Episode Title: What to Expect on Capitol Hill and at EPA OCSPP in 2023 -- A Conversation with Jim Aidala

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

This week I sat down with Jim Aidala, Senior Government Affairs Consultant at B&C and its consulting affiliate, The Acta Group. We discussed what to expect in 2023 from Capitol Hill and the [U.S. Environmental Protection Agency] EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) when it comes to key chemical matters. Jim is, of course, one of the country's most talented pesticide experts, and, as a former Assistant Administrator of what is now the Office of Chemical Safety and Pollution Prevention and a founding member of the Capitol Steps, Jim offers laser-focused insights on chemicals with wit and flair. We cover a lot of territory: EPA staffing deficits, a divided Congress, and the many daunting legal, science, and policy issues that this OCSPP is tasked with solving -- well, at least managing. Now, here is my conversation with Jim Aidala.

Jim, thank you so much for being here today. I've been looking forward to our conversation because you always have so many incredible, entertaining, and interesting insights on the topic of the day, which is what to expect from Capitol Hill and OCSPP in 2023. Thank you for being here.

James V. Aidala (JVA): I'm glad to be here. And yes, we'll be entertaining here, as it always is, but this may be a little more entertaining than usual.

LLB: Let's get into why that may be the case. We just entered year three of the Biden Administration, and there's an awful lot going on in the OCSPP. But aside from the number of topics underway, how do you think things are going?

JVA: Generally, they're going pretty well. This is the third year of an Administration, a new Administration, which means they're moving into adolescence, as I like to call it, for a first term. People are hired, and they did a good job of getting people in early, in terms of

political leadership. You may recall that under Mr. Trump, for example, the permanent AA [Assistant Administrator] position wasn't filled about -- 'til about now.

LLB: I remember that.

JVA: Yes, that was a problem. And usually, it's at least -- in the modern era -- a good six or nine or ten months. They found a way to bring their new political leadership in very early and got them in place, got them through the Senate and so forth. That was good. Now, there's still some positions outstanding, but for our purposes in chemicals and pesticide regulation, that was an early win, which helps, just having people in place. So that was step one, to say the least.

And then what their priorities are. Certainly Administration-wide -- the Administrator was certainly very clear about that -- it's climate and environmental justice and emphasizing some science issues, just generally science integrity, I guess they call it, and then reversing the Trump decisions if they felt they weren't appropriately scientifically based. On that score, they've been doing all those things. Climate is less important for OCSPP, but it doesn't have zero role because, for example, in agriculture, some pesticidal activities and farming practices can affect some climate issues. We might get into that, might not, but that's going to be an issue, for example, in this year's Farm Bill, looking ahead to 2023 and not just looking back.

So climate will be an issue in the Farm Bill, even though the Farm Bill mostly is about the feeding programs, like food stamps and things, and then also the farm subsidy program. But it'll have a -- farming has an impact on, and food production has an impact on climate. And then, of course, when I say adolescence, doesn't mean that -- it may be an unruly teenager, according to some stakeholders, because the programs now have made decisions on things like chlorpyriphos, debate about the [premanufacture notice] PMN program being too slow and unpredictable. [Endangered Species Act] ESA implementation in the pesticide spaces has been the huge endangered elephant in the room, if you will, and clearly has been a major driver of what the program activities are in pesticides. I'm sure we'll get into all those things as we go along this morning.

LLB: Agree. There is just an awful lot on Dr. Freedhoff's plate, who is of course Assistant Administrator of the OCSPP, a position you once held, Jim, so I know you feel her pain, given the intense scrutiny on many different issues on which stakeholders don't always agree. You mentioned, for example, some of the concern that industry has expressed, and it was articulated or reiterated in a *New York Times* article recently regarding the slow pace of new chemical reviews at EPA. That's an issue that has been really tenacious. It hasn't improved very much. But I think, given some of the staffing and funding issues that I know you probably wish to talk about, staffing and funding has been a huge issue for this Administration. How has that changed in the recent past? Is it improved, for example, as I believe it has?

JVA: It has, compared to what you want to call a baseline. But just for the record, too, I'd like to recall my time at EPA as one of joy, not pain. But that's a different discussion.

LLB: Well, it was a joyful time for all of us, Jim, because that's when I first met you.

JVA: Well, that's a whole separate podcast, I think, anyway. But --

LLB: **--** True that!

JVA: The budget, ironically, speaking of my time, I -- wasn't entirely a random segue. The budget peaked in 1999, we read. *New York Times* has recently put a story about it -- at least on the Web -- portrays a pretty front page story on what's happening at EPA's budget. Basically, they went through a decline for a lot of reasons -- under Bush and Obama, both really, brought back a little bit under Democratic control, and that's as expected. Now, in the infrastructure bill, they've been authorized to have even many, many, many more positions to really bring them up. In a bill that was just enacted, the Appropriations Bill, they were slated to try and get even greater amounts of money and positions, especially for OCSPP in particular. That didn't quite happen. They got some of that. For OCSPP, it was about 10 percent of what the President's budget had called for. Again, we can get into some of those particulars, but dollars make a difference. And right now, for example, there's some other reporting in addition to what the *Times* had. There's about a thousand positions that are already authorized at EPA that aren't filled because of money that's -- money and positions that have been authorized, which is really crucial.

First, you've got to have the authorizations -- the way the system works. Now, you got to go out and find those people. You got to recruit them, you got to train them, you got to get them in place. You got to find a place for them to work, which after COVID's a little easier because of office space gyrations and things. But otherwise, that's been a limiting factor sometimes.

In the old EPA building, for those of us that -- speaking of, talk about the painful memories -- but the old building where you just literally had limits to growth from space, from hiring people and things that you did get authorization and things like that. So all that takes time, which is frustrating to a lot of stakeholders. If nothing else, for example, let's go back to the PMN delays that some people complain about. Well, if nothing else, more people will help get decisions through, even if you disagree with the decision, at least the paperwork's moving, to then *have* that discussion with EPA, even if you *do* have some other information to bring to bear to a decision.

Same thing for pesticides. One of the things that happened last year that will be on slate now for '23 is reenacting -- reauthorizing, I should say, extending further PRIA. We're now in PRIA 5, as it's called, which is the sharing of the cost of registration activities with the industry. If you have a new chemical to submit to the pesticide program, that cost, you have to send a check before that application is processed. Similar programs to be set up under TSCA [the Toxic Substances Control Act]. They just – they set up much earlier because that was authorized in the TSCA Two amendments, the Lautenberg amendments, so that program is a little -- far less mature and kind of still getting underway, still needs to be increased fees and things to help pay for the horseshoe nails to be done. So even if you don't like what EPA is doing in terms of policy and other kinds of things, they need people to do it, in order to even -- whatever you want to describe it as: complain about it, debate about it, and just get your paper approved, even if you don't have a controversial issue of any kind.

LLB: For those of us in the space, we are pleased that EPA is making headway in recruiting people, filling some of the vacancies that occurred during the transition from the former Administration to the new one. But as you say, training people in these highly nuanced, very scientific statutes takes time. The fact that there are lots of bodies running around doesn't necessarily mean problem solved. We have been urging our clients to be patient, but after a number of years now, patience is wearing thin, for sure.

You mentioned PRIA, Jim, PRIA 5, as being kind of huge, recognizing that there was considerable anxiety in the pesticide community about when and whether that would go

through. What about some of the other priorities that you mentioned? Chlorpyrifos, worker protection seems perennially to be an issue on the front burner. And of course, the Endangered Species Act, an intractable problem that has existed for a long, long time, probably something that you can reminisce on when you were Assistant Administrator. Can you comment on each of those?

JVA: First of all, chlorpyrifos, as a chemical issue, they made a decision, people disputed, and all things like that. What's interesting there is still the following issue, which is some of the uses call it what we would otherwise say some of the label uses appear to have, according to EPA's own record, to still meet the standard. But EPA, in its decision on chlorpyrifos, said "No, we're taking the position that the label as a whole, the use pattern as a whole stands or falls together. And in particular because of some of the specifics about that case, given the court order to finally make a truly final, full and final, decision on that chemical.

And again, I'm not going to -- we could spend a separate hour on that. But that said, the fact that there are some uses that appeared to meet the standard, according to EPA's own analysis. In historic terms, usually the Agency would let the company then slice and dice the label up to meet that standard, if again, EPA's own assessment said that that would be permissible. In this case, that was not allowed to be done. And there's debate about that:

"Who really offered what?"

Did they really -- "You didn't put it in the label."

"Well, we said we would."

"Well, you didn't."

Again, I'm not trying to get into all the particulars, but the bottom line is, if that's a new template that EPA is only going to look at chemicals at a specific point in time and not allow that back and forth with the registrant, that would be a significant change in behavior. And it's not clear that's a new precedent. It's just -- it may be a one-off, but again, that's something to look forward to as EPA still continues to do the registration review of pesticides as required under the law. So that's chlorpyrifos, and that's a good segue to registration review.

I would say that there's three or four things to point out to the audience in this podcast, things that you may not have paid much attention to that are really important. Really high up on that list would be that in the Appropriations Bill, there's an extension of what was the 2022 deadline for registration review. That deadline has now been extended to 2026, and I assume be conditioned on the inclusion of some kind of reduction to threatened and endangered species reduction in risk. I'm sorry -- not reducing those species, that's a bad idea -- but reducing the *risk* to those species. That is in the bill, and most people didn't see that coming. And it was partly a response by Congress to deal with the, quote, "2022 deadline" that some people were worried -- some stakeholders worried that that would mean that, just under some kind of court order without any real particular assessment, scientific basis and so forth, you might see some kind of action that would be imposed by the fact of a mere passing of a deadline as opposed to based on some kind of analysis. So that takes some of the pressure off.

LLB: Because that is an important change, and I, for one, haven't seen a whole lot of press on that. According to the Section 711 in the omnibus appropriations bill, the pesticide case

covered by that section "not later than October 1, 2026." I kind of thought EPA was making much of the fact that it met the old deadline. This is a substantial extension from 2022 to 2026. Why?

JVA: Two reasons. One is EPA met the deadline for what they felt were -- but what they then called the, quote, "preliminary interim decisions" and "proposed interim decisions" and then the "final interim decision." The reason they kept calling them interim decisions and whatever other adjectives was because it wasn't a full and final registration review.

And if you read the documents, it said for two reasons. One, that they had not completed all the required activities under ESA and still the sort of lingering uncertainty about whether or not, I should say more precisely, what *was* the definition of having a complete endocrine disruptor assessment to a full and final conclusion? And that was always a caveat. And there was always a boilerplate. For endocrine, for example, there is almost a "traditional," quote, unquote, not to be cynical about it, but a paragraph that said, "We're working on the endocrine disruptor program. Right now, we don't think there's a problem, but we're not finished yet." That was the endocrine paragraph. And similarly, there was an ESA section, and that changed over time, but it was certainly conceding that it was not a full and final ESA determination that they were compliant in every which way under ESA.

First of all, EPA -- that's not an EPA decision per se. That's officially implemented by the Services, Fish and Wildlife and NMFS [National Marine Fisheries], appropriately so. The bottom line is that they had -- technically did not have a full and final registration -- re-registration -- registration review decision. And the courts in some recent court cases had started to say that in the Ninth Circuit. That was what led to some of the fear by some stakeholders, especially rural groups, that -- "Hold it. Does that mean some judge could suddenly impose severe restrictions or altogether vacate the registration?" That would be, shall we say, a bad thing from that point of view.

That's why this clears that up. Again, it doesn't just say, "Just extend the deadline. EPA can dawdle." It does say there has to be some -- include some reduction in the potential risk to threatened and endangered species. And that's the important concession. Back to the point of, "Okay, we admit that you're not done with ESA, but you have to show progress."

LLB: Right. It probably provides much needed relief from the threat of litigation and perhaps acts as a deterrent to the initiation of litigation by NGOs [non-governmental organization] and others.

JVA: In that particular piece of the puzzle, that's correct, the ESA piece, which is pretty huge. And if you want to talk about the number one issue for the pesticide program, it is ESA, how the Agency can continue to work toward actually, at long last, finding something that's a feasible, workable ESA program to the satisfaction of stakeholders. If you will, stakeholders are never satisfied, of whatever stripe, but certainly to the agencies, the implementing agencies, and in this case, their sister agencies, and then also to the courts.

That's really the goal of the ESA program. They're making really phenomenal progress compared to the past 30, 40 years, literally. But at the same time, that progress means, okay, the good news is we're making progress. We're starting to add mitigation options on the label. Now, the bad news is, "Okay, how's all that going to work? And who has to do it? And will it really be effective?" But that's still significant progress to the baseline of past attempts by *many* administrations, and at the same time to be determined what the impacts are going to be.

LLB: The progress that is being made under the ESA, do you attribute that to just the passage of time, a renewed urgency to kind of getting this matter resolved, to Jake Li's skills as a negotiator and problem solver? Jake, of course, is the Deputy Assistant Administrator for pesticide programs and is widely credited with being a skilled and able problem solver in this particular area. Or perhaps it's all of the above. What do you think, Jim?

JVA: Sure. Like any good multiple choice question, saying all of the above is a safe harbor.

LLB: Yes, indeed.

JVA: But I think -- that's one reason I did mention the early arrival of the political leadership for this Administration, which included Jake coming in, along with Assistant Administrator Freedhoff. And that meant that there was senior political level attention paid to this important issue, not that past administrations haven't, starting with the early litigation under the Bush -- Bush II Administration. And that meant that Jake's personal credibility in this issue and his skills and competency, I think, have gone a long way. At the same time, now, we've got what looks like -- I shouldn't say we. Well, we all do. We're all stakeholders.

But I mean EPA has a program that's starting to look like a program -- and is starting to turn out decisions that say things like "Here is that early mitigation," which is -- it's a sort of simple summary sentence that has big meaning. But early mitigation on labels to address some, if not most, if not all in some cases of the species concerns. How is that going to work? How's that going to be considered implemented, in effect, considered by the growers to be able to be done? Is it feasible for them to do what is, at least on the initial cut from Crystal City. I'm sorry, they're not in Crystal City anymore.

LLB: Right.

JVA: All those -- they're downtown. Anyway. But the program decisions in Washington to be implemented across the vast space of American agriculture. Will it be effective? How will it operate? Can it be enforced?

Another issue is state enforcement. States have been really -- the state enforcement of pesticide labels has been in longstanding programs. The states are the primary enforcement authorities, but they've never really had to deal with implementing ESA per se. And technically they won't, because technically they're just going to be following this current program. Did the grower or the applicator follow what's on the label?

But the label's got much more responsibilities on the grower to do things like check and see whether there's a species map that shows it could be a prohibition in your specific area. That's much more granular and much more site-specific. And you have to look at the label within a certain timeframe before your application, and, and, and -- much more requirements on the growers. At the end of the day, is that going to be both feasible and acceptable to the growers? I don't mean acceptable that they have to be happy about it. But just can they do it? Can they literally kind of make it work? And that'll be a question as we go forward.

LLB: Well, speaking of going forward, do you expect reasonable further progress on all of these areas? And kind of it's an inverse way of asking, what are the implications of the House turning Republican? Do you expect interference, oversight, or support for moving forward on some of these programs in a way that will ensure their continued success, or something else?

JVA: Can I go back to the all of the above answer?

LLB: Of course you can, Jim.

JVA: Two or three things. One is, will there be more sound and fury? Absolutely. That's what Congressmen and Senators get paid for at some level. Not to be cynical and snarky and too light-hearted about it --

LLB: -- Too late, Jim.

JVA: Underneath that, though, are -- okay, with the other party being in one of these positions to ask those, quote, tougher questions, there is accountability. Accountability is a little bit different when you've got one party in control of the House or Senate, the Administration being the opposite party. There'll be oversight letters; there'll be some hard questions that will maybe, shall we say, may be hard to answer readily and crisply by the Administration. That's not going to be any news generally. But some people have said, "Gee, we expect a lot of oversight from the House side, and it's going to really dog EPA, dog every Administration official across the board," and so forth.

Two things about certainly the space of chemical and pesticide regulation. One, OCSPP, to those of us in the audience that listen and care and talk and are concerned in our careers about these issues, mostly Congress does not care about those. I don't mean that in a bad way. It's just, what are the priorities for Congress and the Administration? Big budget issues, climate, things like that. OCSPP doesn't have a big role in the climate spaces. We discussed all that before.

Now, at the same time, things like farmers -- if enough farmers get agitated about fill-in-the-blank, particularly a pesticide decision, or a particular requirement for ESA implementation, or chemical companies across the board say that they can't get new products to market or it's going to move innovation offshore -- those are issues that do rise to the level of Congressional attention. But at the same time, just having Congressional attention is necessary but not sufficient. To do oversight, you have to have somebody pay attention to it. You have to have somebody who's really getting into the details of it, not just writing a letter saying, "Are you hurting innovation?" And then EPA writes a letter back that says, "No, we're not hurting innovation. We would *never* do such a thing." "Are you protecting the public?" "Yes, of course," etc.

You get the idea. The question is, will oversight be effective? I should say, to *be* effective, you have to have somebody interested. You have to have staff that are educated enough and can get the member interested enough to read the briefing books and to get down into detail so that they press EPA or press a witness in a hearing to go beyond a sort of talking point level of discussions and then really get into the nuts and bolts of it. And that's possible, sure. But at the same time, it takes time.

We're a little bit like EPA having to take time to go staff, and recruit, and train, and actually staff, and then implement changes to their programs. The Hill has a similar thing. They have to go find people who are competent on the staff level. They have to get members that are interested. The committees have to find their own feet on how they're going to address whatever it is, oversight of government agencies. Are we going to spend time on EPA, or are we going to spend time on Homeland Security? Are we going to spend time complaining about the budget across the board, or really going after EPA's budget, and things like that.

And that all will shake out over the coming year. That's why it's going to be an entertaining year.

LLB: I share your views on oversight hearings. They do bring immediate attention to issues of concern to whomever is urging the scheduling of a hearing on TSCA implementation, for example. Or how come it takes a year and a half, two years for PMNs to be cleared by EPA? But absent a sustained effort, these issues come and go and don't really seem to have a meaningful impact on forging change and correcting some of the institutional problems that many of us -- and we write about it frequently on our website -- are concerned about on the PMN program, for example.

Maybe we can transition to the forthcoming 2024 election. Seemingly, we just cleared the midterms, and yet there is increasing noise and attention to the fact that we've got this other election coming. Is it having impact yet, or is it something that will be more pronounced later in 2023? What are your thoughts, Jim?

JVA: It already had an impact because, regardless of whether the House turned or what the candidates may be, whatever you think of your particular candidate or whether, again, the President should run or not run again. Will he, won't he? Mr. Trump, will Trump really go through? He's obviously declared his candidacy, but would he win? All those real talking head kind of things. EPA, even before the recently concluded election, has spent some time worrying -- I shouldn't say, A, my sources have said this has happened, but it's not unusual that about two years in, *i.e.*, program adolescence, administration adolescence, that you start to worry about "What do we really have to get done? What do we really *want* to get done by the time we might have to leave?"

Again, regardless of Trump, Biden, who's running, everything else, this Administration may not be re-elected (or continue), whatever way, just generally, regardless of who is running and all the other dynamics that will obtain over the next two years. What do we need to get done? Because we have to start writing and start with that initiative or start writing those rules, because if we start a rule writing now, because of an important issue, it takes a very long time to write the rule. Pretty much 18 months is pretty aggressive; one year is phenomenal, but okay, a year to write it and get it out there.

Then along with notice and comment, if it's really a big important initiative or rule, it's going to take some time for notice and comment, time to write it, time to evaluate those comments, time for the stakeholders of all stripes to comment on it, so on and so forth. Assuming it's straightforward -- I'm not saying even controversial, but straightforward. Usually there is a synenergy there. Controversial things don't tend to be straightforward; otherwise they wouldn't be so controversial. As a result, it takes a long time, and you can plan at least -- two years would be phenomenally quick from start to finish, from program spark to implementing a final rule.

LLB: That's insanely fast.

JVA: Right. But then if you say, "If it's going to take three years, that means you better start after your first year in a new administration." That's kind of what happened. The programs are already thinking about things like what do we need to get done. That might be an individual decision. For these programs, it might be a bunch of rules. Obviously there's -- in the TSCA space, there's rules that are supposed to get done on the first ten chemicals. But that also then sets up a timer -- and they're going to miss those deadlines. They've said that.

But at the same time, the template of how to do those ten chemicals, the decisions, all those definitional things, like what's reasonably anticipated, whether we should have a whole chemical approach, and other kinds of things. And all those things are inherently very important and a bit controversial. We better get on with it, to be able to set those into place. And that's kind of what's happened -- happening -- and will continue.

And then there's also things -- I remember getting a memo from -- or at least orally, saying, "Okay, we're going to get ready for the election, so let's write down all the good things we did in our space." That meant the laws that we're responsible for. Okay, that's a start-up. In my time -- and that was certainly the case for the re-election of President Clinton. When Mr. Gore was running in 2000, now, a little bit -- 20 years later, it can be told a little more bluntly. We were told that we don't -- "Al Gore is not going to really need to say a lot about his environmental credentials. And in fact, that may be something you don't want to over-advertise." We expected a very quiet time after the election -- actually after the convention in the summer of 2000 until the election in November. And then in our case, StarLink happened. So it was one of the busiest times I had in my day. But that's, again, that was one off.

But basically, there will be some preparation for the Presidential election. Everything defense in terms of, again, even if Mr. Biden were to not run, this Administration is going to defend its record. I think smart money says Mr. Biden *is* going to run. Okay, he's going to be more specific about things he's done, his budgets that have been proposed -- we talked about that -- his appointees, how good they're doing. Certainly, he's going to talk about their accomplishments more than things that weren't quite fully accomplished, and so forth. So that's -- you do start that up. There's going to be some defensive reaction, too. There are, quote, "aggressive House hearings" on fill-in-the-blank. Again, I wouldn't expect too much of that for OCSPP. But compared to climate and WOTUS [Waters of the United States], the water program and things like that. But you'll have some of that, and so you'll be getting ready for those hearings, you'll be getting ready for appropriations questions. They'll be getting ready for, quote, investigations, whatever level of detail they get into. And yes, that starts now.

LLB: Maybe you can remind our listeners about the relevance of the Congressional Review Act, something that was mentioned in the January 23 *New York Times* article, and how that can be used to undo provisions that were enacted by a prior administration. That seems to be another prod to get things done timely.

JVA: It's back to the issue of how long it takes to do rulemaking. Again, elephants have a shorter gestation time than rulemaking does. You have to have two years or so, as we said, that would be aggressive and quick to get a new rule out. And at the same time, because of the Congressional Review Act, 60 legislative days. And one of the really obscure elements of Congressional rules and dynamic is a legislative day is not the same as you and I would call a day. It depends on the number, all kinds of other really insanely inside-the-Beltway kind of considerations. But basically, it's two or three months before the end of the, I should say, two or three months *before* the rule has to be final. And so that just -- assuming it takes two years to do a rule quickly; it really takes more than that, typically. And then you have to allow the two or three months before that to be in place so that the, quote, "new Congress" coming in in January 2025 couldn't, quote, "change it" if they wanted to, etc. The Congressional Review Act is just another time pressure on trying to get rules out two or three months earlier than even the end of the administration, or as I should say, the arrival of the new Congress, which just adds to that time pressure. And if we're going to put *X* issue on the short list, we really got to get moving to get it out the door and fully baked.

Again, if it's going to be a priority for the Administration, or whatever agency, it's going to take time. It's going to take time and senior-level attention by the senior management of the organization because if these are the important two or three things that this part of our agency wants to get done by the time we leave, that means, okay, it's a high priority. What are the particulars? And how can we get that? There is a -- at the end of the administration, especially if there's a party change, you have a tremendous set of pressures on OMB [the Office of Management and Budget] to process -- to do the final processing of the rules that are then pending. And you get told, "Tell us your top one thing you got to do." And then each agency and subagency unit puts in about four.

And then, "No, no, no. We told you one because even your whole agency's only going to get two."

"Okay, here's our four."

"No, we told you one." And that back and forth happens in the last few months of an administration during the lame duck. So that's a bit of a description of some of the pressures. And the sooner you can get done with your highest priority things, the better.

LLB: I think our listeners know that the OCSPP is two big offices: OPP, the Office of Pesticide Programs. And, Jim, you've talked a fair bit about some of the priorities, challenges, and opportunities facing OPP and OPP leadership.

For OPPT, the Office of Pollution Prevention and Toxics, which administers the TSCA program, there are just so many issues that I know in my practice I deal with every single day. But what are the top two or three issues that stand out to *you*? If you were, for example, Denise Keehner, who is Director of OPPT, or her boss, Dr. Michal Freedhoff, what are the priority issues that you see in that neck of the woods?

JVA: The obvious concerns of many of the stakeholders -- and again, and I say it that way because if there's a complaint by the affected industry about delay or overly conservative assumptions or requirements or unreasonable demands on regulatory restrictions or demands on the pesticide application -- excuse me, the new chemical application, that means someone else is probably happy about it. And it's not total opposites, but one person's overly restrictive requirement is another person's appropriate safety determination, and things like that. That said, that's the new chemical review program. And the time it takes to get an approval, let alone any bells and whistles, because they're tending to be much more regulatory bells and whistles compared to the previous Administration of both this law and certainly under the original TSCA program.

Is that overregulation? Is that overly conservative, and so forth? So that's issue one. And then, also on that issue of overly conservative assumptions, it applies to the general industrial chemical, those chemicals that are out there in commerce being widely used. Do we need to restrict these chemicals more precisely, more stringently? Which chemicals? There's a whole lot of them out there. The whole issue of even with the Inventory reset, there's 40,000 industrial chemicals out there. And so, let's assume that a mere, quote, "mere" one percent are problematic, and shoulda coulda mighta always been regulated more, but we're here now. What do we do about it?

EPA, and the law, and the Lautenberg amendments has -- do the top ten in the first couple, three years. Well, they're going to miss those deadlines, partly because of the -- at the very

beginning, I talked about one of the priorities of this Administration is to review everything done by the previous Administration. Not entirely novel, but with more of an edge to it.

The Trump Administration said this would be sufficient controls on a chemical, and Dr. Freedhoff is making it clear that that's affirmatively one of the things she wants to review. So, for example, I think I just read this in some other initiative in the past 90 days where affirmatively there was a remark, "Not only are we doing -- we at EPA -- doing this for these reasons and so forth, we determine and so forth." But affirmatively, it's the opposite of what the previous Administration had proposed. And that's something they're even putting still in their press releases two years later. This is one of the driving forces of why we're doing it this way, why we've done it, done the review again and things like that. So that's a little bit of a harder edge compared to previous times. Kind of -- not going to be news that a new administration takes a different look.

LLB: No, it's just more explicit.

JVA: Yes, and very clear. And so that's the two big controversies. And again, if I'm allowed to say, "Well, new chemicals and then new chemical review and existing chemical review," I think I'm covered in the TSCA space. But again, that's an easy summary but has lots of moving pieces underneath those two topic sentences.

LLB: Indeed. One class of chemicals that seems to span the universe is PFAS [per- and polyfluoroalkyl substances]. We've seen an awful lot of regulatory action in the OPPT space with respect to LVEs [low volume exemption] in PFAS substances and just a whole host of SNUR [significant new use rule] activity. But we've also seen PFAS in the FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act] space, not necessarily *only* derivative of the fluorinated plastic container issue of a number of years ago, but OPP is taking more explicit action now in the FIFRA space. Can you tell us a little bit about that?

JVA: The whole PFAS issue is -- I find it, as an observer of regulatory behavior for 40-plus years now, interesting, frustrating, entertaining, all kinds of adjectives, some of which I won't use on public TV or --

LLB: -- this broadcast.

JVA: Yes. But because PFAS is a broad bucket term. And so -- I've looked for anybody claiming to have a precise number. It's 1,100 chemicals and includes up to 1,700 chemicals. It might be more, it might be less, and all that, because it's basically things that have a fluorine atom in them.

And then one of the other issues as a regulator or regulatory policy, should you look at everything that has fill in the blank number of fluorine atoms: C_8, C_6, C-something? Anything with any fluorine in it is at least suspect. It needs to be reviewed. And for a lot of reasons, the political world has taken on the subject long before the regulatory world has really been prepared for it. And the reason I say it that way is you've got state and federal legislative actions to determine what are the safe levels of PFAS, as opposed to particular members of that class, which *have* been identified as more risky: PFOS [perfluorooctane sulfonic acid], PFOA [perfluorooctanoic acid], other kinds of things.

And that's not to say that those are the only two choices. It's binary between those two chemicals and the 1,700 ill-defined category. But that makes the issue very difficult to see what's really going to happen and to evaluate when various Congressional initiatives have

said, again, state, or federal, or some local -- over time -- initiatives to say, "Blank is bad" or "needs to be restricted" or "shouldn't be used in our jurisdiction," and things like that. If you start to say, "Don't use any unsafe PFAS compounds," it's almost meaningless. But then at the same time, if that's a law, you've got to try and sort that out and what that means.

I note that, for example, even back in OPPT, under TSCA, the agency put out a call for information about PFAS chemicals and products. That makes every sense, at least start to try and get a handle on that question. I just raised about 1,700, 1,100. But who's where? What's where? What are we dealing with here? How big is that elephant in the room (or whatever metaphor suits you)? At the same time, I read more recently that it was EPA's own estimate, not an industry estimate, EPA's own estimate saying that they underestimated the level of reporting cost. I think it was tenfold.

LLB: Oh, yes. Big, big correction, right?

JVA: Yes. I mean, that's -- kidding aside, when the government makes a one order -- we used to like to say around the agency, and now it can be told 20 years later, "Yeah, what's one order of magnitude of risk among friends?" Hey now, just kidding! Then and now. That's an easy joke, but when you're really off as a regulatory agency by a factor of ten, that's not a good thing.

That was the case for that element, that rulemaking, that situation as I read about it in the trade press, and again, reporting on EPA's own internal assessments and things. That's a problem. At the same time, PFAS chlorine products are a real issue. What's the world -- what's EPA going to do about it, and what should the world do about it?

LLB: Awful lot of jurisdictions, both domestically, the federal level, we've got our Section 8(a)(7) reporting rule that is expected out any time now, certainly the first quarter of 2023. Europe is very active in this space. States are very active in this space. Many of us have been struggling with the main reporting requirement for requiring manufacturers of intentionally added PFAS chemicals in products.

PFAS is not going away. It's getting awfully, awfully crowded out there. CDC [Centers for Disease Control and Prevention], I might add, just to make your day, Jim, points to some 9,000 substances in commerce as being PFAS. The numbers are all over the map. What we do know is that we're in for a very bumpy ride this year in the PFAS space. And there are many, many, many commercial, insurance, litigation, toxic tort, reporting, and regulatory issues that will be coming up this year and next as we try to address this particular issue.

So, Jim, any parting thoughts before we say goodbye? If you were wanting to give one or two pointers to our listeners, what might they be for 2023 and Congressional action and senior leadership decisions at EPA OCSPP?

JVA: I wanted to talk a little bit about three things to watch that people maybe haven't paid attention to, which is maybe a version of what you asked already here. Before I'd like to say that -- back to the PFAS question. My last comment on PFAS is it reminds me of something I learned years and years ago, which is -- I think I heard it from someone else, at least especially if you think it's too snarky, blame them. But the biggest cause of pollution is detection technology. If we find things where we didn't think they were and then we have to go wrestle with it. And that's partly the case here in the PFAS world.

You mentioned CDC, and if it's in my body, the other comment over time I've worked on the Hill or EPA or all kinds of different positions in these spaces over the years. Just when you try to explain to your neighbors or your family members, "I work on chemical pesticide regulation and toxicology, and you care about if the rats die or not or ya da da da da."

At the end of the day, somebody says, "This is in my body. I've got this compound. I've read that I got DDT. I still have DDT residues in my body or for my children, my baby, and things like that, my infant. What the heck is it doing there, and why? Who put it there, and is it safe? At the end of the day, is it safe? All you bureaucrats, blah, blah, blah, is it safe?" And those are some of the pressures on *any* chemical issue, and especially in the PFAS world. So that's coming up, you guys.

Three things to watch, that I think are getting little notice. We talked a little bit about the registration review deadline under the pesticide space, a couple of other ones. One is for pesticides, too. Two things. One would be, what's the grower reaction going to be to the ESA, quote, "early mitigation"? Is it feasible, and is it doable, practical? Is it going to be so hard and weird for growers to comply with that they just throw their hands up or get too grumpy or all kinds of other -- again, how is it going to work? And how is it going to be enforced? And those would be critical issues. I really can't determine that ahead of time, but that's something to watch out for.

In the pesticide space, and also in a certain way in OPPT, also for toxics, is the trade issues. The trade issues have always been very clear for pesticides because if our foreign purchasers of the big commodity crops don't allow the chemical in the food, then it doesn't matter what EPA says about chemical pesticide *X* or *Y* or whether corn growers can or should or shouldn't use it. Doesn't matter if no one's going to buy the corn at the end of the day because it was treated with a certain pesticide. That includes GMO [genetically modified organism] issues embedded in that. But the larger issue as a whole is trade issues.

And then for OPPT, again, we talked about all kinds of things: Are they are overly conservative? How do they implement both the PMN program or existing chemical review program and things like that? What I find interesting there -- because at the heart of some of the OPPT growing pains is the definitional issue. What does "reasonably anticipated" mean? What's this "whole chemical" approach mean? Should you assume that if there is a PPE [personal protective equipment] requirement on the product label, is it binding? Will workers really be given the PPE or use it even if they are given it? How do you put that in a risk assessment? All those are issues in OPPT.

At the same time, if in OPPT assessments they're going to assume fill-in-the-blank, that the fenceline risk should be measured at 10,000 feet from the source of the chemical exposure. I've read that recently. That's one of the ways to look at exposures from industrial facilities and neighboring communities as part of an environmental justice initiative, and emphasis, and things like that. And at the same time, things like I just mentioned, PPE. We shouldn't assume that workers will use PPE. In the pesticide space and those risk assessments, they may have a different set of assumptions, for a lot of reasons, sometimes statutory, sometimes by program practice.

All that said, will there be certain conservative assumptions in OPPT that migrate over to OPP? Or vice versa? One of the things that OPP has learned to use as part of their risk assessment methodologies, now that the programs *are* finally, after 50 years, they are together in the same building. Maybe no one's at work because of post-COVID. No one's showing up for work. They're all working remote, but they're all in one family now,

officially in one building. When they are together, when you have the toxicologist from OPP and OPPT sitting nearby, will there be more program integration?

And that's been something that's been assumed over the years. That's one reason, again, since literally the Carter Administration, a goal to have the two programs together. But we now have that at long last. Will that make a difference over the coming years? So those are my sort of watch-outs for things that you didn't maybe see coming.

But generally otherwise, yes. How crazy will the interaction with Congress be, given the House of Representatives? Will people pay a lot of attention to issues in this space and OCSPP issues? Will the world only care about EPA budget as a whole, or federal budget dynamic, and the government debt ceiling, and things like climate, and leave most of this area alone?

There is a Farm Bill that will have to be written in some way, even if it's simply extended in 2023. Will that have some impact on the pesticide space? Those are the kind of watch-outs for the coming year.

LLB: Well, appreciate those heads up, Jim, particularly the interesting observation that might some of these risk assumptions that are applicable in the OPPT space waft over the aisle, as it were, and be deployed in the OPP space? Very interesting.

We'll all catch up with you later in the year to see how we're doing on those and the other observations that you shared with our listeners. And with that, I want to thank you for joining All Things Chemical. You always present extraordinary insights, Jim, that only your perspective and history with EPA can offer our listeners. Thank you so much for joining us today.

JVA: No problem. As you can tell, and you and anyone else I speak with, I'm happy to chat about pesticides and chemicals anytime, anywhere.

LLB: Thanks.

JVA: Thank you.

LLB: Thanks again to Jim Aidala for speaking with me today about his insights presented *only* as Jim can on what we, as chemical aficionados, can expect from EPA and Capitol Hill in 2023.

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