Episode Title: Reflections on TSCA Implementation -- A Conversation with Alexandra Dunn

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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 was delighted to visit again with Alexandra Dunn, now a Partner with Baker Botts, and previously immediate past Assistant Administrator [AA] of [the U.S. Environmental Protection Agency] EPA's Office of Chemical Safety and Pollution Prevention [OCSPP]. As AA, Alex was respected and well liked by a diversity of industrial and agrochemical stakeholders, revered by her immediate staff, and hugely popular as an EPA senior leader. Alex led the Toxics Office at a pivotal time in EPA's implementation of revisions to the Toxic Substances Control Act [TSCA], and Alex worked tirelessly to meet the many deadlines imposed under Lautenberg [the Frank R. Lautenberg Chemical Safety for the 21st Century Act]. We discuss Alex's transition back into the private practice of law, get a sense of the issues on which Alex is focusing now that she is back in private practice, and reflect on current EPA policies under TSCA and FIFRA [the Federal Insecticide, Fungicide, and Rodenticide Act] to understand what has changed since Alex left EPA. Now, here's my conversation with Alex Dunn.

Alex, I am just so thrilled that you're back in the studio. I was looking forward to this more than you could possibly imagine.

Alexandra Dapolito Dunn (ADD): Lynn, thanks for having me back. I always enjoy doing your podcast, and now that podcasts are the hippest thing ever, kudos to you for having All Things Chemical rolling for so long. And I'm really glad to be here with you this morning.

LLB: Super. Tell our listeners a little bit about how the transition to private practice has gone so far. And maybe give our listeners a sense of what you're spending time on.

ADD: I joined a law firm called Baker Botts about three weeks after leaving the Administration, and I have to say it has been a relatively smooth transition, other than starting a job virtually

and largely holding that job virtually since I began, but I'm not the first person to do that. I really enjoy private practice. Many of my years, as you know, Lynn, were policy oriented and not necessarily purely legal. So it is fun to be back in a place where I can bring the detailed legal analysis to my love of policy.

What I'm spending time with are things that I've always put a lot of priority on in my career. With the Biden Administration's focus on environmental justice, it's great timing for being in private practice, where companies -- some -- are very familiar with environmental justice concepts and have them well integrated into their operational frameworks. Other companies feel like they want to learn more. They might be a little rusty on what environmental justice means, so I've worked with a team of colleagues to develop a framework for environmental justice integration at companies of all sizes. And that's been really sort of a labor of love and a great project. And all of that information is on our Baker Botts website, and we're putting a lot of content out that's for anyone to use, much like your firm does, Lynn. I think that's a service that we can all offer is to share knowledge, thought leadership, with the legal and regulatory community. And then I've also been working on -- yes, I have a few matters that involve chemicals, a few matters that involve pesticides, working on compliance counseling. And then I think we'll talk later about PFAS [per- and polyfluoroalkyl substances], which is an area where I'm spending a good bit of time.

LLB: I hope our listeners picked up on the reference to the content, regarding an environmental justice framework that -- I'm going to take a look at that, Alex, because I know some of our clients have struggled with contextualizing environmental justice, compliance, oversight, how to move strategically into an area that is -- I don't want to say ill-defined but growing in definition and impact on the private sector. So maybe you want to just give a shout-out to your website to make sure listeners are directed accordingly.

ADD: Sure. I didn't want to overly plug it, but absolutely; folks should check it out. It's bakerbotts.com/acelas. And those are the six letters of our analytical framework for integrating environmental justice. There are also three webinars on exactly what you said: What is 2022 environmental justice, as compared to perhaps environmental justice five or ten years ago? The field has grown to include climate justice; economic justice; justice in the truest sense of the word, not just with regard to pollution impacts, but with the entire life of a community; and also giving a lot of recognition to the lived experience of a community. So not just assuming that one understands what living in a community where there may be industrial activity means, but hearing firsthand from the people who have lived there for perhaps many generations, and hearing their take as *as* important and, frankly, the *most* important source of information that should go into the input. It's a very, as you said, it's an evolving field, and not necessarily something that everyone's really comfortable with, because it does touch on difficult issues, like race and economics and socioeconomics. And it can bring up some difficult feelings, but our tool kit, I think, gives a roadmap; at least you know you're on the right track in having those conversations.

LLB: Thank you and your colleagues for making that important work available. So *I'm* going to look at it, and thank you for the shout-out on the website address.

ADD: Sure thing.

LLB: Over the past year, just a whole lot has happened under the general heading of Lautenberg implementation, an area that you are *very* familiar with, given your role as AA. Alex, what would you highlight as some of the most significant policy shifts in that area?

ADD: Well, I do have to say, first, kudos to the whole team that's over there with Dr. Freedhoff and her leadership team. Certainly it's easy to sit outside and watch and wonder. But then again, people did that when I was there, too. So I offer these thoughts with full recognition that folks are working hard every day. And the career staff are amazing. I don't think I hear an address by anyone in an appointed position that doesn't really call out the work of the career staff.

But yes, you're right. There have been some, I would say, even seismic policy shifts. And they weren't surprising in many ways because while *I* was at EPA and the last Administration was implementing the TSCA amendments of 2016, we got lots of mail and letters and comments about the policy choices that were being made and the alternatives were being offered.

And now we see these alternatives really coming into play. I mean, the first one that is intriguing and again, not surprising, is this whole chemical approach. Did TSCA's conditions of use analytical approach anticipate what the last Administration did, which was take a chemical, look at its, say, 19 or 20 different uses, and find some of those uses to not pose an unreasonable risk and some of them to, in fact, pose an unreasonable risk? The Biden team has decided to pick up the chemical, so to speak, and just look at it and say, "This chemical in and of itself is -- inherently poses an unreasonable risk" (or does not).

Other than the lowest priority chemicals, I'm not sure one could pick up a chemical and find absolutely no risks, particularly with another one of the policy shifts, which is whether workers are wearing personal protective equipment [PPE] when interacting with the chemical. That's been sort of a hot policy topic. And in the last Administration, we found, for a variety of reasons, that it was reasonable to assume that workplaces were -- because of workplace law and worker protection law and OSHA [Occupational Safety and Health Administration] -- were supplying their workers with appropriate PPE. And when we evaluated a chemical as a team with the scientists, it was assumed that the worker would be wearing gloves, perhaps, if the chemical was a dermal irritant, or eye protection, or even a respirator.

In addition to the whole chemical approach, another sort of policy change has been to assume that workers are *not* wearing protective equipment. And in that case, we're going to have chemicals posing a number of unreasonable risks because certainly many of them are in fact, dermal irritants or eye irritants, or you shouldn't inhale them. And so if you're not wearing protective equipment, they're going to pose risks. And then all of -- those two assumptions, I think, together are kind of resulting in the redoing of so many of the first ten risk evaluations. And that has really left me a little bit surprised at how significantly it has affected the timing of the risk management rulemaking process.

Congress gave a timed roadmap in TSCA, and it is aggressive, as we all know. And one year from final risk evaluation, the Agency was to propose a risk management rule. And we still don't have *any*. And the risk evaluations are sort of being redone. I believe one has been redone so far. So those policy choices are definitely affecting the whole workload. And I wonder, too. There's been a lot of talk about morale, and we all get up and go to do our jobs every day. But redoing a lot of work, I think, can have its morale effect, too. I just wonder how the vibe is, because these are some important policy choices and certainly within the purview of the Administration to make, but it does have an effect on the team. And, Lynn, maybe the last thing I'll say is that the first ten risk evaluations -- agreed, they were done under a lot of time pressure -- but every one of them was peer-reviewed, was fully peer-reviewed by the Science Advisory Committee on Chemicals.

I still believe that the scientists who worked on them stand behind that initial work. So in going back in and kind of recutting and recarving and reanalyzing, I hope that the time and effort, I guess, really gives us a valuable outcome or changed outcome. Or is it just really kind of rewriting the way you get from A to Z, with multiple different pathways? Is the outcome going to change? I don't think we really know that yet.

LLB: Lots of good points, Alex. I know I share your view, and many, many lawyers in the TSCA space do question what the whole chemical approach means. Is it countenanced under Lautenberg? And with regard to the risk evaluations and assumptions regarding PPE, whether the non-use of PPE is a reasonably foreseeable event with regard to chemical exposures in the workplace, reasonable people can disagree and are disagreeing. I'm guessing some of those issues will be sorted out judicially because they continue to be big, hot button issues right now, both in TSCA Section 6, and you know how much work we do under TSCA Section 5, because it's having a very, very chilling effect on the commercialization of new chemicals, for sure.

ADD: That is a great point.

LLB: In that regard, now that you've -- you have just a storied, really, really extraordinary career, Alex. And I say that with all sincerity, because you've been in every kind of sector: academia, and the NGO [non-governmental organization], and government service, and private practice of law, and trade association. What do you tell your clients about what to expect and how best to approach, to achieve the optimum outcome, the new Administration when advocating a position? You've been on both sides of that discussion, so what do you tell your clients?

ADD: That's a great question. What I tell the clients I'm working with is learned from what I saw inside the Agency when there was a high degree of frustration, and what was the root cause of that frustration? And so often, the root cause of a company elevating to the Administrator's office, or to the AA of OCSPP, in a letter saying, "You've had my application for an undue amount of time. We haven't heard from anyone." It really often got down to this breakdown in communication. A lot of work with EPA, as you know, Lynn -- it's very transactional. Something has to be filed, something has to be uploaded, and then people go on with their other responsibilities. And what happens is that things can languish. But really, it's about following up on that submission, finding out who, truly -- the living, beating human person who has been assigned to your case -- who is that person?

And that person has a plate of work. And your case is the next one in the queue. And they don't have any reason to know who you are, what you need, what your drivers may be timing-wise, what your plans are for going to market, necessarily. I think there's a general assumption that very few chemicals are completed within the 90, and even the 180 days. What I tell people is, "Find out who is working on your case; contact them. Introduce yourself to them." I have found that EPA staff are incredibly responsive, particularly to e-mails, maybe more responsive to e-mails than voicemails with the virtual work. But notwithstanding, I do advise an e-mail communication because it's in writing. It's a little bit easier to follow the breadcrumbs when you've got six or seven months, or even a year, of communications back and forth. It's so much better when there weren't three or four really important voicemails exchanged that nobody exactly remembers what communication was in them.

So put things in writing. Meet the people. Talk to the staff about your why -- why you are hopeful that things can be done timely. Listen to them about their constraints. Find out what

gaps they foresee. The staff can be very open about where they think the bottlenecks will be in the process, if it's going to be an eco-risk assessment, or in the human health assessment piece. And ask, "Is there something that we can provide to help the staff?" And then just stay in communication. That's really what I tell people. And if you do need to elevate, if there is a difference of opinion, a true difference of opinion that you really believe is a scientific difference of opinion or a policy difference of opinion -- if after a period of time, you feel like you need to elevate it to the person's manager, let them know. And just say, "Hey, we've reached a place here where we're not making a lot of progress. I'd really like to involve your Branch Chief or your Division Director."

And that's part of the process. But I do think letting people know that it's just part of the process, there's no bad feelings. But you feel that you need to speak to a larger group of people. That's okay to do.

LLB: But that heads-up is super important, as we know, to just make sure that the individual with whom you are dealing doesn't feel undermined or sabotaged by having a broader audience invited into the problem-solving process. Great advice, Alex. Thank you for that.

ADD: And Lynn, you know, too, the first thing that the higher (in the organizational structure) person will ask is they'll turn to the staff member on the case and ask to be briefed. So, recognizing that we're all in the same tent, I think can really help.

LLB: I know one of the issues that many of our clients are struggling with, and derivative of a problem that we know well, and that is, the OCSPP is definitely under-resourced. And Dr. Freedhoff has been asking for -- understandably so, given the workload -- many more full-time employee and equivalents than perhaps it now has. As Immediate Past AA for that office, what advice are you sharing with your clients to address the many bottlenecks that they are experiencing in virtually all areas administered by the OCSPP, especially in the new chemicals area?

You just noted that no one expects the 90 days, or even the 180 days, these days. It's generally well in excess of 180 days to perfect a new chemical approval or exemption. But besides the "Be patient. We're at where we're at," are there any specific strategies you are recommending your clients pursue?

ADD: You know, I will say with the omnibus being signed very recently, it is unfortunate that the budget for the Agency didn't get the bump that the Biden-Harris budget would have given it. But notwithstanding, when we had -- when I left in January 2021 -- a true list of every vacant position in the Office of Pollution Prevention and Toxics [OPPT] and a very aggressive plan to fill those positions within nine months. And that was optimistic. But it's like setting a really big goal and then just pushing toward it. Of course, there's attrition that comes in in the interim, so you hire two and lose three. I mean, that does happen. But with a focus on hiring, there is the possibility under the existing budget to baseline staff, the OPPT; and putting the real focus on it is not just Dr. Freedhoff and her office getting those positions posted, but it's truly across the whole Agency, the H.R. [Human Resources] office recognizing that this office, OPPT, is critically short on staff. Hiring the type of experts that are needed in that office is challenging, particularly with competition from the private sector.

But when Administrator Wheeler asked us to establish a branch of OPPT and OPP [Office of Pesticide Programs] down in Research Triangle Park [North Carolina] with the idea that perhaps that geographic location would be attractive to some scientists who were not

interested in the D.C. area, we were able to bring on 30 new Ph.D.s -- they all had a Ph.D.; one had a master's, and I think there was one bachelor's in physics, which is nothing to sneeze at. So 30 really highly qualified individuals were hired in an aggressive time period. I remain on the sidelines, cheering the H.R. hiring process. It takes a long time to onboard a federal employee. And you almost -- I used to say you have to be like the military, in constant recruiting mode. You're always looking for that battalion, and filling them up every single day. What I tell my clients with regard to the bottlenecks that come from the staffing is patience. Certainly, as I'm sure you do, but also, "Be realistic about your timeframe." If there is a chemical approval that's really critical to your business plan, build in, unfortunately, a year, maybe 15 months to get to approval or exemption, as you said. Communicate, as I said earlier. Try to make sure your submission's complete; anticipate gaps. And then the consent order process, because of the assumptions around PPE, almost every new chemical authorization is going to come with an order. And that's just another step in the process that unfortunately will make it take a bit longer. So I would guess I'd say, "Buckle in for a bit of a longer ride, but calculate that longer ride in your business plan." And if you do, it will be less devastating to your business when things take inevitably longer than the statute says.

LLB: That's great advice, Alex, because I know that the law says 90 days, and for years and years and years, that was a bit of a reliable metric, although it was never a hard and fast truism, even under pre-Lautenberg Act. But managing expectations. The folks that actually prepare the PMNs [premanufacture notice] and get them in, they are generally answerable to others within their entities, so you're spot on with a year, year and a half, just to be on the safe side. If you come in under that, you're a hero, right? But you're not going to come in under 90 days. That's just -- those days are gone.

Let's pivot to what you mentioned a little bit ago, Alex, and that is the work that you're doing in PFAS-related issues. I've enjoyed and witnessed your many presentations over the past year in an area that's very hot across the board in the environmental and chemical space. What, in your view, are the key issues that our listeners ought to be watching for, listening for with regard to EPA's focus on PFAS?

ADD: Yes, absolutely. And Lynn, you and I gave a talk together recently to the American Law Institute, where we got to go back and forth and chat about PFAS. I know what I'm about to say is of no surprise to you, but I'm really glad to talk about it. So per- and polyfluoroalkyl substances (or PFAS), they are ubiquitous. They've been found -- when I was at EPA, we used to say they've been found in the Arctic. They move; they go everywhere. What I encourage your listeners to do, and what I'm telling clients of mine, is to really reflect on what I call "your relationship with a PFAS chemical."

If you're, for example, a refinery, did you (and do you still) have on site aqueous film-forming foam concentrates (or A-Triple F foams), which contain PFOA [perfluorooctanoic acid] and PFOS [perfluorooctanesulfonic acid]? How did you use them? What type of firefighting activities or drill activities did you undertake at your facility? And the fact that you undertook those activities is not the issue. The issue is: did that foam mixed with water leave your site, somehow impact groundwater, impact soil? So it's, again, getting your relationship with PFAS documented and understood. For a lot of facilities, this means that they are in response to, say, state requests -- the state of New Jersey, the state of California -- are asking for industry sectors like petroleum refining, wastewater treatment, and others -- airports -- to do this type of historical analysis and provide the facts, so to speak, to the state. And that information is also being put on publicly available databases. So the information

could -- is very transparent -- could be used by groups that are concerned about water impacts in a potential, even citizen suit or complaint.

So recognize that documenting your relationship with PFAS is an important exercise. Doing that work in anticipation of litigation is probably a sound way to approach it, because the litigation around these PFAS, as the regulatory regime has trailed, litigation is where it's at. People are suing one another for responsibility for cleanup, or responsibility for contamination, or responsibility for making it and selling it and not disclosing certain risks. There's really just so much that -- I call it, "Make sure your head is out of the sand, your eyes are up, and you're looking around."

And you talk to -- in some cases, we've helped companies track down employees who were on site in the '90s and might have overseen certain activities or recall a spill or a fire or an event, which at the time maybe wasn't something that was documented in any particularly detailed way around the foam, because that certainly wasn't the focus back then. The other thing I'll say to your listeners is, "EPA's PFAS roadmap is a great tool. It's got a laundry list of everything that's going to happen over the next two years." Everyone's watching the proposed rule to list PFOA and PFAS, which are only two, as you know, Lynn, of over 600 of these chemicals as CERCLA [Comprehensive Environmental Response, Compensation, and Liability Act, or Superfund] hazardous substances. That is going to be a huge development, and certainly something that's been talked about for a good five, six years that will, if finalized, perhaps result in many Superfund sites being looked at again, reopened, and EPA having authorities to do cleanups that they may not have today.

And the final thing that folks should be watching is the multi-district litigation in South Carolina. The foam cases are being consolidated there. There's over 1,300 of them right now, and they're in full blown discovery around the science, and there'll be a couple of -- three cases or so -- that will kind of lead that pack, that will go all the way to full trial. And based on the findings of that trial in terms of responsibilities and liabilities, then those legal findings can be carried over to the other cases in the district litigation. So that's something to watch.

LLB: And I'm sure your website probably has much more information on the foam cases and the status of the multi-district litigation.

ADD: Yes, there's information on our website. There's also what I call a piece on getting your relationship right with PFAS. And of course, just Google PFOA, PFAS, and you'll land on lots of resources, including some from your firm, Lynn. You have great resources out there as well, so plenty to get smart on. And then I would say, where your legal counsel can help is in the deployment of what you want to do at your company and making sure you're thinking about the different -- as I said, there's so much litigation here that -- creation of records and documents, you really need to think about how those could be used in the future. Not to say you shouldn't do it. In fact, I'm saying you should do it. But you should do it in full awareness that someone may request those documents in the future and think about that as you entertain that step.

LLB: Yes. There are so many moving parts with PFAS and EPA's execution of the PFAS roadmap that you were engaged in when you were AA, Alex. It is a fine piece of work and gives a lot of people a heads-up on where they should be prioritizing actions because being situationally aware is a function of where you are in the food chain, as it were.

ADD: And it's hard to do, right? I mean, it's -- I feel for our folks who are out there trying to make their product or carry on their business operations and to take ten minutes every morning and glean the D.C. news for PFOA and PFAS, and what EPA, or the Department of Defense, or some other agency is doing is time consuming. And I think that's what people like you and I *can* do, Lynn. We actually do get up and read all that stuff first thing in the morning.

LLB: Sadly, that's true.

ADD: Yes, I mean, our business is to track those developments. And so I think we can be helpful to people who just need the quick what's happening pulse check.

LLB: Well, as we record this podcast, Alex, we're at the beginning of serious concern with and focus on the midterm election and the outcome. And there's been a lot of talk about a possible flip in Congress this coming November, although who knows? It's a long way off, and yet it isn't. If Republicans were to take control of the House, for example, what changes would you expect to see regarding EPA chemical management programs and any oversight?

ADD: Right. If there's a shift in the power dynamic in Congress, for example, if Republicans take the House, boy, there are going to be so many issues on the top of their list. I do have to wonder whether oversight of TSCA, how high that will bubble. Notwithstanding, there are committees where TSCA is their jurisdiction. And so they -- I would expect maybe more, as you said, oversight to find out what's going on. Where are the risk management rules? How are things going with the next 20? What's going on with the manufacturer-requested risk evaluations?

I also expect questions about the resources. What's the status of hiring? Some of these policy questions, I think, could be the subject of some questions. As you know, Lynn, a lot of this is really down in the details, and it doesn't make for easy headlines or even easy opening statements by members of Congress around chemical regulation, and a long line of questioning around PPE is going to seem really, really in the minutia. What I do think we would see, though, is maybe more letters to EPA asking for information, briefings. May not see hearings per se, but I do think oversight in the other ways that Congress has to inquire of EPA, to ask for briefings.

I can tell you from being in EPA, when you're asked to go up and do a briefing for the staff, you prepare as much for that as you do to give testimony in front of the committee because frankly, those smaller briefings of the staff are where you *can* get into the details. And some of the follow-ups can be really, really intensive in terms of producing. We had to produce hiring charts and job descriptions when there was concern that we weren't hiring quickly enough by the Democrats, when I was at EPA. And they wanted to know if the Trump Administration was truly prioritizing hiring in OCSPP, and we had to go back and share. Yes, indeed we are, and here's the hiring plan. And here are the people we've brought in, and here are our numbers.

So I do think that there will continue to be those deep dives. And the next round of budget, if it's a Republican House, probably not going to see a big budget boost to EPA. So I do think how EPA can work under the resources it has is going to be the big question.

LLB: You raise a lot of good points, Alex. One of the areas that we've been just kicking the tires on and thinking about is that with all of this emphasis on resources -- and Dr. Freedhoff has made it abundantly clear at *every* opportunity when she is invited to speak, before Congress

and in other venues -- that she's lacking resources. And lacking resources means EPA is missing deadlines. You mentioned it earlier. Some of the changes in policies have resulted in fully developed risk evaluations being pulled back and reviewed, and deadlines are being missed. That almost inevitably means that the failure to meet a deadline could result in a lawsuit. Those lawsuits tend to focus on failures and hence put EPA and OCSPP in a bad light. Do you see that as ultimately helpful, hurtful, or just inevitable? It just is what it is.

ADD: You know, yes, deadline lawsuits -- when I used to sit outside the Agency, I'd view it as pretty newsy to say, "Oh my goodness, there's been a suit. EPA's missed a deadline." And as you know, Lynn, we tried very hard when I was at EPA to *not* miss any deadlines, to avoid that kind of deadline lawsuit distraction.

LLB: Yes, you did a great job, Alex.

ADD: Yes, we didn't miss any! Well, we missed some, but not with enough time that the lawsuit would have made much progress. So deadline lawsuits *may* come. The question is who they'll come from. I think that the NGOs right now are relatively aligned with Dr. Freedhoff and her office's work, so they're unlikely to sue and put EPA under that deadline pressure. And then the question is, does the regulated community benefit from the deadline lawsuit, from pushing EPA to more quickly complete, say, a proposed risk management rule around a chemical that's very important to them?

There may be this "You go first" kind of moment with deadline suits. But if we get some, I think it will be around where are those risk management rules? We do know there was a petition in the last Administration from the regulated sector that sought a rule on risk management rules. They wanted to know what was going to be in them, and pretty soon, more and more inquiring minds will want to know. The only risk management rule that is in the queue is asbestos Phase I; it's been at OMB [Office of Management and Budget] since December. We should see it soon. So again, I think to your point, they are part of the process. I'm not confident it's clear who would necessarily bring that deadline suit. I don't think they help or hurt. They're just part of the process, and EPA will always agree to a deadline that it believes it can *meet*, since it's a court obligation. Ultimately, the deadline suit might get EPA on a tighter schedule, but it will be a schedule that the Agency believes it can achieve, and so it's probably still going to be a schedule that's at least a year or two away from where we are today.

LLB: Agree. Let's pivot and talk a little bit about the OPP. Hugely important area of EPA's work. I know you focused an awful lot on that when you were AA. What issues are you monitoring now? There's just a lot going on with endangered species, pollinators, PRIA 5. What are you watching for?

ADD: My goodness, there's so much. Of course, the registration review process, the 15-year reregistration. That's another big, big workload. And some of the more challenging pesticides were later in the queue. So certainly watching as EPA continues that process of reregistration, but in terms of really interesting policy issues, certainly the Endangered Species Act [ESA] - pesticide interface remains front and center, with Deputy Assistant Administrator [DAA] Jake Li, who's an expert in this area, leading those efforts with Dr. Freedhoff.

The Agency, under the last Administration, because of the Farm Bill direction, did develop several new policies around how the pesticide assumptions should be made for ESA policies. It involved Fish and Wildlife and NOAA [National Oceanic and Atmospheric

Administration], and lots of federal agencies: USDA [U.S. Department of Agriculture] was led by EPA. It involved CEQ [White House Council on Environmental Quality]. There really was, I think, some pretty great collaboration across the agencies that are part of this process. But as you know, Lynn, EPA has announced a new policy that for new active ingredients, the ESA consultation process, if it's needed because of a predicted effect on endangered species, is going to happen at the time of registration and in that early process. EPA has acknowledged that is going to slow new active ingredients getting to the marketplace.

There'll be less litigation, and that certainly is a positive change, but the timing of those new active ingredients, seeing them slowed down getting to market is something that I think we're all watching.

And then of course, PRIA 5. We have until October 23 for PRIA 5, but when I arrived at EPA, PRIA 4 was just coming across the finish line in March 2019. There was so much excitement because PRIA is, perhaps in many ways, the lifeblood of resources that we don't see as much on the TSCA side, although, as you know, TSCA is supposed to work similarly, with fees and funding, but it's much more mature on the pesticide side. And each PRIA comes up with new categories for fees, new actions that EPA can take, new timings for pesticide actions to happen. And what I always enjoyed seeing was just the diverse support base around PRIA, from the farmworker justice groups who were ensuring that there was money in PRIA for worker protection initiatives, to the participation of the growers, the household disinfectant makers, the commercial agriculture groups, the companies that develop new active ingredients. It was just sort of a -- we talked about being in the tent before. The PRIA tent is very large and surprisingly collegial. And so it's great to see, and I'm watching PRIA 5 for sure.

LLB: During your tenure as AA, it was truly an all-hands-on-deck moment to ensure that there were disinfectants made available to address the impact of COVID-19. Our listeners need to be aware that this hit you front and center, Alex, because of your tenure as AA and the onset of working remotely and transitioning to a *very* different work environment, so I think the Agency got *huge* marks for their success in scrambling the jets and being able to redeploy resources to get these disinfectants available. In your view and looking back, are there lessons learned from that experience that are important to remember and perhaps replicate in other contexts? And are there longer term implications for the program that *was* created as a consequence of the pandemic?

ADD: Well, thank you, Lynn. I know, as we're doing this virtually through your virtual studio, we're still feeling the reverberations of the SARS-CoV-2 outbreak, and there are so many long-term implications. I would say one thing was the nimbleness of the Agency. When the virus started hitting the news in January, February of 2020, EPA's Pesticide Office had in place this emerging viral pathogen policy that was ready to go, which essentially said if a product is strong enough to kill a virus that is more persistent than a human coronavirus, more hardy than a human coronavirus, that product, we can presume, will be effective against SARS-CoV-2, even though we knew very little about it.

And the staff made very quickly to create what was then and is still known as List N. And so many products were added, and the staff really was just so dynamic and quick, and they had a plan because of this emerging viral pathogen policy, the first time it was ever used. So certainly, looking at that policy to see if it needs any tweaks to be ready for whatever the next virus is -- and there will be one, whether it's human or animal or -- being ready, having

the policies in place that everyone's comfortable with so that you can just go when you need to go is so important.

I will say an area that we learned was just difficult to deal with, once we were in for a longer experience with the virus, was the number of innovative companies coming forward who had never interacted with EPA before. Many of them were crossover from the hospital space or other types of industries, where they had a technology that they believed could be very helpful for addressing SARS-CoV-2 in the air or on surfaces, and even in paints and coatings -- that was a big area, as you remember -- could we coat everything? The banisters in Metro stations, could they be coated with an antiviral product? Knowing what it would take to prove the product was effective -- and over how long -- really just became quite a burden for the Agency staff. It was so -- there were so many products coming through that were making so many claims about their capabilities, and EPA has to review all of that. And there was no -- although efforts were made to propose one -- no protocol for doing the testing so that everyone coming in was on a level playing field. So you were just getting a wide variety of scientific studies and methods and claims, and it became pretty difficult.

As you know, a couple of novel products were authorized under an emergency basis, and those emergency registrations were later pulled back by the Biden Administration, realizing that they were no longer necessary as the virus began to taper down. But that's where I hope EPA, with any capacity it may have in the OPP, is to look at being situated for those novel product reviews.

And what would that mean? Do you have a team available that can do it? Do you pull people from other agencies? Frankly, all of those things were done during the pandemic before I left, and I'm sure were continued to be done: borrowing staff from other offices, from the Office of Research and Development, detailing people. But it can make for a pretty chaotic work environment, and it would be nice to be nimble and not chaotic simultaneously.

LLB: From our perspective, on the other side of the equation, EPA did just a superb job in scrambling those jets and devoting much-needed resources to ensuring novel products and technologies were made available at a time when they were most needed. So congratulations on the success of that program, Alex.

ADD: Thank you, and kudos to the staff that are still going. They're still working on this because the companies that maybe didn't get through in the process in 2020, 2021 are still hoping and believe in their products. The questions haven't gone away. There's still a need for those protocols and methodologies, and sort of that level playing field to keep the innovative marketplace moving, so EPA is still on duty for this task.

LLB: Absolutely. One question I have, and it might reflect a lack of full awareness, but before you ascended to the position of AA in Washington, you were Regional Administrator in New England. And my sense is -- although this may not be accurate -- that you did not have to address a ton of pesticide issues. So when you arrived at OCSPP and met with staff and learned about the complexity, diversity, and just breadth of the program, what were your first impressions when you took over at the helm there?

ADD: I will say this -- and I chatted about this with Dr. Freedhoff -- is when you go through confirmation for the AA role, because of the jurisdiction of Senate Environment and Public Works, which has TSCA, but not FIFRA (which is with the Senate Ag[riculture] Committee), the nominee gets a lot of questions about TSCA, but doesn't get asked a whole

ton of questions about what they will do with regard to the pesticide program. So I *will* say that when I arrived at OCSPP, my mental portfolio may have been skewed toward TSCA. And what made me -- what surprised me per se -- is that I realized that two-thirds of the office staff are in the pesticide program and how different the pesticide program is from the TSCA program in terms of diverse stakeholders, as I mentioned with regard to PRIA, and so many products and so much public dialog around. Do we need pesticides? Are we using them properly? What are the substitutions and alternatives? The conversation around, air quote, "chemical policy" is very, very open and mature on the pesticide side. As you know, there's the Pesticide Program Dialog Committee, the PPDC; there's the Tribal Pesticide [Program] Council; and there's just so much conversation about do we need these chemicals? How do we use them? What do we want to see? What's appropriate? And it was kind of exciting to be in a place where all of that was happening and, I would say, in a systemized way.

And to compare, the TSCA program was still getting its sea legs, with a new statute and a new funding mechanism. And so the -- it's almost like a big sibling, little sibling relationship, not only in size, but in terms of experience. One of the things we tried to do was bring the office together. And that, of course, as you know, is happening with the co-location downtown of the pesticide office moving from long time in Crystal City, across the river, to the headquarters building, so the programs will be co-located.

But creating a lot of cross-disciplinary teams, science teams where scientists in -- that are looking at eco-risk in pesticides -- could collaborate with scientists looking at eco-risk in industrial chemicals, the same for human health risk, really trying to create a more holistic unit of thought, not to affect necessarily outcomes, but to build capacity. And I know that that's still occurring, and that's an exciting place. There were also a lot of details where people, experts from the pesticide program, detailed over to TSCA for a chunk of time to bring their knowledge from the more mature pesticide program to the newly statuted TSCA program.

So some great opportunities -- if you love organizational management, and you love trying to make big groups of people achieve and do wonderful things and be a part of that -- there's no better office than OCSPP, because it is just an absolute laboratory of collaboration and thought leadership and sharing and mission. And really, it went from, as you know, it was often thought of as kind of a sleepy office to being a pretty front and center office.

LLB: Absolutely. And I'll make one pitch for one of my pet aspirations in life, that the Toxics Office, the Industrial Chemicals Office, embrace more FACA -- Federal Advisory Committee Act -- fora, like PPDC [Pesticide Program Dialogue Committee] *for* industrial chemicals, because I think the industrial chemical community is all the worse for not having a larger number of diverse stakeholder discussion groups to talk about the issues that EPA and the industrial chemical community are facing now, as a consequence of Lautenberg. Talk is good. It's not often helpful in resolving issues, and we have lots and lots of issues to resolve under Lautenberg.

Alex, I just so enjoy chatting with you, and our listeners just love hearing your thoughts and hearing what you're up to. Do you have any last parting thought or reflection you'd like to share with our listeners?

ADD: Lynn, first, thanks for the great time today, and my parting thoughts are to stay a supportive champion of the program as it evolves. It's coming up on six. Can you believe it? TSCA is going to be six in June. I've made analogies to TSCA and its age, and the age of a six-year-

old, which is around a first grader, fairly mature. We no longer have a toddler, so to speak. The statute's really evolved, and it's full of great promise.

Reflection for your listeners is there's so much to come, just like a six-year-old. You don't really know what they're going to --

LLB: Great promise.

ADD: Yes, you don't know what they're going to become and how they're going to focus their time and effort. There's so much going on in this program. It's so critically important. And so I encourage your listeners to stay, as I said, supportive sideline champions of the staff. They're working hard; the political leadership is working hard, and yet also to stay engaged in the policy dialog because these are big, big, important questions as we go forward in our country's management of chemicals. And it's an important conversation to be a part of.

LLB: Indeed. Brilliant, Alex. Thank you so much for a fantastic conversation. We just are very, very grateful that you are able to share your thoughts and spend some time with us. Thanks again.

ADD: Thanks, Lynn.

LLB: My thanks again to Alex Dunn for speaking with me today about life in the fast lane as a successful partner at Baker Botts, her transition back into the private practice of law, and what EPA's toxics policies have changed since leaving EPA as AA 14 months ago.

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