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Podcast Transcript

Episode: "From the FSMA Proposed Food Traceability Rule to Labeling Transparency — Analyzing the Growing Complexity of Food Law, Industry Advances and the Road Ahead Under a New Administration"

Jonathan Havens and Tony Pavel
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Jonathan Havens: Hi, everyone. This is Jonathan Havens. I am co-chair of the Food, Beverage and Agribusiness Practice at Saul Ewing Arnstein & Lehr. Thank you so much for joining us on yet another episode of our podcast, "Don't Miss a Beet." I am thrilled to be joined today by my friend and former colleague, Tony Pavel, who currently serves as the senior food lawyer and Global Food Law Team leader at Cargill. Tony, thanks so much for joining us for today's episode of "Don't Miss a Beet." As your former associate, I can say I've been looking forward to this day for a very, very long time. For once you are in the hot seat. All kidding aside, when we first launched this podcast you were one of the first people that popped into my mind and I can think of no better guest to be on our podcast than you, so we really appreciate you being here.

Tony Pavel: Well, thank you, Jonathan. I'm glad to be here and look forward to the conversation. Really appreciate the invite.

Jonathan Havens: So in preparing for our discussion today — I never came to your office unprepared — I did a little bit of homework and I did some reading on Cargill. And while those of us in the space certainly know Cargill, it's a well-known name and commodity to us, I was reading in a NASDAQ article that Cargill is one of the 10 biggest companies that "you've never heard of." Once our audience members hear a little bit more from you about Cargill's portfolio, I'm sure they'll never forget the name Cargill and remember all the great things that you all are doing. But with that, I want to be quiet, step aside and let you talk a little bit about Cargill and talk about your role. What does a senior food lawyer do at a company like Cargill?

Tony Pavel: Sure, thanks, Jonathan. Well, I have heard that a few times and every once in a while, you'll say "Cargill" and people will say, "Carhartt like the jeans?" and you say, "No, Cargill." Cargill is a very cool company. So it's over 150 years old. We have over a 150,000 employees globally and operate a number of companies. We have a large global footprint. And as you mentioned, we're one of the largest privately held companies in the United States. I like to say I work for a nice small

family-owned business. Cargill started off with grain trading in the Midwest and it has organically grown over 150 years to the footprint that it has now. And within Cargill globally, we have some core enterprises. There's our animal nutrition business, which is animal feed and pre-mixes and that's across most species, from pet through farm species. We have a very large aqua feed business as well. And then we have our food ingredients and bio industrial business. Food ingredients would be everything from Stevia sweeteners to starches, to a range of ingredients that you would typically find in the foods you're buying at the grocery store. Bio industrial can overlap with food and non-food uses. I would say Cargill is actually one of the most sophisticated, large-scale bio, industrial fermentation companies in the world. We have really strong expertise in the space and that can be from a cosmetic ingredients business, it's bio industrial, and then you have products that could go into home cleaners to things that are additives that go into asphalt, road salt, et cetera. We have our protein business, which encompasses both traditional protein, beef and turkey. Cargill doesn't have any pork operations right now, but also, alternative proteins that are coming on the market. So, plant-based proteins and we have some investments in cellular-based protein as well. Then we have our ag supply chain business, which is what I think when you go to the Midwest or when I'm down in North Carolina at the family farm, that's what Cargill is really known historically for in the U.S. within the agricultural sector. And that is sort of seeing soy, corn, specialty crops and trading those crops consolidating. We also have a large, within that part of it, vegetable oil business. So soybean oil, canola oil, sunflower oil, et cetera. All of these can feed into food service with both restaurants and consumers. Part of the reason Cargill isn't broadly known is we sort of sit, in many regards, in the middle of that supply chain. Right? We have the origination at the farm level and then we're distributing, or further processing and creating, either new products that are going into others or we do have, particularly in the feed space, we have a broader range of branded products. And then again, when you look globally too, there's going to be differences. So in Brazil and India, we have far more consumer products than we have in North America. I think the most common Cargill product that people would be familiar with would be Truvia, which is broadly available and was the first stevia brought to the market in the U.S. as a nondietary ingredient. So that's kind of part of the fun, Jonathan, part of the fun for me when I came to Cargill. My life didn't change that much from when we were working together in private practice, but instead of having 70 different clients, I have 70 clients that are all under the one corporate umbrella with these businesses and our global footprint. So to that end, the work I do is something that you'd be pretty familiar with on your end with probably slightly more of an international aspect then when I was in private practice. I work across any of our businesses that are engaged in food or feed to help in terms of regulatory compliance, implementing programs, working with our advocacy teams, working with scientific and regulatory affairs for market access strategy and

approval, prosecution of the new ingredient approvals. It's very much as I described –it's a regulatory counseling practice with the difference being that I'm in-house and it is structured in this sort of enterprise and then regional way. We have a global food law team where we have another really experienced food lawyer in Minnesota, who actually also started at a D.C. firm before going to General Mills and then over to Cargill. We have another dedicated food lawyer just outside of Brussels and then one in Brazil as well as one in China. So that's the structure of our global food law team and then typically, not too dissimilar from private practice, the primary folks we're working with on a day-to-day basis are our food safety professionals, our regulatory professionals, and then coordinating with our commercial lawyers where those intersections are between regulatory strategy compliance and implementation through to deal-making, the contracts and execution of getting that product to the customer.

Jonathan Havens: That gives our audience members a good insight into what Cargill does, which I would characterize as: but wait, there's more. As much as you think you know, there's more and a lot of it in the U.S. and North America, as you said, is B2B. Obviously when you go outside of the U.S. there are some brand names that are recognizable, but if you eat food, you've consumed a product that Cargill has had something to do with, as far as I'm concerned.

Tony Pavel: There's a very high likelihood of, at some point in your life, you've had some Cargill ingredients, and that's another piece of why I'm proud to be at Cargill and part of the decision of why I came. From our guiding principles, the first principle is that we obey the law. Our word is our bond. The mission of the company is nourishing the world in a safe, responsible and sustainable way. And we have a lot of really smart, dedicated people who are pushing the company forward towards those goals. It's a really cool platform to be working from because you get to work on some of these policy issues that are near and dear to me. As you know, I've been – one way or another – involved with the food industry for the bulk of my life so it provides a lot of cool opportunities. And to your point, I'd say maybe not weekly, but let's call it monthly, I'll get an email or a phone call and I'll say, "Oh, I didn't know we made those." And I've been here five years and there's still plenty of new and interesting that comes my way.

Jonathan Havens: Well, it shouldn't make the rest of us feel bad that we don't exactly know the scope, but much appreciated. So, a lot of what I learned about food law was really from you, from working with you. So to me, food law hasn't ever been uncomplicated. It seems to me, and maybe I'm wrong about this, that it's gotten even more complicated. Whether you're talking about traceability or the ever-increasing globalization of the supply chains to consumers wanting to be armed with all sorts of information under the sun, it can be hard to keep up. So my two-part

question is: (1) am I right, has it become more complicated? And even if it's not, I know that it's difficult to keep up because of the diverse constituencies that you serve and how big Cargill is as a company. So (2) how do you keep up with it all? I know you referenced your team of course, but there's a lot that you have on your plate, no pun intended, so both the complicated nature of the industry or not. And then how do you keep up with it?

Tony Pavel: Yeah. I would say you're absolutely correct. I'd say there's been bigger changes and more complications over the course of the last five-six years. And again, there's a big FSMA component to this in the U.S., but I think we're seeing that mirrored elsewhere.

Jonathan Havens: For our audience members, FSMA is FDA's Food Safety Modernization Act — the biggest overhaul to food safety in what, 70 years?

Tony Pavel: Something like that. So that was 2011. Right? And where we're at now, the traceability proposed rule just came out a month or a couple months ago, so we're still not done with the rulemaking for that. But I think this is a bit of a chicken and egg question in my mind. I think FSMA moved the bar in many respects — transparency, traceability, the paperwork chain, up and down the supply chain and you see similarly now, I would argue, that you might've been slightly ahead of where FDA was in terms of some of that and I think that balance has shifted a little bit. But ultimately what it's done is introduced more complexity and not only from a domestic perspective, but from an international perspective. Both in terms of the level of transparency and the amount of information that's being looked at both by us and our customers, when you're talking about supplier qualification, new product qualification, et cetera. and that, in and of itself, shifts. So, pre-FSMA in the food world, while most of industry had HACCP programs in place, it wasn't mandated. Now we have HARPC or updated HACCP, and that applies both to food and feed. And you're seeing in the feed world a lot more scrutiny than you previously would have seen, particularly in the U.S. where you have the split regulation between the federal and the state. I would argue that the game has changed in a material of respect from when you and I were sort of growing up in the law firm world and our mentors who had come out of the agencies, whether we're talking about FDA or FSIS, there really has been a shift I would say in both the volume and complexity. I think this new traceability proposed rule sort of reflects that, if you dig into that a little bit and look at the really data-driven approach that FDA has taken towards the data elements that has been proposed within this rule. I think over the next five years we're going to see even more complexity growing. And the other factor here that I always try not to forget is also testing capability. Right? This isn't something new, chasing zero when it comes to analytical testing, it has been with us forever, but the ability for rapid testing down to .5 part per billion. We are seeing, particularly when you can

get analytics down into the parts per trillion if you have the right equipment and mass spec available. I think that creates different challenges in the food world. And you can talk about them in the context of allergen thresholds or contaminant thresholds. I'm thinking about things like arsenic in rice depending on the growing region and inorganic versus organic and the ability to detect those things. And one of the things that the industry needs to think about is where those quality and safety standards are set, right? When do you get to that point of 750 parts per trillion, is that a toxicological impact or is that data that's going to be out there and needs to be put into context? Because when you grow things in nature, they are pulled out of the soil. And to your other question, it's tough to keep up, but it's a lot of the same things that we used to do. I read the trade press. I read all my food law and cannabis law updates from you, Jonathan, and the combination of that, and then also the trade associations to the extent that I have the ability to participate in some subset of various trade association meetings, it's always been a key way to keep abreast of developments in those particular sectors of the food and feed worlds. But, I do not necessarily have the luxury, for example, to go back and read a preamble.

Jonathan Havens: Well, no one's ever described reading a preambles as a luxury, by the way. I think that's a first on this and many other podcasts.

Tony Pavel: Oh, come on. That's the best part of the regulations. That's where all the good stuff is, Jonathan. You know this. Part of this is that I lean on my team, especially in a global environment. I'm not nearly smart enough to keep up with everything that's going on in the EU and South America and every development in Australia and New Zealand. So I do lean on my team to make sure that I'm at least aware at a high level of significant changes. We've got all the post-Brexit stuff coming out of the FSA in the UK now. So it's a bit of a mishmash, but I would say at the high level it's reading the trade press as much as I can, tapping into my network as much as I can, leveraging the trade associations where I can, and then my internal food law team and then our global regulatory teams. I might not be able to dive into the weeds, but I do my best at least to know what's happening at that top level, but it's a lot. There's been a lot going on.

Jonathan Havens: Yes, there has. So your comment about post-Brexit is a great segue and leads us into our last topic with our just remaining couple of minutes left. So obviously we're coming out of a fairly contentious election cycle. Any thoughts on U.S. federal regulations or regulators and how the landscape might change? Whether it's regarding FDA or USDA or otherwise. I think you and I both understand that there's not going to be this massive sweep out of regulators with a change in president. A lot of the top politically appointed positions certainly could be, but you spend so much time keeping abreast of these developments and sometimes people forget about how changes in administration could mean changes to policy. Any sort

of outlook? I know it's still early in the process, but as we hear about these appointments or policy initiatives, any sense of what the future might hold?

Tony Pavel: I'm going to try to limit my scope to FDA and USDA/FSIS. I do think some other executive agencies are going to see bigger or more significant administration change effects within the agencies, but I would argue, and I think we've had this discussion in the past, Jonathan, but I would argue that that FDA and USDA didn't really skip too many beats between the Obama Administration and the Trump Administration. And that's whether you are looking at rulemaking and at enforcement levels. These are two agencies that are largely made up of career scientific staff, many of whom had been there for a long time. They're very dedicated to the agencies' mission. And I find it hard to point to a significant change in the last four years versus the four years that proceeded. I think there are a few areas, without getting too specific, with some rulemaking and policy development. I think there have been instances where there hasn't been, I'd argue, even not as much transparency or communication with regulated industry. I think that is one piece where if I were to advocate that I'd want to make sure that when there is policy development or regulation-making that there is, and that's not just industry, of course, there should be transparent dialogue with affected stakeholders, right? Whether we're talking academia, NGO world, industry consumers. I do think that's an important piece. There are a few sort of higher level things, like the two-for-one rulemaking executive order, that I could see going away. Now we do have this new HHS proposed rule that wanted to propose review and sunset of the vast majority of HHS regulations — that's in play now. But I do think what some of these actions will do is prompt some — that proposed rule has to be addressed, but I do think there might be, in lieu of these more dictatorial approaches that will perhaps spur some of the HHS agencies, et cetera, to look at some of the older regulations. And as you know, in FDA world, we have standards of identity (SOI) that go back to the 1940s, 1950s. And FDA, yes. There's an SOI project going on, but there are always agency resources and priorities. So, to me the big questions are going to be where are those policy focuses going to be at the agencies ? I would say at FDA, for example, in the last four years, particularly during when Scott Gottlieb was leading the agency, I was actually pretty pleasantly surprised at the focus the agency had on the food side from someone who had, in my mind from his previous times at the agency, much more of a pharma-focused career. But there really was a strong focus from the top of the house down at FDA. Whether the question becomes is there a stronger focus on nutrition, how much do any of the FSMA priorities shift or get adjusted with the new administration, and then FSIS I think a lot of the ongoing programs I expect them to continue. And the question is where are those agency focuses going to be, so it's not the most exciting answer, but I don't see a big tectonic shift happening.

Jonathan Havens: I think it was a great answer and your statement about the one-in-two-out policy and broader kind of government or regulatory overhaul initiatives, those are the ones that I think that could maybe have an impact. But it's the folks at CFSAN — the Center for Food Safety and Applied Nutrition — at FDA or the folks at the Food Safety Inspection Service (FSIS) at USDA that are really governing the day-to-day lives of stakeholders that we've been talking about. That's not really going to change too much, or it's expected that it's not going to. But if you start mandating that agencies like FDA, which have long since regulated by unenforceable guidance documents or some people would argue that, if they have to send all their guidance to OMB or if they have to pull back to regulations for every regulation they issued, those are the sorts of things that could have more of a meaningful impact then, okay well, what's an election going to do to change day-to-day at CFSAN or FSIS, which is probably not very much.

Tony Pavel: I totally agree, but to me that becomes the real question, where are those priorities going to be? The other concern I have is funding for the agencies, because at the end of the day, I'm a bit more bullish on this. I think having a well-funded, well-staffed FDA and USDA, FSIS is critical. And, again those are our regulators, but at the same time for consumer trust we want a strong FDA. I want a strong USDA, FSIS so when people see that mark of inspection, they know the food has been inspected. It's safe and wholesome. When we think about the government expenditures and the challenges of the last 9-10 months, I think one of the things that will have to be contended with is making sure that the agencies are getting the funding they need and the staffing they need. And that's not only for food safety, it's also on the innovation side in order to get, as you are acutely aware of, new ingredients through the process that takes staffing and it takes resources to keep those reviews moving in an efficient and reliable way. So that's the piece, which is less political, but more sort of government coffers kind of concern that I have as we enter into the next couple of years, because there's a lot of expenses for the government right now.

Jonathan Havens: You want robust staff with room for forward-thinking, out-of-the-box ideas to get newer products on the market. You're absolutely right about that. So as I promised it would, the time went by pretty quickly. Tony, I wanted to say thank you so much again. It's really a thrill to speak with you as always. You've taught me quite a bit and as I said when we were launching this podcast, I said, “Tony Pavel has got to be one of our first episodes,” so we really appreciate it. For all of our listeners, please join us on the next episode of "Don't Miss a Beet." If you have any feedback, we'd certainly love to hear about it. Leave us a comment wherever you download your podcasts or shoot us an email, you know where to find us. So again, Tony, thanks so much and we're wishing everyone a happy and healthy new year.

Tony Pavel: Thank you, Jonathan.