Episode Title: Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA -- A Conversation with Richard E. Engler, Ph.D., and Kelly N. Garson

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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'm Lynn Bergeson.

This week, I discuss with my colleagues -- Dr. Rich Engler, our Director of Chemistry at B&C and The Acta Group (Acta®), our consulting affiliate, and Kelly Garson, Senior Associate at B&C and Acta -- our recently released book titled *Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA*, published by the American Bar Association. As listeners know, as a law firm and a consulting firm, we do a ton of work under TSCA [the Toxic Substances Control Act] and have gained a significant amount of hands-on practical knowledge about the law, the 26 Lautenberg amendments to it, and the truly transformative impact these amendments have had on business transactions.

We set out a year or so ago to write a book that explains TSCA through a business transaction lens. Of course, we explain the law in the book, but we really write as business counselors to enable the regulated community -- importers, chemical producers, finished product manufacturers, distributors, and chemical users -- to be TSCA aware. The law has become, whether you like it or not, an important factor in virtually every business decision. My conversation today with Kelly and Rich focuses on several of their chapters in the book, and they explain how they approached writing a book about a law from the perspective of the business community. Now, here is my conversation with Rich Engler and Kelly Garson.

Kelly and Rich, it is terrific that we're able to get together today to talk about our new book, *Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA*. I know I'm super excited and look forward to hearing your thoughts on the book and your contributions to it.

Kelly N. Garson (KNG): Hi, everyone.

Richard E. Engler (REE): It's always a pleasure to be here, Lynn.

LLB: Kelly, let's start with you. Maybe you could give our listeners some background on your legal practice, especially as it relates to TSCA, but you do so much for the firm, both in other substantive areas of the law and litigation. Tell our listeners about yourself.

KNG: I am a Senior Associate with B&C and Acta, and I've been with the firm for about five years now, having joined after graduating from law school. Within that time, I've had the opportunity to work on a tremendous variety of issues and specifically under TSCA, that has ranged from assisting clients in responding to TSCA Section 4 test orders, assisting with compliance with TSCA Section 8 reporting requirements, and has also included working on TSCA Section 19 petitions for review before the U.S. Courts of Appeals. So beginning to work with B&C's TSCA practice group within the first few years after the 2016 Lautenberg amendments provided a really exciting opportunity to assist clients when navigating changes and new requirements under amended TSCA.

LLB: Terrific. And, looking back at when you joined the firm, it was at a very pivotal time of the transformation of TSCA from old TSCA to Lautenberg and the U.S. Environmental Protection Agency's [EPA] implementation of it. You're very modest, Kelly. You do so much for the firm, and you have quickly adapted to our brand, which is to provide meaningful advice and hands-on practical information to clients when dealing with some of these very complicated TSCA issues.

Rich, I know our listeners are much more familiar with you and your practice, but in case anyone is new to the podcast for the first time, perhaps you could tell our listeners about your background at EPA and what you've been doing for the firm the last decade.

REE: Sure. I was a chemist in the Office of Pollution Prevention and Toxics [OPPT] for 17 years, and my main responsibility there was reviewing new chemicals under TSCA. I estimate that I participated in many thousands of new chemical reviews, premanufacture notices [PMN], low volume exemptions [LVE], and other submission types. I also led the Green Chemistry Program for about a dozen of my years there.

Since joining B&C and Acta, I have assisted clients with chemistry issues across all our practice areas, and assisted clients with hundreds of new chemical notices against PMNs, LVEs, LVE mods, and many existing chemical issues. I also helped clients develop their own standard operating procedures [SOP] for document compliance with TSCA and then assist with responding to EPA inspections. And I support all of our TSCA consortia, New Chemicals, Existing Chemicals consortia. And I also help -- and particularly I find it very stimulating to help -- with the complex questions related to whether a product is regulated under TSCA or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), or the Federal Food, Drug, and Cosmetic Act (FFDCA), or some combination of the three.

LLB: When we, as a firm, decided to undertake this project, we, I think, all appreciated that our first American Bar Association book on Lautenberg published in 2017, not long after the law was actually enacted, entitled *New TSCA: A Guide to the Lautenberg Chemical Safety Act*, really needed updating. The book continues to be an excellent resource for an actual understanding of the law as Lautenberg changed TSCA. But because EPA had yet to implement the Lautenberg amendments when we wrote it, the book necessarily does not reflect the extraordinary, both frustrating and important, policy shifts that we have witnessed over the almost nine years since 2016, and now four administrations later. Rich, maybe you

can take a shot at providing our listeners with a very brief overview of the Obama, Trump, Biden, Trump policy shifts as they relate to core TSCA concepts.

REE: Yes, probably the two most significant policy changes from the first Trump Administration to the Biden Administration relate to assumptions about protection in the workplace, and also the whole-chemical, or single determination approach, two terms that are that are used relatively interchangeably. I think formally it's called the single determination approach. TSCA is clear that workers are to be considered as a potentially exposed or susceptible subpopulation. EPA *must* consider workers in its evaluation of unreasonable risk. The debate is what assumptions about workplace protections are appropriate if EPA *does* find potential risk in a workplace and what actions EPA *must* take.

So in my view, it is appropriate for EPA to evaluate exposures with and without workplace protections, such as engineering, administrative controls, and personal protective equipment, or PPE. But if EPA identifies potential work in a workplace, EPA should then consider whether protective measures are already required under OSHA [Occupational Safety and Health Administration], and if so, are those measures sufficient to protect workers? But in June 2021, Dr. Freedhoff announced that EPA's policy was to assume that protective measures are *not* always used, but what that meant in a practical sense is that EPA assumed that workplace protections are *never* used -- which is a very different interpretation, but from a practical standpoint, that's what the policy meant.

That relates to the whole-chemical, or single determination, approach. That is also an issue that's under vigorous debate and the subject of current litigation. The question there is when EPA makes a determination about unreasonable risk or a chemical, if EPA may, must, or is prohibited from determining that some conditions of use are not an unreasonable risk and other conditions of us are, and then essentially bifurcating and issuing orders saying, "A chemical under these conditions of use is not an unreasonable risk, and under these other conditions of use *are* an unreasonable risk, and therefore those will go forward for risk management." So we've got a bunch of -- all the five risk management rules are being litigated, plus the framework rules being litigated. This single determination approach -- I think we'll see some resolution in the courts in 2025 or 2026.

LLB: We hope so. I know for listeners who may be unfamiliar with TSCA and Lautenberg, these concepts may sound kind of detached from reality and very cerebral, but in the real world, with clients that are subject to TSCA and have business operations, we tried very hard in our book to explain what the impact may be.

And Kelly, this has been very frustrating, with these relentless swings of the policy pendulum between and among the administrations since 2016. But they're not surprising and somewhat predictable, right? How have you gone about counseling clients, recognizing the fluidity of these matters, and recognizing that at the end of the day, clients have businesses, and they need to comply with the law. Because of the fluidity of the law, how have you calibrated your counseling to clients, given the lack of clarity on some of these topics? And then after you finish, Kelly, maybe Rich, you can take a shot at it as well.

KNG: One effect has been that amid several policy shifts, EPA's regulatory actions under TSCA have invited significant litigation, and it has been important for stakeholders to monitor both regulatory developments under TSCA and the outcomes of judicial challenges. There have been significant cases under TSCA that have involved TSCA Section 4 in regard to test orders, TSCA Section 5 in regard to EPA's significant new use rules. And as Rich has mentioned, ongoing and complex litigation under TSCA Section 6, first challenging EPA's

risk determinations and now challenging EPA's risk evaluation procedures and specific risk management rules. This has created some uncertainty for those who may be subject to the requirements under EPA's current risk management rules and for companies seeking to be proactive regarding chemical substances in their supply chains that may soon be slated for evaluation and risk management. Keeping an eye toward these developments stemming from the judicial branch has been a significant part of maintaining an understanding of some of these policy changes.

LLB: Rich?

REE: Yes, I would add that it's been a significant challenge. The whipsawing between one administration to another leads to real uncertainty. And I know business doesn't like uncertainty. It leads an apparent sort of arbitrary decision that some companies face what they view as overly burdensome and unjustified restrictions. Of course, other stakeholders view EPA's action as insufficiently protective. But when you get these different standards between the different administrations, you can get regulatory outcomes that don't align with policies that were implemented previously. These issues cry out for adjudication or clarification from Congress, and I'm hopeful that we'll see some -- certainly some judicial -- decisions that I mentioned earlier, but also maybe some congressional action, this year or next, that can help bring some clarity, both to EPA and to the broader stakeholder community, and to companies that are seeking to do business in the TSCA space.

LLB: I think that increasingly we're hearing from the regulated community that judicial determinations and the litigation pathway tend to be an indeterminate and uncertain pathway forward. That said, having judicial clarity or having clarity from multiple judicial circuits, ultimately heading up to the Supreme Court, may be what is required here, simply because TSCA and the Lautenberg amendments lack specific definitions on key terms. It may well be that the court is going to have to backfill on that. And even if, Rich, to your point, if there is some legislative action in our future, given the opening occasion by the fee reauthorization that lapses in September 2026, that too could be the subject of multiple judicial challenges going forward. At some point, we just need closure, clarity, and specificity on key terms of TSCA, and judicial clarity may be exactly what the doctor ordered here.

Circling back to "Why did we write this book?" This is our second major book on TSCA. The central thesis is that TSCA is no longer the obscure and not well-understood federal law that it used to be. Many of us who practice under old TSCA, or the TSCA law that was enacted in 1976, really appreciate that it was thought to be somewhat arcane and largely relegated to the activities of domestic chemical producers. But over the years, EPA's expansive interpretation of the law makes its understanding by domestic product manufacturers and chemical and product importers, chemical users, distributors, just critically important.

Let me just read one quick excerpt from the introduction of the book to give listeners an understanding of what we're trying to accomplish here. And I quote:

> The goal of this book is to provide those in the business community with an understanding of TSCA so that they can make informed business decisions. Businesspeople throughout today's supply chain -- not merely lawyers and compliance advisors -- need to understand TSCA's growing commercial relevance and application over chemicals and manufactured goods produced both domestically and abroad. TSCA affects business decisions from choice

> of raw materials to whether a manufacturing operation should be located domestically or abroad, what materials and or products can and should be imported, how to assess the compositional elements of a product, and much more. We seek to answer these questions from a business transactions perspective, rather than an academic and overly legalistic perspective.

Now I'm not trying to denigrate lawyers and legal treatises on TSCA, but sometimes they tend not to be approachable or relatable. So here we try very hard to be relatable from a business perspective. So if you pick up the book -- you're a chemical importer, or a domestic article manufacturer, or an importer of articles -- we're really trying to give people a solid understanding of what the heck this law means and what some of these open-ended legal issues are all about, and how does it relate to your business. So with that as background, Kelly, why do you think it's super important today to understand how TSCA imports the supply chain that is so central to business transactions of all sorts today?

KNG: TSCA may apply to companies before, during, and after the chemical substance is introduced into their supply chains, so the significance of understanding what chemicals are present within a company's supply chain -- one example here is further underscored by the PFAS [polyfluoroalkyl substance] reporting requirements established under TSCA Section 8(a)7. For those listeners who may not be familiar with this requirement under TSCA, Congress amended TSCA in 2019 to establish new and expansive reporting and recordkeeping requirements for PFAS specifically, with EPA issuing its final rule to implement those requirements in 2023.

Any person that manufactured or imported PFAS for an immediate or eventual commercial purpose in any quantity, including as part of finished goods or articles, as defined under TSCA, are subject to these reporting requirements. Furthermore, all companies that may be subject to reporting are expected to conduct a due diligence review to determine whether these reporting requirements apply. So for article importers, Section 8(a)7 requirements have introduced a new array of companies to requirements under TSCA. The inclusion of articles in reporting requirements under 8(a)7 reflects a new, increasing emphasis on the composition of articles. There are some limits to TSCA's jurisdiction. As Rich mentioned, this may include, for example, pesticides, and food drugs, and medical devices that fall under the jurisdiction of the Food and Drug Administration [FDA], among other exclusions. While the scope of requirements under TSCA has always extended to articles, articles have largely been excluded or exempted from regulation in the past. For chemicals of concern such as PFAS, all companies -- from those that deal with chemical substances and mixtures to those that solely import articles -- they must now be aware of chemical substances in their supply chains due to this increased focus on products and articles.

The impacts of TSCA on supply chains has also been evident in the regulation of chemical substances under significant new use rules, or SNURs, under TSCA Section 5. A SNUR will permit the use of chemical substances for certain uses and under certain conditions with the aim of preventing unreasonable risk to human health and the environment, and also establish criteria where a certain use constitutes a significant new use that cannot be commenced unless a company has submitted a significant new use notice, or SNUN, for EPA's review. Companies that have or seek to introduce a SNURed substance into their supply chains have needed to be keenly aware of applicable requirements and investigate where applicable provisions of a SNUR that are confidential in order to fully understand the scope of the regulation and permissible uses of a substance and comply with applicable downstream notification requirements. But the impact of a SNUR will resonate throughout a

supply chain, therefore familiarity with TSCA -- what is a SNUR, what is a SNUN -- the ability to investigate and identify applicable requirements is of central importance.

LLB: You raise a super good point, Kelly, and that is-- in my way of thinking anyway -- EPA's really expansive definition of what is subject to TSCA, and the slow or not-so-slow erosion of the article exemption in SNURs, and EPA's wanting to look at products that contain chemicals that are chemicals of concern for purposes of EPA review ought to be part of the system has really broadened significantly the universe of entities that are now needing to know what TSCA is. I mean, historically, to your point, chemicals that are embedded in finished product goods that are imported in the United States have largely been exempt from a lot of the TSCA requirements. Not so anymore, and so people that are bringing in products that they have been importing for years are suddenly chemical producers for purposes of this federal law, and they may or may not be aware of that.

To me, Rich, that's been one of the pivotal changes brought about by not just the law in the amendments in 2026, but also the implementation of it through the Biden-Harris Administration, this very expansive review of what should be subject to TSCA. Articles are no longer largely exempt from regulation, inviting a new class of entities that are subject to the law. Whether or not they know it is another matter.

REE: Yes, and this has been a real challenge for EPA to reach out to these nontraditional companies that are subject to these rules. EPA doesn't know where to find them, and they've certainly reached out to the more traditional stakeholders seeking help to reach out to those folks, but it's tough.

LLB: That's why we wrote this book. But in any event, Rich, your chapter on new and existing chemicals does a terrific job of explaining why, ironically, new chemicals, often more sustainable than perhaps the existing chemicals that have been subject to TSCA regulation for a million years, why those new chemicals are now very, very challenged in entering a commercial phase. Maybe you can share with our listeners how you approached that chapter, because it really invites a lot of subtle, yet complex, science policy and regulatory decisions, and how you have imparted your lessons learned over the last eight and a half years on new and existing chemicals in the contributions you made to the book.

REE: I'm sure many of our listeners are aware, but if someone's new, let me just explain. TSCA splits the chemical enterprise -- list of chemicals -- into two categories. Existing chemicals -- there are over 86,000 chemicals that are listed on the TSCA Inventory. Those chemicals are existing chemicals.

Anything that's not listed on the Inventory is a new chemical. For new chemicals, EPA is required to do a premarket review, so a potential manufacturer (which includes an importer) must submit a PMN, a premanufacture notice, to EPA prior to that manufacture for a non-exempt purpose, and I'll talk about exemptions in just a sec.

EPA must review and determine if the substance is not likely to, that it may, or that it will present an unreasonable risk. For existing chemicals, EPA is required to do a postmarket review. These are things that are already in commerce, so EPA is reviewing them because they're already in the market. Then for each existing chemical, EPA must evaluate, look for an unreasonable risk, and identify whether a substance does or does not present an unreasonable risk under the conditions of use. In either case, if EPA identifies a potential for risk, EPA must issue a restriction to protect against the risk identified. There are some

similarities there, but critically, new chemicals, it's a premarket review -- it's supposed to be a shorter review -- and then the existing chemicals review, EPA does have more time.

But what we're seeing in the vast majority of cases is that if EPA identifies any hazard, other than low hazard for health *and* the environment, then EPA is concluding that there is or there might be a risk and therefore issues a restriction. We have not yet seen that data on releases or exposures can ever convince EPA that exposures are low enough that a substance is not an unreasonable risk, because EPA simply assumes that releases or exposures may be higher, leading EPA to then conclude that there is or may be an unreasonable risk, triggering a restriction. My view is that this hazard-based approach -- it *is* a hazard-based approach, rather than a risk-based approach that's specified in the statute. But this is one of the potential issues that may be resolved in current litigation, or it may also get clarified in congressional action to see whether EPA is implementing TSCA as Congress intended.

But what's happening in new chemicals is this hazard-based approach means that EPA's issuing restrictions on nearly everything. It's up to about 92 percent of PMNs in the last four years. For the highly hazardous substances that EPA has focused on for the existing chemicals review, this is not really a surprise. They're highly hazardous; there are significant concerns, and there is a mix of conditions of use that are not an unreasonable risk. But it has been quite surprising in EPA's approach to *new* chemicals. For these highly hazardous things -- existing chemicals -- it's not surprising that EPA is issuing restrictions. But when you look at some of the new chemicals for which EPA is issuing restrictions, you see this departure, where on the one hand, EPA is saying, "Okay, methylene chloride is deserving of significant restrictions." But new chemicals that are listed, for example, on EPA's Safer Chemical Ingredient List (SCIL) are getting restricted as well. It's not clear to me that that's what was meant by Congress and that EPA is implementing these sections appropriately.

But what it means for business when you're submitting a new chemical is you need to expect to get restrictions, and now your new chemical which carries restrictions is -- you're probably not competing with one of these highly hazardous things. You're probably competing with something that's much lower hazard and is not likely to be undergoing existing chemical risk evaluation. So the new chemical is going to be restricted, where the incumbent that you're seeking to replace is not, so that puts you at a competitive disadvantage. That, for a lot of our clients, is sort of baffling and frustrating, and I understand their frustration, but this is essentially what we're seeing.

LLB: Yes, you spoke about it at length, Rich, when you gave testimony before the House Energy and Commerce Committee back in January, January 22, 2025. I think EPA has been fundamentally a little bit resistant to appreciating business consequences of restrictions on new chemicals. From an academic perspective, it's like, "Look. This is what our analysis indicated we need to do -- limiting releases to water or requiring downstream notifications. But all of those restrictions have the business impact of making chemicals, even though they're more sustainable and perhaps have less of an environmental footprint, less commercially resilient, to be perfectly blunt.

REE: Yes, and it's an enforcement risk. So if your new chemical -- your wonderful new chemical -- has these restrictions and EPA definitely questions, "What's the big deal? We said the restriction allowed you to do what you wanted to do." That's great, but now our customers are at enforcement risk that they're not at risk if they stick with the old existing chemical that's not undergoing risk evaluation. As a result, some of our clients are just abandoning the TSCA market. They can commercialize under FFDCA, or they certainly commercialize

elsewhere in the world. And it's just -- we're missing out. The U.S. economy is missing out on some really terrific things because they're just not competitive in the market.

LLB: We might have to just think of a new way of defining these restrictions if the restrictions need to be applied at all, because there is a specific and a very perplexing adverse prejudice to chemicals that are subject to restriction, full stop, period, and we just might need to start defining terms differently in order to get over that very prejudicial effect of significant new use restrictions on chemicals that are promising and certainly more sustainable than that which they seek to replace.

Kelly, same question to you. You authored the very important chapter on imports, which to me is a trickier business practice today than it was pre-Lautenberg. Why is that, and what are some of the key takeaways from your chapter?

KNG: In a practical sense, the import and manufacture of a chemical substance are two very distinct activities, but under TSCA, the manufacture of a chemical substance is defined as including the import of that substance into the United States, whether it is part of a mixture or a finished good or article. The inclusion of import within the scope of TSCA's definition of manufacture is significant because it enables EPA to track and regulate all chemical substances present in U.S. commerce, whether they are introduced via domestic manufacture or via import, so for companies that import chemicals or mixtures as a cornerstone of their business, this definition under TSCA is not a surprise. For companies that have only sourced products domestically in the past, or who are one-time importers, or companies that have only imported articles in the past under TSCA, they may not realize that their activities may be covered under TSCA.

For ensuring compliance with TSCA, all companies that import chemical substances or mixtures must ensure they comply with a checklist of issues, including first, whether the activity is subject to regulation under TSCA, and then ensuring that the product is listed on the TSCA Inventory, determining whether other regulations apply, among other requirements. Companies may not realize, however, that the one-time import of a chemical substance may trigger regulatory requirements well into the future. For example, under TSCA Section 4, EPA interprets its authority to order the development of new information as extending to companies that imported a chemical substance in the past. This could include a company that imported a chemical substance within the past five years. Therefore, the need for awareness of potential future regulatory requirements is also exemplified under TSCA when it comes to TSCA Section 8(a)(7) reporting requirements.

The reporting requirements under Section 8(a)(7) not only extend to imports between the ten-year period, between January 2011 and December 2022, but as we've discussed, they also apply to chemical substances that are imported as part of articles and in any amount. So this has thereby extended the reach of TSCA to companies that are often expressly excluded from reporting and notification requirements. When considering whether to import a new chemical substance or a new article, it is important for companies to have a baseline knowledge of requirements that could apply under TSCA, and to ensure compliance with any immediate requirements, and to also understand the implications of the decision should the substance become the subject of a TSCA Section 4 testing requirement or the focus of reporting requirements under TSCA Section 8 in the future.

LLB: That's a terrific response, Kelly, and before I push on, Rich, did you have anything you wish to add to that?

REE: No, it's -- again, how do we get the expansive community that's actually affected by this aware and properly informed? And to your point Lynn, that's part of why we wrote this book.

LLB: A couple of responses to your very, very good response, Kelly, and that is, we tried super hard in this book to make it very, very hands-on, and -- to use a much overworked term these days -- accessible for anyone importing or exporting chemicals, or manufacturing chemicals domestically, or distributing them domestically, and how the application of TSCA as amended by Lautenberg applies to those business operations. Each chapter begins with key messages and ends with takeaways. We have charts, diagrams, a glossary, to your point, Kelly, checklists -- very, very hands-on practical information for busy businesspeople. We have flowcharts, links to EPA resources, some of our own resources since we do so much work in TSCA.

I was wondering if both of you could just give a few examples from your chapters so our listeners can better understand how the book is just really useful. I mean, I have no bias against scholarly legal works, but this is not that work product. We write a lot of articles on policy disputes and how whole-chemical review may or may not align with what Lautenberg intended to accomplish when Congress amended the law in 2016, and similar policy disputes. But at the end of the day, businesspeople have a business to run. I run a business, and I want hands-on, practical information that will help me be a better, more successful businessperson. So maybe starting with you, Kelly, what are some thoughts from your own perspective in the chapters that you contributed to the book?

KNG: In terms of imports, the chapter provides an overview regarding how imports are regulated under TSCA and what companies need to know to make informed business decisions and ensure compliance with TSCA. Importers of chemical substances must ensure that they comply with TSCA prior to importing a chemical substance. Under TSCA Section 13, importers are required to certify that a shipment complies with TSCA in a statement called an import certification. The import chapter reviews step-by-step the process for determining whether a company is considered the importer of record that is subject to certification requirements, how to confirm that a shipment is regulated under TSCA, and the requirements for preparing any applicable import certifications. The intent is to ensure that companies have a firm understanding of key definitions, as well as all of the potential issues to consider before and after importing a chemical substance.

LLB: Rich?

LLB: From my perspective, a key to understanding TSCA obligations, in particular for new chemicals, is when a substance is eligible for an exemption. There may be a variety of potential exemptions, and one is, if a substance is used -- it's manufactured or imported -- for a non-TSCA purpose, like a food, drug, cosmetic, then it's exempt from the PMN requirements. To Kelly's point, when you import, you would make a negative import certification because a negative import certification is not whether or not it's listed, it's whether or not it's subject to TSCA.

But there are also other several self-executing exemptions, those that do not require notification to EPA. Article exemption is one. If a substance is part of an article -- it is not intended to be released from the article -- a new chemical would not be subject to the PMN requirements. Substances that are manufactured for an R&D [research and development] purpose are not subject to the PMN requirements -- the manufacturer and its customer, as

long as it's clear that the substance is being manufactured for an R&D purpose, that would be eligible for the R&D exemption.

Non-isolated intermediates are exempt. This allows a company to design a process to not isolate an intermediate and then not have to submit a PMN for that. A byproduct that's formed during a chemical reaction may be exempt, but only if it's disposed of as waste, or burned as fuel, or used only to isolate a substance that's already present in the byproduct. So when you're looking at a process and deciding whether you're going to try to derive some value from a byproduct of your process, understanding whether a PMN is required prior to using that byproduct for a commercial purpose helps you make that business decision about whether you can run that process economically if you're not getting economic value from the byproduct.

All these things go into a business plan -- designing your process, figuring out where you're going to get your value out of your products and byproducts -- all of that informs a commercialization plan. Can you begin? Early on, can you make money if you are diverting your byproduct and sending it for waste while you wait for a PMN to be submitted and reviewed by EPA? Or can you not make that an economically viable process without getting the value for that byproduct? These are all things that go into a business plan and making business decisions, and you really need to understand some of these key subtleties about TSCA and when exemptions apply and when a PMN is necessary.

LLB: That's a very good example, Rich, of the lens through which we try to tee things up in this book. It's very important to understand the law, but it's very difficult to translate that understanding into pivotal business decisions. So our whole approach to this book is taking the law and trying to identify opportunities to use it for competitive advantage, and certainly design your business decisions and understanding of the law in a way that will avert problems down the road, but also identify pathways forward in a way that make compliance with TSCA less challenging than it has been.

Speaking, Kelly, of compliance with TSCA, you co-wrote the chapter on enforcement, which is always an important topic for our listeners and our clients in the business community. Maybe you could tell us a little bit about TSCA enforcement, especially given the fluidity of the law. Sometimes I'm challenged to explain to clients why the Office of Enforcement and Compliance Assurance (OECA), which is the program office at EPA that really takes the lead in enforcing TSCA, is sometimes a little bit, in my view, detached from the day-to-day uncertainties in the law. But you have a lot of very good pointers in the chapter on enforcement, so tell us how you approach this chapter and what your takeaway messages are.

KNG: Yes. My colleague, Lisa Burchi, is Of Counsel with B&C. The two of us prepared a chapter on TSCA enforcement that discusses in-depth topics such as EPA compliance inspections, and how to navigate the process if your company is subject to an inspection, EPA's enforcement strategies for ensuring compliance on targeted issues, recent enforcement trends, and the potential outcomes if EPA discovers that a violation occurred, in terms of civil penalties and in rare cases, criminal penalties.

In general, the book focuses on how to ensure compliance with TSCA, and this chapter is one that hopefully readers will not need to reference as closely as others. But even so, any company could be selected for inspection by EPA. And it is furthermore important to understand the risks of noncompliance to help ensure that sufficient time and resources are dedicated to TSCA compliance. TSCA is a strict liability statute, and the civil penalties for

noncompliance with TSCA, adjusting for inflation, are close to $50,000 per violation. This includes violations of TSCA involving TSCA Section 8 and chemical data reporting requirements, failure to submit a complete form U, or a submission that contains inaccurate reporting. Those types of violations could similarly lead to a six-figure civil penalty. Some of the key takeaways include the importance of understanding EPA's enforcement priorities, steps that companies can and should take to ensure compliance, including periodic self-audits, knowing the law to both engage in trainings within the company to prevent noncompliance, how to comply with a TSCA inspection if a company does receive a notice, either by mail or by e-mail, understanding what types of penalties EPA can assess under the inspection enforcement provisions of TSCA Sections 11, 15, and 16.

LLB: You noted the $50,000 per violation, which in some instances can be rendered per day, per violation. That's why we get these eye-popping, multi-million dollar penalties that always surprise our clients. One of the themes in the book that we focus on is how to avoid that. Some of the checklists and other documents that are available through the book are intended to help our clients, and others reading the book, avoid precisely that result. Because TSCA enforcement matters are just something you really, really, want to avoid. They're not only very time-consuming and transactionally expensive, but in terms of brand damage and diminished reputational issues for a recipient of a multi-million dollar penalty; even if it's for a recordkeeping enforcement action, these things can be very debilitating. And penalties are not getting lower; they're getting higher. So thank you for that response, Kelly. One final question to both of you: Maybe you can tell us why anyone would want to buy and read this book.

REE: To your point earlier, we tried to write it to be a more practical and approachable guide, rather than our more detailed, for instance, LexisNexis TSCA book, which gets very much into the weeds.

LLB: Which we also edit, right.

REE: Yes. It's trying to give a higher level view, but still anchor that to the specific policies, and procedures, and regulations, and statutory language, to your point, to help businesspeople make decisions about what they're going to do. When should they take one direction or another, and what are the potential risks of doing one thing or another?

REE: Kelly, why would you want to buy and read this book, trying to separate from the fact that you wrote it, but what can you tell people about why they should buy it and read it?

KNG: One of my first introductions to B&C was reading the firm's 2017 publication, which was titled *New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation*. I still find myself reaching for that book as a valuable resource to understand the impacts of the Lautenberg amendments on current regulatory developments on what is new versus what is now considered old TSCA. So as Rich notes, this book was written as a practical guide, both for companies that may not be familiar with TSCA to understand TSCA and for companies that may already know the ins and outs of the statute with the aim that the reader can flip to a particular chapter. If, for example, they do receive an inspection letter, they can review the chapter and have an initial overview as to what they can expect and what issues to look out for. The book, and each individual chapter, provides a very valuable resource in that way.

LLB: We think highly of the book. We are super excited as a firm that many of our distinguished professionals participated in its creation. For more information on the book and how you

might order it, look at our website, www.lawbc.com. We would welcome feedback on it. I'm sure there will be other iterations of the book, because TSCA is an amazingly expanding, really living law. Adapting it to business transactions now and down the road will be the source of continuing interest and activity. Kelly, Rich, thank you so much for not only this podcast and your thoughts, but also your contributions -- fabulous contributions -- to what we all believe to be a wonderful new resource for our clients and others. Thanks very much.

REE: Thank you, Lynn.

LLB: Thanks again to Rich Engler and Kelly Garson for speaking with me today about our new book, *Chemical Product Law and Supply Chain Stewardship: A Guide to New TSCA*. We are very excited about the book and hope you'll give it a spin.

All Things Chemical is produced by Jackson Bierfeldt of Bierfeldt Audio LLC.