple with every single day, Heather.

HJB: Yes.

LLB: I can't imagine people being wildly enthusiastic about, "Oh wow! Now we get to prove *X* about a chemical that we either produce or use." What *has* been the receptivity of stakeholders for these orders?

HJB: On the manufacturers side, I think -- especially the larger manufacturers -- I don't want to say that they enjoy it or they're embracing it, but they are to some extent, I think, taking it in stride, so to speak. I did notice, when I looked across the 20 high-priority chemicals and you look at all the fee payers, for example, the big fee payer list, there are a number of companies that are subject to multiple risk evaluations right now. They're dealing not only

with the risk evaluations, but now potentially responding to multiple test orders. I'm sure they're not enjoying it, but again, sort of taking it in stride.

We have also spoken with some stakeholders that have said their company's thinking about exiting the business, or maybe they already *have* exited the business, but because of the nature of the fees rule have been on the hook still to do some of these things. On the flip side of that, you've got the processors that, as you say, are getting immersed into TSCA for the first time. I can tell you, they're more than a little shocked at the price tag that's on this sort of thing. I think they're thankful to be able to share costs, but still not thrilled about their share of the cost, because it is costly. By the time -- as Rich suggests -- the dermal absorption test or study and then all the exposure studies, depending on how many facilities you have and how many different use scenarios you may be trying to cover -- it's quite costly.

REE: There's also some confusion about the effect of the order. Some of the members of a consortium might simply be transporting containers. They never opened the container. They never transferred from -- they never take a large container and fill smaller containers. They are simply receiving a container, sealed, and then shipping it wherever, still sealed. That's their entire role in the supply chain. The question arises, where should we test? There is no opportunity for dermal exposure. There is no opportunity for inhalation exposure. Where in this process does EPA want us to test? That's another conversation we're having about the applicability of some of these orders in certain facilities or for certain processors in particular, that they're -- they just don't seem to apply to some of the circumstances. But EPA didn't know that when it issued the order. This is that information-gathering stage that we hope happens before the next round of orders comes out. EPA has done, what, 11 out of the next 20, so there's another nine that we think will get some orders. We're hoping that the manufacturers and processors can inform EPA's test order decisions so that the orders better align with the conditions of use that the folks are undertaking.

LLB: Yes. A couple of questions for you, Heather, because I know there's a difference between assisting consortia that exist with satisfying a test order versus rounding up the cats, as it were, when a test order is issued. Are you managing some of these newly formed consortia, and are you forming consortia as we speak in response to these recent test orders?

HJB: Yes. We have one that we are managing now that's actively responding to a test order, one of the chlorinated solvents that just received a test order. Yes, that consortium did not previously exist. It wasn't until folks received test orders and we reached out that they began to have some interest in forming a consortium. But mind you, the clock is ticking, once you've received the test order, because there's a 45-day period at which you need to submit an initial response to that test order. One of those responses can be [to] form a consortium. It was difficult to get the right folks on the line to have that conversation, for them to go back to their businesses and have the business discussion about whether or not it made sense to form the consortium.

But once we were able to bring the parties together to form the consortium, then we really hit the ground running. There are certainly the administrative tasks that have to be completed in order to form a consortium. But more importantly, we had to very quickly identify a laboratory where we could place the study, get proposals, all of that, and the timelines to submit the initial test plans were really unrealistic. Extensions have been necessary and other things, but I don't think -- even though our consortium didn't exist previously, I know we've heard from others that, even where consortiums existed, they still had a very difficult time meeting those timelines.

LLB: Yes, 45 days is the blink of an eye. You have competitors, disparate entities in the commercial space that received these orders saying, "You need to produce a bunch of data by a time certain." And you're ordered to do so. This is not a negotiation, as Rich indicated. I think you're being very low key, Heather, suggesting that -- it's kind of pandemonium. You have to find the right person in the companies, explain the need, especially for entities that may be less familiar with what a Section 4 test order is, and go into the value proposition. There is considerable value in collaborating with others, leveraging information and resources, and collectively meeting a testing obligation that really should be borne equally among members of that community. What are some of the more formidable logistical challenges that you face in forming consortia?

HJB: I think -- particularly this consortium, because of the diversity of the members being manufacturers as well as processors, they really have a variety -- a wide range of different interests, different roles in the value chain. Trying to find that common thread that everyone has -- obviously, responding to the test order is a common thread, but really understanding the differences and the challenges that each is going to have in terms of responding to the test order. It's kind of surprising really for a wide group of people that all have interest in the same substance, but all have just their own unique sets of challenges in facing that, whether it's, again, the differences in their manufacturing, the size of the company, their availability of in-house resources that can understand these requirements versus needing more assistance from us in order to understand and interpret some of the requirements.

Some had more comfort with perhaps approaching EPA, whereas others will have less experience doing that, and that's where we can help. There are a lot of challenges -- it's trying to -- that initial (I call it the honeymoon period) where everybody's trying to get to know everybody. Likewise, we're trying to get to know them so we can understand best how to meet their needs.

LLB: I'm guessing because importers are considered manufacturers under TSCA, is there also kind of an international component here, or is this largely U.S.-based companies?

HJB: It's largely U.S.-based companies, although they're -- many of them were impacted by this because perhaps they're exporting the material for processing and then bringing it back into the United States for sale or for distribution or use themselves. There is an international component to it, but all the activity is U.S.-based.

LLB: As you suggest, Heather, there are rules of engagement for consortia in responding to these test orders. I know B&C Consortia Management recently submitted comments to EPA, I think where the Agency solicited suggestions or comments generally on what some of these rules of engagement are. Did you suggest on behalf of BCCM improvements or changes to these rules of engagement?

HJB: Yes. We did submit -- this was when the fees rule, the TSCA fees rule was open for comment, the proposed changes. We did make some comments. One in particular, as it relates to consortia, is EPA's position that it encourages the formation of consortia. In fact, we even saw in the test order communication that one of our members received, it even said in there EPA encourages the formation of consortia.

But it's difficult for these companies to know who else received test orders, although EPA publishes the list, but literally the person that received it and how to reach out and contact them and get organized. That was one of our suggestions to EPA was let's make that easier, make it easier for manufacturers and processors that received these test orders to know one

another, to know how to reach one another or even allow firms like ourselves who manage consortia to have access to that information so we can broker those conversations. That helps those companies to mitigate risk and to get past that antitrust risk, but also get past that awkwardness of contacting a competitor and seeking to collaborate on something like this. We think that's an important part of this whole equation of helping EPA to get what it needs in order to do the risk evaluations for these chemicals.

LLB: Let's fast-forward to the data development phase. Let's say the data are developed. They're submitted to EPA. We've talked a little bit about that a bit ago. Once EPA reviews the data, it probably determines the data are adequate and we can move on with our lives, or perhaps the data might reveal certain other features that might elicit yet another test order. Is that a probable or likely scenario? What might happen next? If you have a test order satisfied, the data are in, and then what happens? Rich, do you want to take a shot?

REE: I think it depends on the particular test that's being done. It may just be, okay, the dermal wipe sampling showed that the average dermal dose was whatever it was. And the inhalation monitoring gives an eight-hour time-weighted average that EPA then uses instead of its modeled numbers to assess the workplace exposures. As EPA routinely does when they do their risk evaluations or risk assessments for new chemicals, if there's exposure data, EPA will use that exposure data to calculate again a margin of exposure that looks for an unreasonable risk.

What I have yet to see, or I'm interested to see, what comes of the data that are being generated is -- if the data are generated and EPA says, "Thank you very much. We got these inhalation data, which shows whatever, for the hour that the activity occurred," that the exposure was whatever it was, and then goes ahead and assesses eight hours of exposure. They extrapolate that out. Will the ordered data change what EPA foresees? Or will it just change that the particular activity at that particular company is not an unreasonable risk and doesn't change EPA's view of the overall, what is reasonably foreseeable? If the worst case is reasonably foreseeable, then I really question the need for the data for the risk evaluation. I question the need for the data.

If EPA says, "Eight hours, the limits got to be whatever, 0.01 as an eight-hour time-weighted average," and that's what EPA is going to impose on risk management, then it's just up to the facility to show that they can meet that. I don't know why EPA needs that for the risk evaluation if the worst case is always going to be the worst case.

I think that depends. The dermal absorption, again, it may show that things are not as absorbed, so that may reduce EPA's concerns. I think for the aquatic toxicity, that will be more specific to help EPA refine the surface water concentration limit that they might set for those chemicals. Some of the -- when it's a hazard endpoint, I think it's more clear that EPA will use the data to refine its point of departure, its, air quote, "safe dose." But for the exposure, it's not clear to me how that's going to change EPA's risk evaluation.

LLB: Okay. It sounds like it can help a risk evaluation, it can put to rest some questions the EPA may have. Submitted data could elicit more questions about a chemical, in theory anyway, elicit another round of testing, but that's probably less likely than simply putting to bed whatever question EPA may have had in the first place with why the test order was issued, correct?

REE: Yes. I think it's different for this first group, because this first group are relatively data rich in the toxicological endpoints. I think for later substances, as EPA gets into more data poor,

we might see multiple rounds of tiered testing where EPA orders some intermediate level of test, then based on the results of that test order, a higher tier test. Now that takes more time. Each round of testing can take a significant amount of time. A 28-day repeated-dose oral study is, despite the fact that the exposure -- in-life exposure -- is only a month, it's six to 12 months from initiation of testing to when you get the final report. If EPA is going to do a 28-day and then follow that up with a 90-day, you're talking about multiple years before EPA has the final data, but I think we'll start to see that as EPA gets into prioritizing what comes next after these first 30.

LLB: One of the major goals -- the 2016 amendments were intended to shore up TSCA's authority in many significant ways, one of which was enhance EPA's ability to compel the production of toxicological and environmental fate data, and that's what we've been talking about.

But another goal of the 2016 amendments was to diminish industry's reliance upon animal testing. Where do alternatives to animal testing come into this discussion? Can the data EPA seeks be generated using newer, non-animal testing alternatives, or are we not at that phase yet of testing?

REE: That's exactly what we're seeing for the dermal absorption. EPA has -- the test orders are for *in vitro* dermal absorption rather than *in vivo*, so they're not using an animal model for the dermal absorption. They're actually using an *in vitro* model. We're seeing that in this round. EPA has been taking their non-animal testing obligations very seriously. I've been very impressed by how aggressive EPA is being about pushing more and more to *in vitro* models, rather than using animals. But there are -- some endpoints that -- they simply are not yet reliable *in vitro* models. And again, those tend to be higher tiers. We may see more of those in the future. Presumably, EPA will answer appropriately when it seeks to issue the order, because one of the things they have to respond to, or one of the things they have to address, is whether there is a non-animal method that's available.

LLB: Heather, in your experience, are some of the newer testing techniques that are being used to satisfy the test orders, does that give rise to confounding factors in selecting a lab? Is there lab capacity out there? Is everybody flocking to the same handful of laboratories, or is it relatively easy to find and contract with a laboratory to timely respond to these test orders?

HJB: I do think that lab capacity is going to become a challenge. Besides the fact that these test orders have been issued for multiple substances for the exact same endpoint does make it challenging because you've got labs that are being hit by multiple consortia to do these studies, but then you also have regimes all over the world right now that are requiring data to be generated as well. Labs are definitely being inundated with requests for testing, and so it has been challenging to find laboratories with capacity in the timeframes in order to meet the deadlines that EPA has requested.

LLB: Not surprising. One point that I neglected to mention a bit ago is what do you do if not everyone wants to play ball, as it were? If a chemical producer or processor that is the subject of a test order simply declines to respond at all, what are the consequences? Does the consortium do anything different, or do you just allow EPA to respond to a test order that is not timely being addressed?

HJB: I think it's probably the latter. We do not have all of the -- in the test order consortium that I mentioned earlier, there are a couple of processors that are not members of the consortium. They declined to become members. Therefore, they're not able to share in the cost, obviously, of the work that's being done by the consortium. They would not be subject to

the *in vitro* dermal absorption study. But let's say, for example, one of the manufacturers or importers declined to join the consortium. There is a provision in the test order that says if you're not going to generate the data, but you wish to rely upon data that's being generated or is already available from another party, you're required to seek that person out, seek that entity out, and compensate them for whatever the study or the data are that you're relying upon. EPA doesn't give them a free pass, just because they choose not to join a consortium. They're still required to compensate if they rely on other people's data.

LLB: Which invites a whole different round of commercial challenges, like, if somebody doesn't cite your data and offer to pay for them, presumably the data owner, that would be the consortium, can go after the entity that is relying upon your data and force some sort of data compensation, correct?

HJB: Right. Yes. Now the processors were only subject to the exposure studies. In that case, I suppose it's conceivable maybe a processor could rely on another processor's exposure data if they had really similar manufacturing operations, but for the most part, it's probably less problematic when a processor opts out, as opposed to a manufacturer or importer, that has to do a laboratory study, like an *in vitro* dermal absorption study.

LLB: Let me ask a question of both of you. The legislative process is necessarily imperfect and cannot envision all possible scenarios. To some extent, legislation is aspirational. It's trying to fix a problem in ways that conceptually seem to make sense, but when things play out in the real world, maybe things could have been done differently. If you were in the room when Lautenberg was being negotiated, knowing what you know now, would you have done anything differently? Rich, you want to go first?

REE: I don't know. I think this is -- this round, I think it's more EPA figuring out how it's going to exercise its test order authority. I'm hoping that the lessons it learns from the current round EPA will apply to the second half of the next 20, and hopefully those test order discussions that will start with a discussion with the consortia to talk about what are -- I mean, I guess my view is EPA used this round to say effectively, "These are the data gaps that we're struggling with, and we need to know more about dermal exposure and dermal absorption and inhalation exposure. All you manufacturers and processors, do this testing. Because of the very compressed timeline that they got, EPA basically just figured out what protocols to point to and issued those as orders, which EPA appears to have the authority to do. They identify a data gap, and they issue an order.

But to make it more efficient -- because what we're doing now is a lot of discussion for specific particular circumstances. I think it would have been more efficient to have those discussions before the orders were issued, to talk about data availability, or some of the circumstances that we're facing in terms of these members saying, "That doesn't really apply to us because we don't ever get dermally exposed," to have those discussions so that EPA has a better picture of where the data gaps might be and tailor the orders to those. I don't know that for the Section 4 -- I don't know right now that I have enough information to say, "Oh, Congress should have done *X*." I think at this point, it's like, let's see if industry can work with EPA to identify better what the data gaps and data needs are and talk about ways to address those. And then, whether it's an order or an enforceable consent agreement, or whatever it is, but get the data to EPA that EPA needs.

HJB: I think Rich's points are spot on, but ultimately, I think some of this -- because we've spent a bit of time talking about timelines -- to some extent, goes back to the timelines that are associated with the risk evaluations. And I appreciate that there's a desire to not waste time

and to get this done, because we have so many existing substances we need to get through, and so forth and so on. But I think we're seeing that the timelines that were built into Lautenberg to get these risk evaluations completed perhaps need to be revisited because the things that Rich is talking about are very good things.

It's sort of pay me now or pay me later. We could have the conversation on the front end, before you issue the test order, or we can enter into this debate all during this time that we're all under these time pressures to get all this work done. And it's not just time pressures on industry. It's time pressures on EPA. And so perhaps it's readjusting those timeframes so that it isn't as compressed and there is time to have purposeful, meaningful, productive discussions that result in, hopefully, a better outcome and a risk evaluation that reflects reality.

That one's probably a big one, readjusting all the timelines around Lautenberg, but it has a ripple effect on all these other pieces and moving parts within TSCA.

LLB: That's a great segue into the next question, which is recognizing that we all have a pretty good sense of what chemicals are going to be the subject of high-priority risk evaluations. The workplan chemicals. We've got ten down; another 20 have been identified and are in varying stages of that process. But recognizing what we've been talking about and how EPA operates and what its new testing authority is, what parting words of advice to industrial chemical manufacturers and others in the chemical community -- what might you suggest they do right now, recognizing what we know and where EPA is likely to head with respect to data development?

HJB: Well, for sure, these high-priority substances that are -- we hear that there are going to be more test orders coming soon for the remaining substances. I think, first of all, if you haven't formed a consortium, you probably ought to give some pretty serious consideration to that. But probably more importantly is pull out the test orders that have been issued already and start reading through those, because that's probably going to give you a good sense of maybe not the specific endpoints, but how this whole process is going to play out. Start thinking about what will be your initial response to that test order.

There are options. There's an option in there, for example, to certify that you're going to cease to manufacture the substance within 90 days of the issuance of the test order. Is that a practical option that your business wishes to consider? Maybe it is, but that's still not a trivial decision. It takes time to get all your ducks lined up and to be able to actually certify you're going to not manufacture something. If that's a possibility, you should start to explore what those responses are that your business might have *to* the test order. Start identifying -- you can figure out who's going to receive those test orders by looking at the fee payer list. You look at who else is on the hook for the risk evaluation fee; they're for sure going to receive that test order and probably some downstream processors as well. You have some idea of who the other parties are, and you can start thinking about that. But I think forming a consortium early is definitely the right move.

LLB: Yes. Rich, any thoughts?

REE: Yes. I actually want to echo Heather's point about forming the consortium early. Forming the consortium is a relatively low effort, just to put the consortium in place. That should probably happen during the prioritization, as soon as EPA announces prioritization, or if they start to take comment on whether or not a particular substance is going to be prioritized. I would form the consortium then, so that the consortium is -- I think it's going

to be very unlikely that EPA nominates something for high priority and it ends up *not* being a high priority, at least for -- we've got another 50-odd chemicals on the workplan list. Those are certainly going to come through high priority, at some point.

Once EPA starts wrapping up the first ten, or I guess it's not until they start to wrap up one of the next 20, but the next time EPA prioritizes, it's very likely that whatever it is is going to come out of the workplan list. I would form then. It doesn't have to be a heavy lift, but identify who's who, spend a little bit of time and effort to set up the consortium and then use that as a vehicle to respond to the scoping, to start identifying the potential data gaps that EPA may be looking to fill. Be ready to talk to EPA about those data gaps and how to fill them. Then if it turns out that the consortium's not really needed, then you can lay it down. The consortium doesn't have to be a big, ongoing expense if there is not the ongoing common need.

I just want to go back to Heather's point about phaseout. If you are looking to potentially phase out something and you look at that workplan list and you say, "Oh, this substance is in our supply chain and maybe we need to get out of this business." If you get out early enough, you can avoid the risk evaluation fee in addition to the orders, but you have to be out of the business in advance of the prioritization to avoid the risk evaluation fee. You might want to take a serious look at the next 50-odd substances that are on the list if that's going to be an option. As Heather points out, it's not a nontrivial exercise to go from saying, "Hey, do we really need substance *X*?" to actually getting out of that business. That may take a while, and thinking ahead is a good idea.

LLB: You both raised a lot of very good suggestions and have given our listeners lots to think about. Are there places that you can direct listeners to to get more information about Section 4 testing, options for forming a consortium? What are the considerations as to whether or not you should even be the recipient of a test order, and so on and so forth? Where can listeners go to get more information?

HJB: EPA's website actually is pretty good. They have an entire page that's dedicated to test orders and shows a whole list of substances that currently have test orders. You can go through there and look at all those and view any test orders that you wish to look at. And there's really some good links on there to read more information about what's involved in a test order, and you can get access to the regulations and that sort of thing. And then of course, there's the Bergeson & Campbell website or the BCCM website, as well, to give you some information about forming consortia.

REE: And there's the 2014 workplan chemical list, which is still up on EPA's website. That's the crystal ball for what's coming next.

LLB: Exactly. Well, Heather, Rich, thanks so much for a very engaging discussion on a topic that will continue to be front and center in the industrial chemical community for years to come: Section 4 testing. Thanks so much for being with us today.

REE: It's always a pleasure.

HJB: Thank you.

LLB: My thanks again to Heather Blankinship and Rich Engler for speaking with me today about the new normal of industrial chemical testing and why organizing competitors around satisfying a shared regulatory burden is not as straightforward as you may think.

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