



Episode Title: Changes to TSCA for Small Businesses? — A Conversation with Bruce Jarnot, Ph.D.

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

This week, I sat down with Dr. Bruce Jarnot, Senior Manager of Product Compliance with Assent Compliance. Bruce is a board-certified industrial toxicologist with much experience assisting businesses with chemical product compliance. I have known Bruce for many years, but over the past several months, Bruce and I have spoken often about the U.S. Environmental Protection Agency's (EPA) implementation of the Toxic Substances Control Act (TSCA) and certain new rules that apply to manufacturers of finished goods called articles under TSCA. Several rules issued in 2021 specifically apply to importers of finished goods, downstream entities, and small businesses historically exempt from TSCA reporting requirements. We discuss these rules, their commercial impacts, and speculate on whether these broad reporting requirements are the new normal under new TSCA. Now here is my conversation with Bruce Jarnot.

Bruce, I am so thrilled that you're here with us today recording this podcast on a topic of enormous interest to our respective clients. Let's begin with some of these reporting obligations that have been causing so much fuss over the last six, seven months. As you and I have discussed many times, EPA is under a lot of pressure to implement the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) timely and as Congress intended. I think most of us absolutely, positively knew that the regulation of chemicals of concern was going to be a priority, and is a priority. What is less clear to me -- and I'm wanting your thoughts on this -- is whether the regulation of chemicals in articles, you know, finished goods, was as predictable. What are the commercial implications of the application of TSCA to articles, and what are your thoughts generally about the state of the commercial community and its, quote unquote, "TSCA readiness" in this regard?

Bruce Jarnot (BJ): That's a great question, Lynn. "TSCA readiness" -- I don't think I would use that as a real term because industry is not ready for TSCA. I think you mentioned in a

presentation to the Retail Industry Leadership Association that this is not what you think. Industry is accustomed to having TSCA affect the very bottom of the supply chain. This is the chemical manufacturers and the importers. But finished articles. Look. TSCA Section 6, and its restriction of substances, it has been so seldom used in the past 45 years since TSCA was implemented, you know, lead in paint and mercury and consumer goods like glass thermometers that we used back in the day. Industry is just not accustomed to federal-level regulations like Europe has become since REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) was implemented in 2007. It took a while for Europe to get its feet under it and understand the requirements and so forth. That's where we are right now. We're back in 2007. Industry didn't see this coming. Yes, they should have, but industry did not see this coming because we're just not accustomed to seeing regulation at the federal level that impacts articles and finished products the way that these new TSCA rules do that came out on January 6.

LLB: Well, that's a great point, because that January 6 rule continues to cause all kinds of chaos. And just to update our listeners, EPA issued a final rule on that fateful January 6 day, imposing a hard stop on the import of certain articles containing a widely used plasticizer and flame retardant called PIP (3:1), or phenol, isopropylated phosphate (3:1). This retardant is used in a lot of electric and electronic device products, basically anything you plug into the wall. So maybe you could take us back to just before the March 8 compliance date. I know virtually all of our TSCA clients were really biting their fingernails for a whole bunch of reasons. But maybe you can tell our listeners what was going on in your world.

BJ: Well, going back a little further, even to January 6, when these rules came out, industry was caught completely flat-footed, and by industry, I mean all of the trade associations, from IPC for the electronics folks, the National Association of Manufacturers, Outdoor Power Equipment, the entire gamut. All these new rules come out speaking to articles, and [they] were floored. There was quite a bit of running around with hair on fire, hands in the air, and just tons of comments being submitted to EPA at that time. And EPA said, "Wait a minute. We came out with a proposed rule in 2019." And everybody said, "Well, we didn't notice that."

LLB: A little bit of fault on both sides.

BJ: Yes. Again, just because industry wasn't looking at TSCA Section 6, this was -- it had been five years since Lautenberg. Lautenberg was a big deal in 2016, when it came out. But five years later, everybody had -- at the finished product level in industry -- had forgotten about it, and the requirements, and the risk-based chemical assessments, and all of that. So when these rules came out, it was pretty much hitting a telephone pole for industry. It woke everybody up, and then people began researching a bit more and understood. "Wait a minute. This isn't a one and done. This is going to be a big deal rolling forward. Oh, wait. There's impact not only in our finished products, but on our operations as well." Yes, sending in tons of information. And look, PIP (3:1) is perhaps the most important flame retardant that's used to meet government-mandated electrical safety requirements and flame retardancy requirements. If you see a UL (Underwriters Laboratories) tag on the back of your refrigerator power cord, that's what it's all about. It's about containing PIP for that electrical safety and for the flame retardancy. It might even be your laptop power supply. You see that UL marking on there; it's about safety.

And industry had relied on PIP now because industry thought they were doing the right thing and moving away from halogenated flame retardants. And by and large, we have moved away from things that contain chlorine and fluorine and bromine as flame retardants

and look like a phosphate ester. PIP was a safe bet to go to, and as you say, plasticizer? Yes, it's found in virtually all vinyl insulation on wires. It's found in thermoplastics that are injection molded for switch bodies and fan boxes and any kind of a plastic case that's used, again, for flame retardancy, so this is hugely impactful.

LLB: I'm guessing, Bruce, given everything that happened when the final rule was issued and the compliance date rolled around and everybody, as you suggest, ran around with their hair on fire, EPA wisely did issue one of these very rare, very rarely issued No Action Assurance [NAA] letters where the compliance folks at EPA say, "All right already, we get it. We're not going to enforce the provisions set out in the final rule." That thing lapses on September 4 at 11:59. We're continuing to see a lot of challenges in the regulated community occasioned by the PIP rule in particular, and recall for our listeners' benefit, there were actually five PBTs (persistent, bioaccumulative, and toxic chemicals), PIP being one of them, that are implicated by the final rule. What are you telling your clients about September 4, and what might EPA do, recognizing the ubiquity of PIP and the very important functionalities that it imparts in a lot of electric and electronic devices, and the availability of substitutes, and qualifying for UL standards? I mean, that all takes time.

BJ: It does indeed take time. And that's, I think, the biggest issue for industry right now, is getting more time to adapt to these changes. Industry understands -- well, those that are aware of the rule -- and that's a big deal still, that many players in the industry domestically here in the U.S. aren't aware of this even yet. The requirement to change over is absolutely going to take time. So first off, for those companies that are keeping up to speed, a lot of industry doesn't have internal legal counsel or doesn't have internal compliance folks. They've got procurement people that are gathering. They're looking to the low-cost vendor. They're not thinking about regulations, even something like California Prop [Proposition] 65. Still, we find people that are unaware of that, since 1986. So these new ones from January, we're still finding many players are unaware. But for those that *are* aware, they first have to find out where these substances, the five persistent, bioaccumulative, and toxic PBTs, *are* in the -- not only in the products that they make, but also in the materials that they use operationally, even things like hydraulic fluid, that are treated with PIP to be flame retardant because if you ever see a leak in a hydraulic system, it creates a cloud of aerosol, and you can't have that flammable.

So there's going to be impacts. And again, I'm going to make the analogy back to REACH in Europe. When REACH came into force on June 1, 2007, this totally upset the applecart in industry in Europe. We're seeing basically the same thing here, where it's going to take several years to get industry to become acclimated to TSCA Section 6 being a big deal and new chemicals being restricted in certain uses. Right now, industry is collecting data to find out where things are. And as you mentioned, Lynn, finding out where, what are the alternates, talking with their suppliers. "Right. PIP's out. What can we use, and what's not going to be an unfortunate alternate, an unfortunate selection that's going to be restricted further down the line?" So, yes, they're trying to identify what's a good choice.

LLB: I'm not an expert in qualification scenarios, but I would imagine that entities like UL and other certification organizations have a say in what is and is not suitable for a particular application to impart flame retardancy properties, for example, and that process often takes a bit, so I'm --

BJ: Exactly.

LLB: My guess is that Dr. Freedhoff, being the exceedingly astute TSCA expert she is, is listening carefully to regulated entities and probably considering either pushing out the compliance date or providing some renewed exemptions from some of these requirements to accommodate some of these supply chain challenges, because you can't qualify a new material if you're lucky enough to be able to isolate it in a product that you are procuring from others that are dealing with other suppliers upstream of them. You just can't do that in a short period of time. And although the NAA was intended to last for 180 days, which is great, it's probably not sufficient for a lot of these products.

BJ: No, exactly, and that's why industry did run around with its hair on fire, because the original 60-day accommodation -- Look, when we manufacture products, when industry manufactures products, oftentimes when you tool up for a new product, you might put inventory for three to five years' worth of whatever may be in a warehouse. And then you switch over to making another product, and you put another three to five years' worth of that product in, just because of the cost and time that it takes to set up a manufacturing line for a particular style, a particular attachment or accessory.

So industry has all this product on their shelves in warehouses. They do need to find, first off, an alternate material. If you look at something like PIP, it's not used as a pinch of pixie dust. It's three to ten percent in something to provide that flame retardancy, or plasticity, flexibility in a vinyl wire. And when you change three to ten percent of a chemical out of a formulation, you know it's not only going to impact that flame retardancy, but it might affect durability or even something minor, like aesthetics. So there's going to be a lot of testing required, first to meet the industry standards for, again, electrical safety, flame retardancy. But then, well, how is my product going to do? Am I still going to achieve the same life expectancy of my product? And so the original 60 days wasn't time enough. And through September, industry is seeing that as EPA is affording itself that time to come up with extensions and exemptions like they did for the aerospace industry and the automotive industry, giving, I don't know, decabromodiphenyl ether (decaBDE) until 2024 in airframes, giving automotive replacement parts until 2036 for PIP. That kind of timeline is what we need for all of these substances across the board. I think that's what industry is hopeful for, that there's going to be somewhere, three, five, seven, ten maybe years to make the transition. It's like, "All right. We know things are going to happen. We want to comply with EPA's rules, but please give us the time to do this because we were napping. We weren't paying attention to TSCA."

You know, this is not a normal TSCA rule. This is -- again, everybody's expecting things to be like the chlorofluorocarbons were. It's being impacted upstream, and it's the raw chemical manufacturers and importers. And there's going to be something like a SNAP (Significant New Alternatives Policy) program to transition from the chlorofluorocarbons to the hydrofluorocarbons, et cetera. It's going to be a phased-in process. We can work with that. But just saying you can't use this material anymore, it would shut down U.S. industry completely, just because these are so ubiquitous, the first five PBTs, especially PIP, as you mentioned.

LLB: Let's pivot to another related issue that is likely to induce migraine headaches for regulated entities, and that's the [fiscal year] FY 2020 National Defense Authorization Act, or NDAA. It added, interestingly, a legislative vehicle entirely unrelated to TSCA -- added a new section to TSCA, Section 8(a)(7), requiring EPA to promulgate, and I'm quoting here, a rule "requiring each person who has manufactured a chemical substance that is a [PFAS (or pre- or polyfluoroalkyl substance)] in any year since January 1, 2011," end quote, to report certain information to EPA. Now I want our listeners to focus on the 2011 part. I think

everyone recognizes that was ten years ago. But EPA announced a proposed rule just a week or so ago, on June 10, that would require all manufacturers, including importers of PFAS, in any year since 2011, to report the categories of information set out in the proposed rule. And for those of us familiar with TSCA Section 8(a) reporting obligations, we appreciate that's chemical identity, categories of use, volumes, so on, and so forth. But what is very, very, very interesting about this particular proposed rule is that it does not exempt the categories of regulated entities that historically have been exempt, including manufacturers of the chemical substances embedded in articles and importantly, small businesses. So I'm going to stop there, Bruce, and take your temperature on that soon-to-be-published in the *Federal Register*, coming to newsstands near you, this new reporting obligation, which is even more awesome in its application than I think the PIP rule.

BJ: I agree with you, Lynn. The PFAS -- first, you're talking about a category of substances: per- and polyfluoroalkyl substances that -- thousands of substances fall into that. All these short-chain or what are called fluorotelomers, oligomers, small fluorocarbons that are present either intentionally manufactured, as we still find in cosmetics, we find in firefighting foams, we find in surface treatments in stain repellents, things that are repelling not only water but oil. And they do a great job at that. So things that you find on outdoor boots or clothing that might be used in a workplace or just rainwear. You still find these PFAS substances being intentionally used for that. But then you have the incidental content of residual monomers. These materials -- used to be PFOA, perfluorooctanoic acid that was used to make Teflon or other PTFE, polytetrafluoroethylene polymers. So we're talking about fluoropolymers, the nice slick things that we're accustomed to in our fry pans, but also fluoropolymers like ePTFE, expanded polytetrafluoroethylene, that are substances like GORE-TEX fabric, where -- GORE-TEX is a brand name; Teflon is a brand name, but just as an example. So it's GORE-TEX in your rainwear. It's GORE-TEX material that's in your automotive fuel sensor, the oxygen sensor in your fuel. So it's tremendously impactful also.

And as those compounds were manufactured not only by their U.S. entities, like Chemours in the spin-off from DuPont, that is making one called GenX, which is a big deal. It's -- basically, it's a monomer. How do you make a polymer? You take little short things, and you stack them together, or you click them together like Legos, and you make a large polymer. Well, in 2009, DuPont switched from PFOA, which was already looked at with a kind of a negative attitude. They said, "All right. We're going to go to this more sustainable GenX, which is a hexafluoropropylene oxide dimer acid mouthful." And --

LLB: It is.

BJ: Well, no, that's still a PFAS. That's still one of the bad things. So it's going to be impactful for those materials that are intentionally made, again, in things like cosmetics, like lip gloss and foundation, mascara. It's used on food wrappers to keep grease from dripping through. It's still prevalent, but it's also polluting drinking water and blood tests. It's bioaccumulative and toxic, just like the PBTs are. These are the same way. They're extremely persistent. The fluorocarbons do not degrade in the environment. And so they persist. They accumulate in our bodies. We've been exposed to them from fast food wrappers and cosmetics. And again, the runoff from the manufacturing plants. Folks in North Carolina have been extremely attuned to what Chemours is putting into their water. So I think the rules are required. These need to be reined in. But you're right: this is going to be impactful for substances that are intentionally used, the fluorotelomers or these PFAS substances that are intentionally used, but also those trace monomers that are still in the polymers that we use and we think of as being inert and safe, yet it's a polymer, whether it's

a pan coating or some kind of a glide or whatever it may be. Those are inert, but they still contain significant amounts of monomer. And that's the problem.

LLB: Yes, I see a number of very challenging issues here with regard to this PFAS reporting proposal. And it's important for our listeners to appreciate that we're not talking a final rule here. We're talking a proposed rule that hasn't even been published in the *Federal Register* as of this recording, but probably will be by the time this is broadcast.

I also wanted to focus on not just the class of entities that are likely to be included in the -- certainly in the proposal, but probably in the final rule, that is, manufacturers of articles that are imported into the United States for distribution in the United States and importantly, small businesses, because PFAS is a problem. EPA has been focused on this for literally years now. The ubiquity of the dissemination of PFAS substances is a real concern. And so the reporting rule reflects EPA's interest in obtaining as much information as possible because this is a one and done. This is not a recurring obligation like Chemical Data Reporting. This is a one-time reporting obligation, but it's also important for our listeners to understand what standard applies with regard to whether you know or not a PFAS is in an article. The proposed rule states that it needs to be "known to or reasonably ascertainable by." That is the standard that would define the type of information that must be reported. And it includes all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know. Then one final aspect that is in the preamble discussion of the proposed rule, the standard would require that submitters conduct a reasonable inquiry within the full scope of their organization, not just the information known to managerial or supervisory employees.

So there are some subtle issues here. And I know as advocates for our clients, Bruce, we will be urging our clients to read this proposed rule carefully because there are some subtle differences with regard to the scope of the reporting obligation and how this reasonable person standard is interpreted. It's not just the reasonableness of the person complying with the information. The inquiry goes to the scope of the full organization, which, again, these are issues that reasonable people can speculate and talk about for hours. But it will be really important to know what this rule is contemplating and comment on the practical aspects of complying with it. Agree?

BJ: Agreed. And I think we may have a better ability to grasp this because -- and correct me if I'm wrong, Lynn. I see this impacting mostly the upstream players, the manufacturers, the importers of raw substances that are going to, downstream, be formulated into things like cosmetics or firefighting foams or whatever. But those upstream players typically have in-house legal counsel that read things carefully and have compliance teams that are more robust than small businesses. And you mentioned that this impacts small business as well, and that's absolutely an incredibly important piece.

But the big manufacturers and importers, the suppliers, I think, are going to be most impacted by this, or at least most paying attention to this and providing the most material information to EPA. But the key phrase in there about a reasonable expectation that a substance occurs is, I think, perhaps most important for those fluoropolymers, things like Teflon and other types of PTFE and other fluoropolymers, that, hey, these are still going to be trace contaminants. They're reasonably expected to contain this. Folks that make breathable membranes that are fluoropolymers are going to know, I would expect, that they need to comply with this. The smaller downstream folks, or sorry, smaller upstream folks that do not have, again, in-house counsel or compliance members perhaps aren't going to read down in the weeds of this rule, I think. And that's going to be a problem, but perhaps

not as much as the PBT rules. That's just my expectation that since this does seem to target more the upstream, the big chemical manufacturers, the folks that are supplying customers that are then formulating these materials into the products, it may be most impacted at that level.

LLB: Do you think, at some level, Bruce, the PBT, PIP experience has served as a suitable kind of heads-up, and maybe nontraditional chemical stakeholders, at least with regard to TSCA reporting obligations, might be a little better prepared to be considering how they might be implicated by the new PFAS proposal, and certainly by the time any final rule is issued, maybe the sensitivity regarding who's in, who's out, who has to report, who doesn't might be clearer a year from now? You think?

BJ: I do. I do, and you make a great point, Lynn, in that the PBT rule was a wake-up call across industry. That was, "Hey, we've been asleep at the wheel when it comes to federal regulation of chemical substances at the article level." And the PFAS rule affects the article level also. The wake-up call indeed has industry looking closer, and I mean industry, the individual companies, and the trade associations, and the trade association council, and the regulatory folks that are on the staff of that trade association paying much more attention to TSCA. So overall, it was a good thing to get better alignment with industry. It poked industry in the shoulder and said, "Hey, over here."

LLB: Big time. Right. There are a couple of other facets of this business conundrum that I think are worth mentioning here. That a chemical substance is being reviewed by EPA and is the subject of intense regulatory scrutiny, and with regard to PFAS, that's being reviewed by regulatory bodies globally, right? So in addition to the prospect of potential noncompliance with respect to these reporting obligations, that's an incentive to be much more mindful of what these rules mean and trying to discern whether or not they apply to my organization. But more broadly, as a supply chain expert, Bruce, I'm guessing that many of your clients are just being much more sensitive to the products that they procure and are being much more attentive to asking about what's in the finished good that they may be transacting either as a further processor or a distributor of that product. Because even if there aren't regulatory obligations, there's a certain sensitivity with regard to the inclusion of products that contain chemicals of concern that are broadly scrutinized and perhaps consideration to deselect or to find an alternative so they can just get out from under these reporting obligations. You think?

BJ: Absolutely. But let's take the example of PFAS for a moment. Industry has been looking to what's called a full material declaration widely. "Tell me what's in the product that you supply me. Dear supplier, tell me what's in here." So if a supplier said, "Oh, it's 100 percent Teflon," they may -- and I'm just using that brand as an example. They may not disclose that it has GenX because they don't know that. They don't know that, oh, in Europe, these PFAS -- or at least PFOA, the old PFAS -- is regulated now to 25 parts per billion. Those levels are not going to occur to a supplier to declare. It's trace contamination. "We know that we buy this fluoropolymer and we sell it, and it's 100 percent Teflon. This part that I sell you, it's a Teflon screw. It's a Teflon washer. Period." They're not thinking about what might be the trace material that's still in there residual from the polymerization process.

On the other hand, if you're using PFAS intentionally as an ingredient in, say, a cosmetic, that's going to be more easily understood, I think. Or you're using it as a coating on a food wrapper. That's going to be more easily understood. It's the trace amounts; that is going to be more problematic. But yes, industry, you're right. To your original point, Lynn, industry has become much more attuned to sustainability, and understanding what its supply chain is

delivering to their company, and gathering, trying to gather that data not just on the regulated substances, but on the more holistic bag of substances that come in from each supplier, and understanding how those might be either regulated in the future or how they might want to deselect.

One of them is over in Europe, you cannot use hexavalent chromium. It's a carcinogen. Here in the [United States], we still can. It provides better rust protection than trivalent chromium. And so the [United States] has been using hexachrome for many applications that are not restricted under TSCA or not regulated. Sure, it needs to be declared on Prop 65, but not a big deal. I think that at least in larger companies we've seen that switch. This is more -- industry has become more attuned to that and saying, "Look, let's not have so many different items procured that this is okay in this market, but not okay in that market." Europe has done a great job of leading the way with REACH and getting us, driving away from bad things.

LLB: And just harmonizing product specifications in a way that discourages the need to be so mindful of what is and is not permissible for purposes of export/import. If you're a very, very large company, you may have the means and the wherewithal to be mindful of jurisdictional limits that are nonconforming and nonconsistent. But if you're making a product and want to market it in as many places as possible, you're going to be aligning your product specs to the most stringent of the product specifications around, which will have the tendency of deselecting chemicals that may be permissible here but are disallowed elsewhere, as you suggest, Bruce, most particularly in Europe, the European Union under REACH.

BJ: You make a great point. "Harmonized" would be perhaps the biggest word that industry would love to hear from regulators. Let's make, not only the [United States] and Canada, which do a great job harmonizing, but the [United States] and Europe, the [United States] and Asia, Asia North, Asia South. Let's make things harmonize so we can make one product and sell it anywhere regardless. But oftentimes in supply chains, cost is still a driver. And low cost, if we can buy something low cost and sell it in one place, that's a driver to have two supply chains. This one we can sell over there because it's less expensive, versus this one over here. So there's still a bit of incentive for industry to have dual sourcing, two product lines because we can sell this one here, that one there. If the regulations were more harmonized, that would be ideal. And I really like the fact that TSCA is getting its feet under it again because the federal preemption, or having a federal guidance rather than multiple state laws, as were coming out before Lautenberg, makes it very difficult for industry to operate within the [United States]. Maybe I'm going too far afield here, but just looking at a company that manufactures a product for sale in the [United States], how do you logistically keep this product out of California, for example, or how do you keep that product out of Washington State, if it contains a particular flame retardant and it's an upholstered product?

LLB: Those are challenges that product manufacturers think about all the time. Bruce, I'm going to conclude our discussion pretty much starting where we started, and that is, in my view -- and I think you agree -- article manufacturers seem increasingly to need to know the identity, the full material declaration that you mentioned of every chemical component in the products they purchase and sell. I don't see this trend going away. What do you think people listening to this podcast, your clients and anybody else who is listening up, should be doing right now to avert the kind of train wrecks that we saw earlier this year and that I see piling up on the regulatory Beltway there in light of the proposed PFAS rule? What are you encouraging folks to do right now?

BJ: I think it comes back to what you said earlier, Lynn, and that is, understand the substances that are in materials, parts, products that you buy from your suppliers, whether it's a full material declaration or at least some insight into the composition of the materials that you buy from your upstream suppliers. To be able to then have that information when something comes out like it did on January 6 or with the new PFAS proposal that you can wrap your mind and your arms around it a little easier.

LLB: Bruce, you are the font of so much wisdom when it comes to supply chain issues like this. Your distinguished career being an industrial toxicologist has served you well. And you've got the best radio voice I've ever heard.

BJ: Thanks.

LLB: Where can our listeners obtain more information on you and the services Assent Compliance offers?

BJ: Assent basically helps collect that supply chain information that we're talking about today, gathering the chemical level information, whether it's full material disclosure or a declaration that you have or don't have particular PBTs that are restricted under TSCA. They can go to assentcompliance.com. It's one word: assentcompliance.com.

LLB: Excellent. Bruce, thank you so much. Learned a lot. You're great at what you do, and really enjoyed being with you today.

BJ: Thank you very much for the invite, Lynn.

LLB: Thanks again to Bruce Jarnot for speaking with me today about new TSCA reporting requirements applicable to nontraditional chemical stakeholders, the commercial chaos these obligations are causing, and what businesses should be doing right now to prepare for what could be the new normal.

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