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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 am Lynn Bergeson.

This week, I sat down with Dr. Michal Freedhoff, Assistant Administrator, Office of Chemical Safety and Pollution Prevention [OCSPP], United States Environmental Protection Agency [EPA], and arguably the busiest person in Washington, D.C. Dr. Freedhoff is EPA's top Toxic Substances Control Act [TSCA] official and also administers the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]. Dr. Freedhoff discusses Office of Chemical Safety and Pollution Prevention's [OCSPP] priorities, plans for the New Year, and focuses on a few key issues, including new chemical review, industrial chemical testing, EPA's PFAS Action Plan, and how OCSPP is dealing with a workload that is not matched by existing resources. Now, here's my conversation with Dr. Michal Freedhoff.

Dr. Freedhoff, I am so delighted to be chatting with you today. You bring an extraordinary wealth of experience from your time on Capitol Hill and your very distinguished academic background. Let me ask you a question so our listeners can learn a little bit about you, the person. Did you intend to stay on Capitol Hill in 1996 when you were a Congressional Science and Engineering Fellow? In other words, did your policy work basically have you at hello and just never let you go?

Michal I. Freedhoff (MIF): First of all, Lynn, thanks so much for the invitation. It's great to be here. It's funny you should ask that question because before I went into chemistry, I actually graduated as a theater major from a high school for the performing arts.

LLB: No kidding? I wouldn't have known that.

MIF: Apparently, I have a history of detours. I enjoyed my Ph.D. research a lot, and I think probably one of the reasons why I went and got a Ph.D. was because my mother was actually the second tenured female physicist in Canada's history. So for me, when I did

move into the science space, that was the natural next thing to do. But somewhere part of the way through my Ph.D., I started to realize that I liked talking to other people about their research a lot more than I liked doing my own. So at some point, it was kind of this, "Well, what does that mean?" I guess that means I want to know a little about a lot of things, as opposed to a lot about one thing. And someone showed me the ad for the AAAS [American Association for the Advancement of Science] Congressional Science and Engineering Fellowships. And without really knowing anything about what I was getting into, I was like, "That's it. That's the thing. I want to do that." So I actually moved to D.C. the day after I defended my Ph.D., without a job.

LLB: Wow, that was gutsy.

MIF: Felt like I'd get a job, you know? And I did, for the ten months before the next fellowship cycle was going to start. But honestly, I really did never look back, and I didn't come to D.C. thinking, "Maybe I'll go back to the lab someday." I came to D.C. knowing that I would not.

LLB: Appreciating other professionals' research just makes you intellectually curious. And you knew what you liked, and you found it, and you've been just extraordinarily successful.

Apart from the drama background that I didn't appreciate before now, my next question relates to the fact that much of your career has been really spent behind the scenes on Capitol Hill. Those of us that know you and have been very appreciative and respectful of your distinguished career know that you've been exceedingly instrumental in lots of different legislative initiatives. To you, what has been the most striking about the transition from being behind the scenes, and so much of a technical and scientific support to legislation, to now being the face of EPA's TSCA and FIFRA programs? I mean, you are that person. What's it like?

MIF: It's definitely very different. I was used to writing things for other people, writing someone's quote, writing someone's speech, writing someone's amendment and someone's talking points. When I was on the phone with reporters, I could say whatever I wanted, as long as they agreed to quote me, if they were going to quote me, as a genderless, unnamed person familiar with the matter, you know?

LLB: Right.

MIF: I don't have that anymore. I'm also used to being able to talk to colleagues outside the Agency very openly. I tend to be very direct when I talk to people, and now, especially when I'm talking to people who have business before OCSPP or in other cases, litigation before OCSPP, I really have to watch myself a lot more than I ever did before. I think that's really the biggest adjustment is there's times when I feel like I just want to talk the way I used to talk, and I know that I just can't sometimes.

LLB: That transition has been absolutely effortless, because I watched you during your confirmation hearing, watched the Subcommittee hearing last month. And you're so fluent and conversational with people with respect to your job. You've made a fabulous transition.

MIF Thank you.

LLB: There are so many priorities in OCSPP. TSCA, as you know, has been demanding for years since the 2016 amendments that Lautenberg occasioned. But the Federal Insecticide,

Fungicide, and Rodenticide Act [FIFRA] is equally important, very scientific, and there are many compelling issues that I know are occupying your colleagues' time in the Office of Pesticide Programs. Just a point of curiosity, I think to me and many that I have spoken with. How do you allocate your time between two major, heavily scientific statutes like TSCA and FIFRA, and also, just balance your personal life? I know you have a family, and those are difficult decisions to make, but how do you do it?

MIF: In a way, it's easier than it was on the Hill, in terms of the predictive part. Here's an example. When the BP oil spill happened, it changed my entire picture of what my job was going to be for the better part of a year.

LLB: Wow! Of course. That makes sense.

MIF: And since we just launched -- we were -- this was when I was on the Select Committee for Energy Independence and Global Warming staff and the Energy and Commerce Committee staffs. The legislative and oversight response to the BP oil spill became the thing we were working on. All the new things that we had planned on doing in the better part of that year really took a backseat to responding to the BP oil spill. I would say that doesn't happen in the current job.

LLB: Happily.

MIF: Not really. I mean, not yet. Yeah, that's true. And so normally I generally know what's coming up. I generally can mentally prepare for what the next day is. As I said earlier, I love jumping from thing to thing. So if I'm going from a biotech briefing on PIPs [plant incorporated protectant] to a meeting on how to move forward with a particular TSCA thing, to an interview with you, that's a great day for me. That's energizing and stimulating for me.

In terms of work-life balance, that is always a hard thing to strike in these jobs, and I've always worked pretty hard to impose boundaries on my personal life -- ever since I had kids -- because honestly, there's too much about these jobs that could lead you to conclude that you're so very necessary at all times that you have to skip all the parent-teacher meetings and doctor visits and hockey games and college visits. But the truth is you don't, so setting boundaries is something I work really hard at, and that doesn't mean that there won't ever be an exception that causes you to work super late or miss a family event. But you just have to force yourself not to let the exceptions become the rule.

LLB: Yeah, absolutely. Five, six, seven years ago, since the run-up to the Frank R. Lautenberg Chemical Safety for the 21st Century Act, was much before June 22, 2016, you worked so extensively with Congress on that exceedingly important law. Dr. Freedhoff, did you ever imagine when you were there in the room that you would now be, five and a half years later, Assistant Administrator, basically implementing the very amendments to the law that you were instrumental in writing?

MIF: After TSCA was enacted, there were many, many, many parties in our staff, and I really loved hanging out, and there were just a lot of parties to celebrate because we had all really just worked so hard on that law. And honestly, I remember, at one of these parties after it was enacted, someone came up to me and asked me if I'd ever thought about becoming the Assistant Administrator for this office.

LLB: No kidding! Wow!

MIF: Yeah!

LLB: How timely.

MIF: And I, honestly, I never had. It didn't even occur to me that that was a thing I could do until after the law was passed. It's a crystal clear memory in my mind about when that moment was, and I've always sort of puzzled over it, like, why didn't I ever think that, but I honestly didn't.

LLB: Well, we're glad that you are, given your vast, experiential background that brings so much to the job and of course, your academic background. But knowing what you know now, being in the position you are in -- and I know hindsight is always 20/20 -- but looking back at the amendments and knowing what you know now, would you do anything differently?

MIF: Congress, and in particular, Senator Markey, my boss at the time, felt very, very strongly during TSCA reform that we make sure that the Agency operated on very tight deadlines, especially for some of the TSCA Work Plan chemicals, because people had been waiting decades for EPA to address some of those chemicals. Of course, this country shouldn't have had to sit and wait while dozens of other countries were able to take strong action to address asbestos while we were able to do nothing. And I will admit that throughout the TSCA negotiations, EPA consistently told us that our deadlines were too aggressive, and we consistently ignored them.

So here we are, five years in, struggling with deadlines. The last Administration missed the deadlines on nine of the first ten risk evaluations. While I've recently talked about resource requests not being made of Congress, the truth be told is that resources is only one of the challenges. There is a lot about the inter- and intra-agency processes that I didn't fully appreciate before I got here. I still think the tight deadlines were the right way to go, given the health risks we're trying to address for some of these chemicals. But in hindsight, I wish we'd thought more about the tools and the structure that EPA might need in order to meet those deadlines and do what Congress expected.

LLB: I suspect there are many on this side of the aisle in the industrial chemical community that would agree with that, simply because it has been very demanding on both EPA and industry to keep up with the tsunami of regulatory deadlines occasioned under the law. And EPA has done an admirable job, given resource constraints to which you alluded, and the complexity of the law, and the newness of some of the provisions and concepts. So a little bit more time certainly would have been desirable, but we're at where we're at, and people make good with what they have, right?

MIF: Or just time in different parts of the law, right? I mean, when you think about the prioritization and risk evaluation time period, those are a much bigger chunk of time than the rulemaking part, once we finish the risk evaluation, so it could just be sort of a structural thing that we might have done differently or thought about doing differently, had we known.

LLB: Indeed. Well, let's transition to new chemicals. That's an area of considerable interest. We do an awful lot of work under TSCA Section 5. There is, as you know well, both from probably phone calls from our staff and others that there is some discontent with the level of review, the quality of the reviews, and the length of the reviews for new chemicals. One topic that I wanted to touch upon, Dr. Freedhoff, relates to incentive to conduct testing in connection with new chemicals. To our eye -- and this might be just a very biased view -- it seems that there may be less incentive to do that if the testing only changes a protective

level that EPA uses to inform a risk management practice. We keep hearing that from some of our clients, but could you help us understand how EPA views the addition of new testing in connection with a PMN [pre-manufacture notice] submission?

MIF: First of all, I'd say data is always better than no data, and that's especially true in the new chemical space, where characterizing the endpoint or finding the right structural analog is not always easy. And testing can also remove some conservatism that we otherwise would put into the assumptions in order to address the uncertainties that the fact that it's a new chemical brings to the table. So we think -- we also always weigh testing actual data that we have on a new chemical more heavily than we would weigh studies on structural analogs. So I actually think that it helps us provide more precise risk assessments and therefore more precise and targeted risk management. So I think we feel like when data comes in with a PMN submittal, that -- always assuming it's a well-designed study and all of those caveats -- I do think that it gives us more confidence in our risk assessment and more assurance that the protective measures that we might put in place if needed are the right ones. So I'd always encourage that companies come in for pre-notice consultations to ask us that question because it's -- maybe there are times when we know enough about the structural analogs, where the data wouldn't be as helpful as in other times.

LLB: Well, we certainly support the pre-submission consultations and have found those to be very helpful, although we know it's burdensome for an already overstretched EPA staff to accommodate those requests. But with regard to new testing, we had heard or perhaps read somewhere that EPA was working on not necessarily guidance, but just a clearer articulation of when new data -- as opposed to analog or read-across or other type of information -- might suffice for purposes of new chemical review. Is there anything in the works in the Section 5 program in that regard to articulate when new data might be most needed and most helpful for EPA?

MIF: I think we are looking more generally at ways that we can work smarter, not harder, like Senator Markey always says. And I think -- so I don't know that I have a specific answer to you about a moment in time where we'll send out a piece, send out a release or something that just says, "Now you don't have to do this test or that test." But I do think we're working generally, some with specific sectors and some in a broader context, on ways that we can be clearer about what we need and ways that companies can more effectively and efficiently navigate the regulatory and health assessment landscape.

LLB: Right. That would be most helpful. And with regard to the numbers of new chemical notifications being submitted, there are lots of different independent sources that would suggest the numbers of cases has declined, some would say somewhat dramatically over the last several years. I'm not going to go into all of the metrics, Dr. Freedhoff, because I think you would agree that that's a fair statement. But to what do you attribute that decline?

MIF: So in terms of submissions, it's been either actually up again in 2020 and 2021. I'm not a correlation equals causation person, but I will say that the decline in new chemicals submittals started just about immediately after the 2018 TSCA Fees Rule was finalized. And so one could ask industry -- because I think industry would be the ones to have an answer here -- whether companies are being a little more judicious on when they hit the Send button on their PMN submittals because of the fees and the recognition that, unlike the pre-Lautenberg days, there will be a full risk assessment and review done on every new chemical submittal.

LLB: That's a good point. I know when the fees went up, they had been at $2,500 a submission, and then they're now $16,000 or $16,500. I don't recall what it is, but that is a material difference. But the workload for those of us that are much more familiar with PRIA fees under FIFRA, $16,500 or $16-even, it strikes me as still a very modest amount, given the amount of work that goes into a new chemical review. It's quite substantial.

MIF: I would agree with you generally that there were a number of -- I call them compounding errors, honestly -- in the budgeting space that occurred since the law was enacted. I think Congress really expected that more funding would be needed, not just in new chemicals, but also to be working on ten risk evaluations at once in the first few years, and now ten rules and 20 risk evaluations at once in this next series of years. And Congress wrote of these requirements that up to 25 percent of the fees of some of the TSCA cost of implementation could be recouped through fees. And when you take a backward look at what happened for four years, Congress was never asked for any additional funds.

The Fees Rule was finalized in late 2018, so there weren't any fees collected until 2019. The highest cost activity, which is the first ten risk evaluations, was completely exempted from fees. Then as a result, the Fees Rule recovered only about 13 percent of the authorized TSCA costs, not 25 percent, which is what Congress was thinking about. And that was 13 percent of an already too-low baseline. So we've just been -- I have to hand it to the staff. They're amazingly resilient and creative and smart and resourceful, but they've been operating on a shoestring budget for four years now, and I really can't stress enough that I think it's in everyone's interest that the program be able to operate in a sustainable way. And one of the answers to sustainability is sufficient resources.

LLB: I couldn't agree more. I was really quite stunned when you noted at the recent House Energy and Commerce Subcommittee meeting that EPA is operating with less than 50 percent of the resources it believes, you believe, are needed in the New Chemicals Division alone, which is a shocking number. Because we work both sides of the program, both TSCA and FIFRA, we know that one of the ways you've probably been able to triage this shortfall is to rob Peter to pay Paul, as it were, take some scientists out of the FIFRA office and put them in the TSCA office. But when you squeeze a balloon, you're displacing things in other areas which invite resource problems. So how were you triaging this shortfall? And do you expect the cavalry to be headed your way any time soon on the appropriations front?

MIF: I sure hope so. This was the first year, the FY22 budget request, that there was sort of a down payment request made to put the pieces back together when it comes to the budget. And it's not just different TSCAs. The pollution prevention programs, which were not exactly well loved by the last Administration, were decimated in order to shift some of those people into doing TSCA work. I think we have less than one full-time employee who is working on lead regulatory efforts for TSCA, partially as a result of these constraints. So I really-- I'm very hopeful and cautiously optimistic about Congress and the appropriations process, but at the same time, it's going to take time to recruit people; it's going to take time to hire people; it's going to take time to train people. And it'll be well into the second year of the Biden Administration before we realize the benefits of that down payment, when it comes to having more trained expertise on staff that are ready to run.

LLB: Finding people that are gifted scientifically and have a facility or an affinity for regulatory science is challenging. I mean, we have challenges in that regard, right? And nine of our scientists are former EPA employees here. In addition to just the numbers, I know the disciplines is an area that you have noted is something that you're focusing on. For example, it would be most helpful in the New Chemicals Division to have additional resources in the

industrial hygiene area because that's a huge -- worker exposure -- is a huge issue with regard to new chemical review. Do you anticipate finding these people and training them up, as you suggest? Or is that likely to be a big challenge this year and next?

MIF: I very much hope so. I think human health assessors, some toxicologists is another pressing need. Another strange policy that -- or not policy -- this was more of a practice, was that in the last Administration when very senior non-supervisory scientists retired or moved to different jobs, the offices really struggled to get permission to fill those slots with other senior, similarly qualified non-supervisory scientists. And so there was also -- and of course, a more junior scientist can be brilliant -- but it's not the same as having somebody with decades of expertise and experience looking at these types of problems. So there's -- it's not just about a type of scientist or the number of types of those scientists that we can bring on board. It's also about striking a balance between having folks that have the level of experience with some of these issues and bringing in new scientists who can be trained and become those people in time.

LLB: It's a daunting task, but we certainly applaud your efforts to populate the offices that you are implementing or have jurisdiction over, Dr. Freedhoff, with competent, talented people to help just distribute the workload in a way that is able to fulfill EPA's job under a very demanding statute, TSCA being one of them. But FIFRA is equally important, and there are lots of deadlines under that statute as well.

MIF: Yes.

LLB: Let's transition to existing chemicals in the remaining time we have, which is not much, so I'll move this along. There's been a lot of talk about the application of the Toxic Substances Control Act to articles. I'm not going to go through the somewhat tortured tale of PIP (3:1). I think the takeaway message there is that the law and the regulations implementing the 6(h) rule under TSCA applies to some nontraditional cohorts with regard to articles and per- and polyfluoroalkyl substances, otherwise known as PFAS. The 8(a) proposed rule that came out also applies, should it be implemented in final along the lines of the proposal, which I am confident it will, because this is an NDAA [National Defense Authorization Act] creature, not an EPA OCSPP creature. It would apply to again nontraditional audiences and cohorts. Is EPA planning on engaging in an extensive rollout to ensure that everyone in those areas is sufficiently aware of what the rule requires and how best to comply with it?

MIF: Yes. Honestly, it shocked us when the PIP (3:1) compliance issues came up in just the first couple of days that I was at the Agency.

LLB: That must have been quite a Welcome to My World moment.

MIF: I was like, "Oh, this is the first thing I'm doing on TSCA, I guess."

LLB: Implementing a Trump Administration rule that no one likes.

MIF: It was just shocking. Honestly, I think you heard me say it at the hearing in Energy and Commerce. I don't think the Trump Administration did anything wrong on that from a procedural perspective. They did all the things the Agency normally does. They did Listserves, they did webinars, they did public comment periods, they did outreach. And yet it wasn't just small companies who aren't normally familiar with regulatory things in D.C. who missed it. It was giant swaths of the economy and huge trade associations that have people who are dedicated to following what the Agency does, so it was shocking to us.

We're absolutely thinking along those lines for the PFAS Section 8 rule. I've said it before, and I'll say it again, if anyone in industry has ideas for how we can make sure that we're better communicating, since we clearly didn't succeed as we attempted to in the PIP (3:1) case, we really welcome those ideas.

LLB: That's good to know, and I hope our listeners listen to your suggestion there and assist EPA with any thoughts or ideas. When our clients started to look at the January rule that was to be effective in March on PIP (3:1), there was definitely a disconnect there. PIP (3:1) has been in the EPA Work Plan chemicals since 2014. It was in the proposed rule. The response to comment document suggested that PIP was used a lot in various electronics, so it was a teachable moment, and one that I hope is never, ever repeated, because as busy as you were, we fielded a lot of calls, too, with some very, very stressed importers, article manufacturers, distributors being very concerned about the March deadline. The No Action Assurance was most appreciated, and in my view, a suitable response to it, an urgent situation that I hope never arises again.

MIF: I feel the same way, and it was surprising to us, and we clearly felt an obligation to respond, even though we were surprised. But I think what I further say to people is that we need to write legally and scientifically defensible rules, so it's not enough for us to hear, "We can't do this because we have no idea what's in our supply chain." We need specific information; we need to understand if stakeholders feel like they need to be exempted, or if they feel like they need a different gauge, or if they feel like they need some other particular accommodation. And when we propose a rule, we need to understand precisely why. It's not enough to just say, "We can't because we don't know."

LLB: I think in more recent -- and that's not to say not in the older rulemakings, but certainly in extending a proposed rule to extend the deadline in some respects to 2024, you've made it abundantly clear. What are the data elements? What should comments look like if you're in need of an extension beyond that deadline? We are on notice in a very significant way what exactly the information is needed in and why.

Let me ask you one more question about existing chemicals, as I know our time is coming to an end, and a topic that is of great interest to many of us is the whole-chemical approach to TSCA Section 6 risk evaluations. You had mentioned it, maybe to my ear, the first time in June, when you spoke at the ELI, GW, and B&C TSCA at Five, that EPA intends to take a whole-chemical approach, and if you determine a whole chemical presents an unreasonable risk, how might that affect the risk management of specific uses? Have you thought through all of the implications of that in a way that our listeners can understand better what the whole-chemical approach means?

MIF: Sure. First of all, I wouldn't mind taking a minute to clear up a common misconception that probably results from our failure to better communicate in the first place. The framework rule and Congress expected EPA to evaluate the conditions of use, and we're still going to do that. One industry stakeholder asked me at one point whether this shift to whole-chemical meant that we were going to just find that one condition of use posed a risk and just finish the risk evaluation, stamp the entire chemical to be unreasonable risk, and move to rulemaking. That's absolutely not what we're doing. The analytic component of what the previous risk evaluations contained is still going to be there, so you're still going to be able to read it and see that we've looked at 20 different conditions of use, and we've identified those conditions of use that are driving the unreasonable risk determination.

Your question really focuses on what are we going to do about it then? I would say, speaking very generally, I do think we would generally be targeting our risk management approaches to the conditions of use that drive the unreasonable risk determination. But just to use a really stark and extreme example, let's just say we were going to ban the manufacturing and processing of the chemical because those activities showed an unreasonable risk that couldn't be addressed in any other way. Even if the distribution and commerce didn't show such a risk, you could still imagine how banning the upstream manufacturing and processing would also implicate the downstream distribution use. So I don't want to speak in absolutes and say that our rules will only ever impact the conditions of use that pose unreasonable risk, because there could well be implications on other uses as well, but as a general matter, we'd be looking to address the risk in the uses with known risk.

LLB: That's very helpful. Appreciate that. And I would expect EPA's articulating its thoughts in this regard in the context of the specific risk evaluations that will be rolling out throughout the new year.

MIF: Yes.

LLB: Dr. Freedhoff, I know we're coming to the end of our time together, but I thought I'd give you this opportunity to add any other comment or statement or topic that I didn't have an opportunity to ask you about. But if you'd like to add anything, please do so now.

MIF: I would love to, and thanks for that opportunity, Lynn. More than any rule on any one chemical, what I'd really like to do when I leave here is be able to say that I left behind a program that was running sustainably. To me, sustainability is not just about resources; it's about scientists and the right kind of scientists. It's about processes that work for industry and are predictable and transparent for stakeholders. It's about finding efficiencies when we can find them, and it's about working collaboratively, not just with environmental organizations, but also with industry and other stakeholders. So I really hope that in communicating with stakeholders, I've made that really clear, but I thought it would be useful to make it clear here and just say that my door is open, and while I don't expect that there'll be unanimous agreement with everything the Agency does in the coming few years, I hope that there will always be a recognition that we've explained ourselves and shown our work and that people understand the basis for our decisions.

LLB: Well, thank you, Dr. Freedhoff. You know, I heard four key terms: predictable, transparent, sustainable, and collaborative, and those are concepts that I think we can all agree upon. Allow me to thank you for joining the conversation today, to thank you for your work. You have been a superb leader for an EPA staff that is working above and beyond the call of duty, and believe me, we appreciate that. It's been a tough, tough last several years, and I think the EPA team that you lead are extraordinary people and really do their darnedest to get the job done, and we appreciate it, and we appreciate your leadership. Thank you so much.

MIF: I wholeheartedly agree with the shout-out for the EPA staff. They're wonderful.

LLB: Indeed. Thanks so much, Dr. Freedhoff.

MIF: Thank you.

LLB: My thanks again to Dr. Freedhoff for speaking with me today about a wide variety of TSCA issues and her plans for the new year. We packed a lot into this conversation, and we hope you found it useful.

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