Episode Title: The New Era of Smarter Food Safety -- A Conversation with Karin Baron

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

This week I welcome back to the studio Karin Baron, Senior Regulatory Consultant at B&C and our consulting affiliate, The Acta Group. Karin and I discuss the U.S. Food and Drug Administration's (FDA) initiative called the New Era of Smarter Food Safety. The goal of this initiative is to diminish the number of foodborne illnesses, which surprisingly has not diminished since the Food Safety Modernization Act (FSMA) was enacted 11 years ago. We discuss FDA's Blueprint for the Future (Blueprint), as the initiative has come to be called; the use of emerging technologies to achieve FDA's goal; and how FDA is trying to change the culture of food safety in the United States. Now here is my conversation with Karin Baron.

Well, Karin, it is so great to have you back in the studio. You are without question one of the crowd pleasers here in our podcast, so thank you for joining me.

Karin F. Baron (KFB): Oh, my pleasure. Happy to be here again.

LLB: Well, the subject of today's conversation is FDA related. I've been hearing an awful lot about a relatively new initiative known as the New Era of Smarter Food Safety. Maybe you can help our listeners understand what this is and how it relates to the FSMA.

KFB: Sure. The New Era of Smarter Food Safety was introduced, I believe, around April 2019. And the actual -- the first time we really saw what it was meant to do -- was when they introduced the Blueprint in July 2020. Now, I will be the first to say that timing is very terrible, when you think about what was going on in our country during 2020.

LLB: Yeah, nothing?

KFB: I know, right?

LLB: Because we were shut down.

KFB: We were pretty shut down. And I think what's important to understand is -- when I first saw this, my initial thought was, is this meant to replace the FSMA, which was enacted in 2011? But FDA was very quick to say that was not the intent, that the New Era of Smarter Food Safety was meant to be an enhancement to the FSMA. And they often talk about it just being -- always being the intent to visit the technology we use, how we improve predictive analytics, how we respond more rapidly to outbreaks, and then how to address business models, reduce contamination of food, and foster a stronger food safety culture. That was pretty much what the New Era of Smarter Food Safety was meant to do: leverage technology. It was meant to be an enhancement to FSMA.

LLB: Okay. Well, that makes sense. And FSMA is, as I think our listeners all know, the Obama-enacted law that was intended to modernize food safety and the infrastructure here in the United States. It required the promulgation of some seven major rules, all intended to achieve the goal of modernizing food safety in the United States. Maybe you could share just a little bit about the background of this, what was then and is now a truly massive undertaking. And what has transpired since FSMA was enacted back in 2011?

KFB: Sure. And I always warn people, when we talk about the FSMA, it is not one -- it's not one thing. It's, as you noted, seven major rules, but it ends up being about 14 laws that were enacted as part of FSMA. But the intent of FSMA was to establish standards for adoption of modern food safety prevention practices. It was the idea that foodborne illness exists. And FDA statistics, which have been on its website for over a decade now, mention that roughly one in six individuals will be sick each year from foodborne illness.

The idea of FSMA was to not only look at the expansion of our global supply chain, but to implement preventive controls. We go from an idea of being reactive to being proactive. And in doing that, FDA established what it referred to as its pillars, or its core elements. And that then produces the seven rules that you talk about. And those elements were on the concept of prevention, which is how do we control our food and feed facilities? It included mandatory produce safety standards.

It also gave FDA enhanced authority to recall. If it felt that a facility wasn't initiating a recall fast enough, it enhanced their ability to do so. But it also mandates inspection frequency and testing and then FDA acknowledging that we are in a global food supply chain. It looked at import safety, so food from abroad. And FDA has always stipulated that it doesn't matter where the food is made, it must comply with U.S. safety standards. And then this concept of now we have more inspections, now we have more preventive controls, now we have import safety. How is FDA going to manage all of this?

FSMA talks about enhanced partnerships, not only partnering with federal and state and local, but also foreign organizations. And that lays down then those seven foundational rules that speak to each of those elements. And in the end, I think it ends up being something about 14 because they split certain rules out. For example, you have the Current Good Manufacturing Practices (CGMP), and Hazard Analysis and Risk-Based Preventive Controls (HARPC), which is a mouthful. That's a huge, huge piece of legislation. That's Part 117, Subpart C of the Code of Regulations. But they split those out between human food and animal food. So those are two separate laws.

And then you had sanitary transport because once you look at all of these practices, once you look at how you manufacture food, how you hold food, how you package food, you perform a hazard analysis, you develop a preventive control if there's a risk that's introduced.

And then you have to transport all of this around. You have sanitary transportation of human and animal food, so those are separate rules. And then FDA acknowledged again that our supply chain is global. You have the Foreign Supplier Verification Program (FSVP), but each rule has its specific exemptions. And we're going to talk a little bit more about what that meant and that there are some specific rules that are just all-inclusively exempt. A really good example is a lot of these rules, you're subject to the rule if you have a facility registration, so FDA requires that if you manufacture, package, hold, produce food, that you register your facility with FDA so that FDA is aware of where you are, who to contact, who's in control of that particular facility.

But things like food contact substances, which is a subject near and dear to my heart, they are exempt from facility registration. You're going to find that, when you look at all these specifics in the rules that if you're in a food contact space, which means you're managing things that go into packaging that's used to hold food, that you're going to be exempt from a lot of them. It is important to understand that the rules are very specific, the rules are very complex, the rules are incredibly detail oriented, but there's a lot of exceptions and exemptions to each rule.

LLB: And listeners need to be very mindful of who's in, who's out, right? Because it's complicated.

KFB: Exactly. Yes.

LLB: You mentioned a statistic that I saw in the Blueprint, the New Era of Smarter Food Safety, and that is the one in six: that one in six people will continue to suffer from some form of foodborne illness each year. And as the Blueprint makes clear, that statistic has not really changed since the enactment of FSMA. Does the Blueprint for the Future indicate that FSMA is maybe not hitting the mark or needs tweaking? You were very clear in your introductory remarks that it's not intended to replace, but rather complement and augment, but that the statistic has really been unchanged, is that a cause for concern, or what do you make of that?

KFB: I think it's FDA acknowledging that the tools we use are not sufficient enough, that we aren't able to address issues in a timely fashion, that while the rules do speak to a proactive approach, they're very complex, they're very labor intensive. But when you're in a real-life scenario, I think what FDA is acknowledging is that it's very difficult to trace a supply chain, especially in a global economy. My impression is FDA has had a decade or so to look at FSMA. FDA has had a decade to evaluate what is still missing, what do we still need to get to that end game of reducing foodborne illness and acknowledging that there's still a long way to go. That's what I'm -- my view is as I look at the Blueprint and at what FDA's goals are with the Blueprint.

LLB: And I would imagine, well two points here, that the pandemic and all the supply chain disruption that it invited kind of set FDA's agenda back a number of years, recognizing that but for the pandemic, we might have a clear line of sight on issues like traceability. Maybe not, but it's just speculation on my part. Now, my second component question is the role of emerging technologies, because the Blueprint makes much of that, the fact that emerging

technologies are going to be absolutely essential to achieving the goal of diminished foodborne illness.

Have there been any bright lights on the horizon or any new traceability technologies, in addition to the ones of which we are already aware? Nanosensors and many other innovations that have been rolling around for the past decade or so are all helping, but we don't have any killer new technology that you're here to announce. Or maybe I'm wrong, Karin. Maybe you *are* going to tell us about killer new technology.

KFB: I'm not aware of it. But I will say, one of the things FDA talked about last year was, how does FDA address that attack in a low- or no-cost way, understanding that when you talk about global supply chain, you could be dealing with very small operations that may not be able to afford expensive tools to monitor and track? So they had a contest. And if you go out to the New Era of Smarter Food Safety website, you'll see when they talk about -- they had a low- or no-cost food traceability challenge, where they actually asked folks to submit concepts for enhancement in tech that could be then -- FDA could use as part of building these tools. But no, I'm not aware of super tech that's available right now that FDA is holding in secret in its warehouse.

LLB: It's -- timing is everything, right? I mean, in October through December 2019, FDA was engaging stakeholder constituencies, having brainstorming sessions around tech-enabled traceability topics. And then, in March 2020, the pandemic hit. So it's almost like there was this big run-up to rolling out aspects of the Blueprint only to have everything stall out until kind of now to launch it yet again. It's just regrettable that the pandemic probably slowed the momentum, but I suspect FDA's revving this all back up because the need is great and the problem is fairly severe.

KFB: Yes, absolutely.

LLB: In that regard, Karin, core to the FSMA is the shift from responding to foodborne to preventing it, which of course is the name of the game. Responding is wonderful, and I'm sure FDA's efforts have been more urgent and comprehensive than in years past. But preventing it seems to be the real essence here of achieving the goal of FSMA. What do you see in this space, based on your experience? Has FDA's implementation had a real-world impact on clients when it comes to preventing foodborne illness?

KFB: I believe that this is still in progress, and I think even FDA acknowledges that, that FSMA has brought us a lot further than we were. FDA states this is the largest overhaul since its inception of 1938, so we were in need of some changes within the legislation, but I don't believe the ultimate goal -- and the statistics show that the ultimate goal of prevention or even reduction in foodborne illness -- has been seen. And some of that, you're starting to see that acknowledged in some of the newer rules and the New Era of Smarter Food Safety, in that all of these complex laws that they put into place have brought us further, but we're not there yet. We still have a long way to go.

LLB: In that regard, I know late last year, FDA proposed to amend the agricultural water provisions of the product safety regulation that covers farms. Lots of changes included in that extensive proposed rule, one of which is to amend the microbial criteria and testing requirements for preharvest agricultural water for covered produce. I would imagine that that is probably a pretty important role, given how integral agricultural water and how it applies to produce could impact diminished foodborne illness. Do you have any thoughts on

that proposal? Where it's headed, what it covers, and what the role of maybe farming is generally in this space?

KFB: It's an interesting idea. It seems to me that it's late to the party, one way to put it. One of the foundational rules under FSMA were standards for growing, harvesting, packing, and holding of produce for human consumption. And I think if you look statistically at the recalls, you'll see a lot of recalls are associated with leafy greens, produce, those types. Exactly. And it feels like this idea that the agricultural water provisions and even the microbial criteria and the testing requirements for preharvest, it seems like we should have been looking at that sooner. It feels like 2022 is very late. That should have been something explored in the original foundational rules in 2011.

And I think part of the problem was as they introduced a lot of these rules and, not to be critical, it does feel like these things were left out, or these things were controversial, or these things were elements that parties struggled with, that there were a lot of comments made, a lot of discussion internally and externally over this rule and previous rules. And there still are a lot of comments ongoing, but our root cause analysis should have noted that this is one of the major indicators of foodborne illness. This is a problematic area that FDA continues to struggle with. So much so, I think I saw an article recently where they now have folks stationed at key areas around the -- some of these problematic growing regions -- where they are analyzing real time before the food is even released off of the farm. So they're getting there. But to me, I feel like this was very late. We've fixated on Current Good Manufacturing Practices, Hazard Analysis and Risk-Based Preventive Controls, but we kind of left out this aspect of our food. And this is the area that tends to be the one we see occurring most often.

LLB: Well, that old adage -- better late than never -- rings true here. But no, I take your point. And perhaps having these folks who are embedded in the agricultural sector who might be at higher risk or statistically show they are the source of some foodborne illnesses more regularly than others strikes me as a really good step in the right direction.

We talked a little bit about the pandemic as both slowing the momentum of the implementation and rollout of the Blueprint, but to what extent did the pandemic, in your view, Karin, influence FDA to focus more on supply chain logistics and supply chain challenges? Because pre-pandemic, supply chain logistics didn't seem to merit as much attention as it is getting now. Does that seem to resonate with you at all, that it might be both a cause for delay and a cause for a renewed emphasis on improvement?

KFB: Yes, I think we can all agree: how we receive food and how food is globally provided was deeply impacted by the COVID-19 pandemic. And anyone of us who looks back on it, we laugh now, but we talk about the great toilet paper shortage of 2020.

LLB: I know; the hoarding that went on.

KFB: And I think what we learned was that it underscored the need for modern approaches that our demand and our food system, we had unprecedented imbalances in the marketplace. We saw huge challenges, not only on the FDA side, because when you shut down workforces and FDA inspectors can't go out and inspect, that raised issues not just with FDA, but I think every regulatory agency felt that. And even just highlighting how consumer behaviors changed during the pandemic, it just kind of pinpointed how delicate our supply chain can be and how, when we have a minor disruption, it just caused unexpected issues.

And I know I heard stories about issues and especially importation points along the coastlines where they would have barges full of food that were just rotting because we didn't have -- yes, we didn't have transportation infrastructure in place to move food from point A to point B.

I think the pandemic just kind of brought to light how delicate our food system can be and how we need to take a step back and kind of look at what are real-time (FDA calls it) "nimble approaches" to ensure that our supply chain is stronger and that we have a resilient food system? That comes directly out of some of FDA's comments on the significance of COVID and the New Era of Smarter Food Safety.

LLB: Well, that raises another question in my mind. And it's a source of confusion, I think, both in my own head and perhaps in the general public's thinking. And that is the twin concepts of supply chain and traceability. These are clearly related topics in the context of FDA's implementation of FSMA. But are they the same thing, or are they different or simply complementary themes to the general concept of making sure that our supply chain is both resilient and safe? How are supply chain and traceability related?

KFB: I think what FDA is looking at when they're talking about food traceability is we have these concepts, we hear this farm to table. Food traceability is how do we rapidly identify where food is? And then how do we mitigate the seriousness of an adverse health consequence? How do we track all that back? And what the food traceability rule is looking at, it's very pinpointed right now. It's looking at specific substances. They have a Food Traceability List, so it's not all food that FDA is considering, but it's looking at key data elements and critical tracking events.

And FDA says with their Food Traceability List they have the ability to add items to the list or remove items from the list. But the list focuses on those elements that are typically associated, one, with recalls. But then how do you track something back? Once you discover an issue with cucumbers, cucumbers are on the list. How do we then track and trace all of this back to the consumer to let them know that something has been recalled? And I think we all can agree that that concept lacks specificity right now, that we know we have troubled areas: leafy green vegetables, sprouts, fish, cheese. Those are all on this list, nut butter, tree nuts. But then how do we build the tools we need when there is an issue and a recall is initiated to trace and track back and then to remove those things from the consumer market to prevent illness? They're all very interrelated, but it's very specific on that particular rule. FDA is really fixated on its Food Traceability List.

LLB: You mentioned recalls. We have certainly gone through a number of them here at the firm, Karin. Difficult, very, very difficult. They're challenging. They're definitely unwelcome realities for members of the food supply chain. When our clients are in the midst of a recall, it's nothing but trouble. Lots of headaches, insurance concerns, legal costs, liability, you name it. A recall is regrettable, but to some extent it really reflects a failure of FSMA to achieve Congress's goals, right? That is, a recall reflects a food safety threat that escaped detection and escaped prevention at the source. Are there fewer recalls today than a decade ago? Will we ever have a reality that is recall free, or is that just a bridge too far?

KFB: Yes. Having walked through a few of these, I do not feel that there are fewer recalls today. But I'm not sure that's necessarily a bad thing. I think our supply chain is more educated with the FSMA rules to know when to initiate a recall. The idea that we would be ever at zero, I just don't see. But I think when we look at the recall, there [are] aspects of recall that folks may not realize in that some recalls may or may not result in adverse health outcomes.

And FDA is the party that decides the class of recall and determines whether that recall should be a very prominent recall -- one that *does* result in an adverse health outcome -- and so they get very engaged.

Or there are recalls where we are acknowledging that something happened, a disruption in a manufacturing process that resulted in the introduction of something that's not supposed to be there. FDA refers to that as *adulteration*. Companies are becoming more cognizant about acknowledging that there is something in the food or the food additive that results in it not being up to code, up to spec, manufactured the way it was supposed to be, because that's all part of that hazard analysis, risk-based preventive controls, Current Good Manufacturing Practices, and then taking the initiative to remove those materials from the market, acknowledging that the health aspect of that may not be as great. I do see that we have probably got more recalls than we used to, but they're not all going to result in a fatality. Let's put it that way. And I don't ever envision a time when we'll be at zero.

LLB: You raise a good point about FDA has varying degrees of engagement in cases of a recall, say, a standard adulteration type of situation. In your experience, Karin, is it kind of a one size fits all that FDA will respond consistently from headquarters and its various regional offices, or are some regional FDA outposts a little tougher than others? And what is your sense generally with respect to compliance? Is FDA tough on compliance? I come at this from the perspective of EPA, and EPA is really tough on compliance. It's certainly -- this Administration has made a point of being very, very clear about its goals of enforcing the law. What can you share with our listeners regarding FDA's approach to compliance?

KFB: Yes, really, having seen the two sides of that coin, working with the firm on some of these EPA issues and then working with clients on some of these FDA issues, it definitely feels different. I feel like FDA is more collaborative and cooperative. If you are intent on just addressing your issue, removing your contaminated, adulterated product from the market, and FDA sees that you are actively engaged in that, you will not face further issues. You may get inspected a little bit more -- expect an inspection -- but I don't see them as aggressively approaching these types of things. And most of the recalls that we've been involved in, some of them have been more severe than others.

FDA is a little more engaged when the hazards are viewed to be more problematic. But I've never felt that they were very aggressive in their approach. I always felt that they just wanted to work with the food manufacturer to address the issue, get the problematic product off the market, and then deal with going back and looking at what happened, that hazard analysis, and again discussion and putting in better preventive controls. I've yet to see FDA get truly, truly aggressive when it comes to that, unless they see folks that are repeat offenders. Their mechanisms for how they address that are different than EPA's, so while FDA under FSMA was granted more authority, you don't see the same fine and structure that you have under EPA built into the legislation. It ends up going to the Department of Justice for addressing some of those issues.

LLB: The Blueprint also talks about something that I find both very interesting and challenging at the same time, and that is changing the culture of food safety in the United States. Two questions. The first is how is FDA intending to go about doing that? Because changing the culture of anything is pretty darn hard. And number two, are there segments of the supply chain, Karin, in your view, that are most in need of change?

KFB: And it's a really good question. We talk about the New Era of Smarter Food Safety and these core elements. Core element number four is food safety culture, and like you, I kind of look at that and say, "That's interesting. What does that mean?"

LLB: Right, exactly. What the heck does that mean?

KFB: What are you talking about?

LLB: Sounds good, but what does it mean?

KFB: And I think in this way, what FDA is stating is that a lot of it's educational -- educating staff, educating inspectors, educating and developing -- looking at behavior, organizational principles, things that make up a good food safety culture. You're looking at manufacturers that have stellar records and understanding a little bit about how they built those records and then using some of that as a case study, conducting literature reviews, looking at, when you have a barrier, what is that barrier? How do you remove that barrier? How do you influence people's attitudes? But I look at it as food safety education is going to be a big part of this, because once you go through -- again, this program is targeted on technology. Once you develop this technology, these tools, these ways to enhance food safety, you're going to have to train people on how to use those tools. And if all of us learned very quickly how to read a menu off a QR code in a restaurant, can you imagine that on a global scale?

And how is FDA -- once they have these tech and these tools available -- being able to then use the tools developed, launch the tools, train not only their staff on the tools but train others in the food supply chain to use the tools? I think that's a big part of their food safety culture. But it will be really interesting to see how that tool develops, how that core element develops over the next several years. Because right now I see a real focus on the smarter tools approach, which is core element number two, and tech-enhanced traceability, which is core element number one.

KFB: Got it. Got it. Before I let you go, Karin, maybe you can tell our listeners a little bit about a forthcoming webinar that you are in on October the 26th. Yes. Give us a little promo.

KFB: Sure. So this podcast speaks to some of the content we will be covering on the webinar, a discussion on FSMA. After all this time, where do we stand with FSMA? Looking at the New Era of Smarter Food Safety, looking at how we enhance, where we go from here. What are the next steps? The webinar will focus a little bit on that, with a good colleague of ours, Tom Dunn, on that webinar. He's assisted our firm with some audits, so he'll bring some insight into some of the things that he sees when he's out in the field and he's actually auditing facilities that are manufacturing food and food additives. That will be an interesting webinar on October 26.

LLB: Indeed. I look forward to it, Karin. And so, listeners, mark your calendars for noontime East Coast time on October 26, where we will spend an hour spending more time on FSMA, on the Blueprint, and how it is really influencing FDA's approach to addressing a very, very important problem, which is eliminating foodborne illness in the United States.

Karin, thank you so much for being here with us today. We always enjoy and appreciate the clarity of your remarks and the broad scope of your wisdom in these FDA-related areas. Thank you.

KFB: Thank you. My pleasure. Have a good day.

LLB: Thanks again to Karin Baron for speaking with me today about the FDA's new approach to ensuring food safety in the United States.

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