Episode Title: GRAS: Are Changes in Our Future? -- A Conversation with Karin F. Baron

Episode Number: 20240111
Publication Date: January 11, 2024

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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 welcome back to the studio Karin F. Baron, Director of Hazard Communication and International Registration Strategy at B&C and our consulting affiliate, The Acta Group (Acta®). Karin and I discuss today an old but evolving concept in Food and Drug Administration (FDA) circles called GRAS, generally recognized as safe. As listeners may know, food additives require pre-market approval by FDA. Substances generally recognized as safe under the conditions of a substance's intended use are excluded from the definition of food additive and thus are not subject to mandatory pre-market review by FDA and may be added to human and animal feed and food. How companies make GRAS determination, what is FDA's role in the process, and whether the GRAS concept should be modernized are a few of the hot topics Karin and I explore. Now here is my conversation with Karin Baron.

Karin, welcome back to the studio. Always a pleasure to have you.

Karin F. Baron (KFB): Thank you. Happy to be back this morning.

LLB: I'm so excited to be talking about the topic at hand: generally recognized as safe. FDA, Karin, has long, long stewarded this process, known as GRAS. Way back in 1958, Congress amended [the Federal Food, Drug, and Cosmetic Act] FFDCA, and the amendments at that time defined "food additive" and required, then, as now, premarket approval for new substances used as food additives. Based on my understanding of this space, Congress provided in those amendments, substances "generally recognized, among experts qualified by scientific training and experience to evaluate their safety," and if the substance is shown to be safe for inclusion in human or animal food -- and this is important -- "under the conditions of [a substance's] intended use," the substance is excluded from the definition of food additive, and thus *not* subject to mandatory premarket review by FDA under FFDCA. That's, as most of our listeners know, Section 409.

That sounds all well and good, but the whole "generally recognized" raises questions of by whom, and under what conditions. I'm interested in your practitioner's view, Karin, of how does this work in practice?

KFB: GRAS -- and we always laugh. We always say, "Not the fun grass. This is a different GRAS."

LLB: Right. Not that other stuff.

KFB: Not that other stuff. Essentially, what FDA is saying here, and what they did -- there's a very long history, as you mentioned, of what FDA was reviewing, what they were mandating under their purview. And then at some point in time, they actually did codify certain substances as GRAS. You can go to the Code of Federal Regulations, and you can find ingredients that FDA viewed, either through what they referred to as something that had been used commonly or through this former food additive petition process, as GRAS.

These are the things that FDA documented, and it's things like you would expect: corn syrup. Duh, right? Fatty acids, algae, enzymes, starches, things that we are commonly seeing in -- what we would consider a food additive and direct use in food. But what FDA states here is that a food substance can be GRAS either through scientific procedure, as you talked about, where there is a general recognition of safety through scientific procedures. But what FDA also says is that they expect, through this self-affirmative process, that the same quantity and quality of scientific evidence that you would be expected to actually put together for a formal approval of a food additive is put into your self-affirmation procedure. You are supposed to put together data and evidence and then convene a panel of experts to, by consensus, agree and collaborate that this substance, its use, and its intended conditions of use are safe.

What FDA says is the difference between a traditional pathway, like a formal submission, and GRAS is basically who has access to the data and who has reviewed the data. In FDA's thinking, to be GRAS, the use and the data must be widely known, and there must be consensus among experts. But they also put in a little stipulation that if the food was actually used, if you can document that your food additive was used before 1958, which is not as easy as it sounds --

LLB: -- well, no.

KFB: No, but if you could do that, then just the experience of its common use in food is also considered GRAS. Then that's kind of applied through your basic self-substantial history of consumption.

That's a very big, broad picture overview, but from FDA's standpoint, these are substances that are supposed to be widely known. There should be available data, and then a panel of experts should be reviewing those data and then confirming that they concur and agree that it is GRAS. That's kind of how the process is supposed to work.

LLB: Okay. No, that's super helpful, Karin. I appreciate that.

Couple of other points that, as a lawyer, I find just super interesting. There have been multiple iterations of this process over the years. And I know as a matter of principle and law, FDA has long maintained that it institutionally has no legal authority under the FFDCA to require premarket review or notification of GRAS substances. But I think, as many of our

listeners know, many such manufacturers voluntarily have sought FDA confirmation of their independent GRAS determinations. In thinking about it, who wouldn't, right? It positions a company in a more legally favorable position.

FDA has, as noted in various iterations, accommodated this request over the years. As you noted, it created this GRAS list way back in '58. Early on, FDA responded to requests by industry to confirm their independent determinations in so-called FDA opinion letters. FDA also offered an opportunity to submit a petition, a GRAS petition process. But I think over the years, the agency determined that that was a very long, time-intensive process, generally taking around six years for each petition.

KFB: Sounds about right.

LLB: As a voluntary measure, I think, institutionally, that must have been just like, "Oh my gosh. Why are we doing this?" Then in 1997, FDA proposed to replace the GRAS affirmation petition process with a notification procedure. And again, correct me if I'm wrong, Karin. Under this process, *any* person could notify FDA of its determination that a substance was GRAS. In 2016, FDA formalized that process with issuance of the so-called "Final GRAS Rule," replacing the *voluntary* petition process with a voluntary notification procedure, where a substance's manufacturer shares its determination that a substance is GRAS, and that rule was effective on October 17, 2016.

That's a lot of background, and a lot of iteration, and a lot of fluidity in a process. I guess I'm interested in your practitioner's view of how that all worked. It sounds to me like it could have been very confusing, frustrating, and the product of these various reviews might have disparate legal or kind of regulatory utility, but again, help us understand from a practitioner's perspective what all that meant and where we're at right now.

KFB: Yes. The 1990 -- I know it's --

LLB: It's kind of a mess.

KFB: This is not one of my favorites. It *is* a mess. This is not one of my favorites, but it's not one of my favorites because, as you describe it, it's so very ambiguous in its intent, because if you look at it, FDA views GRAS as supposedly things that are generally recognized as safe, so it's a lower risk. In the 1997 proposed rule, they basically operated under this interim voluntary policy, where FDA would exercise its good-faith efforts to follow their timelines, which clearly they weren't bound by, because you're looking at six years -- that the final rule, which came nearly 20 years after, still speaks to a process that's entirely voluntary. When you look at this, FDA's [Questions and Answers] -- their own Q&A -- states, "You don't have to submit. You can." And if you do, they've put some timeframes around it, but those timeframes are not shortcuts by any means. I think the timeframes specify that they'll contact you within 180 days, but they can extend by another 180 days, by 90 days as needed.

It's still a very long voluntary review period, but you're under no obligation to wait for them. If you're correct in concluding your substance is GRAS under the conditions of the intended use, you're under no regulatory obligation to submit to FDA. FDA is under no regulatory obligation to approve. So even if you wait for FDA in your decision -- you make the decision to submit your GRAS notice, which is entirely voluntary. FDA is not going to give you back a stamp of approval. It really does beg the question of it's almost like the buyer beware situation. You can formally put together your own GRAS self-affirmation.

You can receive a 20-page letter from a lawyer, but that doesn't mean FDA agrees. FDA *won't* agree, unless you decide to do a formal submission through other avenues, like a food additive petition or food contact notification. It is a bit of an ambiguous space when it comes to FDA.

LLB: Unsurprisingly, a group of food safety activists, including the Environmental Working Group, sued FDA in 2017, not long after the final GRAS rule came out. It's the *Center for Food Safety v. Price* case. The claim was that the GRAS rule violates the Constitution, the FFDCA, the Administrative Procedure Act, and possibly other authorities, because FDA has no authority to require manufacturers to notify FDA of their independent GRAS conclusions.

Ultimately, the court sided with FDA and concluded that the remedy the plaintiffs in that case sought was one that really resided with Congress, and not the courts, and not the FDA. Given this kind of checkered background, the extraordinary administrative process, and the tumult that we've seen since 1958 regarding the disposition of these GRAS determinations, what is your experience today? Do your clients feel that these voluntary determinations continue to be useful and offer utility? Or given this background of lawsuits and the iterative nature of the process, that, "We just may as well go and submit a food additive petition to the agency"? What do people do, and what are the considerations that come to your mind in making determinations of how best to proceed?

KFB: I think the important thing when we look at whether this is the appropriate path to market is whether or not you can justify that your substance is generally recognized as safe, and convene a panel using the amount of data that's quantitative and qualitative, as FDA states. It's going to always be very circumstantial. I read through this case history. It was really interesting. And then there's also been -- and you and I've talked -- a lot of recent articles in the press about food safety in general, but they both had some staggering statistics that kind of indicate that, in one article, they mentioned something like 10,000 food additives that are currently on the market that have utilized this process.

LLB: Wow!

KFB: And then when you -- yes. Then when you look at FDA -- what has been voluntarily submitted to FDA -- for a non-opinion, it looked like -- from the GRAS notices page -- you can go look at all this. This is all publicly available. If you do voluntarily submit, it is publicly out there. There are roughly about 1,100 or so entries in the GRAS notices page, which says that this process, if you believe that there are 10,000, that only a little over a thousand -- and only about ten percent of folks in the industry -- have formally submitted to FDA under this voluntary process.

It speaks to me, and to folks that do ask if this is a valid option for them, that a voluntary submission with an outcome that is not an approval seems empty, and that a lot of industry is not going down the formal process of a food additive petition -- and we'll talk a little bit more about why -- and that 26 years after all of this, we now have the introduction of some new food safety laws, including FSMA [the Food Safety Modernization Act] and the New Era of Smarter Food Safety. You would hope with some of this that we might see a different avenue emerge and that Congress, like you said, has to be the one that leads that charge.

When we look at priorities, what we saw coming out of Congress with respect to FDA this past year dealt more with cosmetics and not necessarily this avenue. I don't know if it's on their purview, but it's always going to be based, on FDA's side, on Congress's inside, on

just a variety of things going on, whether that's political or whether there are issues with food safety.

We'll talk more about some of those things that have been happening. But there's definitely, I feel like, it's time to revisit the most -- as you see from the statistics, it seems like the avenue of self-affirmation has been very popular.

LLB: Yes. That's a wonderful segue to my next question, Karin, because if the voluntary approach seems to hold some appeal, notwithstanding some of the issues we've been talking about, what is the mandatory premarket food additive approval process all about? I am guessing it's not too dissimilar from similar approval processes under [the Toxic Substances Control Act] (TSCA) and [the Federal Insecticide, Fungicide, and Rodenticide Act] (FIFRA), whereby there's a process and a timeframe with some at least expected outcome within a reasonably foreseeable period of time. But I could be dead wrong. What is that process all about?

KFB: The issue with a food additive petition, and even a food contact notification, is they are formal submissions. You do actually receive some kind of response from FDA, so it is an approval or notification or listing on their inventory page. But with it, the burden of proof lies completely with the submitter. I know this is a little bit of a difference from when you submit a new substance under TSCA, where the U.S. Environmental Protection Agency's (EPA) doing a lot of the evaluation. When you put together a food additive petition, you're putting together all of the data to support, not only the identity of your substance, the intended use of your substance; you're also putting together your own risk assessment. And risk here, we're talking about dietary consumption. Based on a certain profile, there can be an intense amount of toxicological data.

LLB: Got you. Right.

KFB: Yes. Putting together a food additive petition is no small thing. It takes years to put together the data that would be necessary. And then once you finally get all that data and you actually submit to FDA, you're still stuck in what is essentially a two- to three-, to sometimes five-year process because it has to go through the Code of Federal Regulations.

Ideally, we don't see a lot of new food additive petitions coming through, and we watch the *Federal Register*. We just don't see a lot of them coming through. Now, ironically, color additives also have to go through this process, and they're regulated a little bit differently than food additives. We do see those come through every once in a while. There are fees associated with the color additive aspect, but not with the food additive petition. I think that, too, talks through the priorities, and FDA's timing, and having to go through the *Federal Register*. Anytime you have those things coming into play, you get delays. You just get delays. It's just the nature of the beast. It is -- you're right. It's timely, it's lengthy, it's costly, and at the end of the day, the outcome is very uncertain.

LLB: Wow. That sounds about as appealing as a root canal.

Let me ask two questions, because this is interesting to me. Is it a fee for service? In other words, a food additive petition will cost, you know, $50,000 in administrative fees and at least there is an expected timeframe? Or is it entirely dependent upon the complexity and the amount of information submitted by the submitter? Is there a fee, and is there at least a projected timeframe?

KFB: And the timeframe is like you stipulate it. In the more complex -- you know, if you're looking at something that has a higher dietary consumption, so it's being introduced as a food additive into a food that we have a higher dietary consumption expectation, and perhaps the profile of the substance requires consideration for some endpoints that are not desirable. You know, we consider it high risk, that will clearly take longer than something that's got a lower consumption with a lower toxicological profile. Yes.

LLB: Right. And one final question on that. Might a company submit a food additive petition and simultaneously have made a GRAS determination to allow it to go to market without an FDA imprimatur of safety through an approved food additive petition that has been approved, or you can't maintain simultaneous statuses that way?

KFB: I would say you can't. It doesn't mean people haven't tried. But I would argue that if you are going down the path of a food additive petition and you're using GRAS, then you've kind of violated the idea of GRAS since GRAS exempts you from the food additive petition process. I think that's something you have to consider when you look at which path you choose, because you can't really do both.

LLB: Right. Intellectually, I appreciate that, but if you meet the requirements of GRAS and you're going the belt and suspenders route, I think to your point, Karin, it raises issues.

KFB: Definitely.

LLB: So unsurprisingly, food safety advocates have for years/decades, expressed a lot of concern with the core scientific integrity of this process, and, unsurprisingly, have pointed to a long list of what I call food calamities. I'm not trying to trivialize the consequences or the harm people may have experienced, because people have been sickened, and in some cases even succumbed to very serious injuries as a result of food additives that have posed risks that were unknown to the manufacturer at the time.

For example, last year -- this garnered a lot of headlines all over the place -- about 100 people were sickened, and some, in fact, lost their gallbladders because of, reportedly, a tara -- that's T-A-R-A -- protein flour included in a product that was included as a food additive. The tara flour reportedly contains very high levels of a non-protein amino acid that can break down and form harmful substances in humans, and that gave rise to the gallbladder incidents. This is just one example of a long list of calamities that have occurred over the years. A lot of people have been clamoring, and perhaps with greater intensity in the more recent past, for a better process. This process has been shown to be flawed in some material respects, in my view, but it hasn't been modernized in any meaningful way for a long time. Why do you think that is?

KFB: When you look at this specific case study, I would say that the evolution of food science has clearly outpaced the agency, and I think even FDA has acknowledged that how we viewed the facets of our supply chain and how foods were manufactured from when these regulations were first envisioned, like 1958, that FDA (1) There is just not a clear understanding of how much has changed. And even, you could say over the last decade, so much has changed from a technology perspective, from the supply chain, from where we get our food. This tara protein is actually manufactured in a foreign country.

These concepts, these ideas of introducing new food to the U.S. marketplace by introducing new processes for manufacturing -- there've been long arguments about genetic modification, nanomaterials, all of this. I think FDA has been caught off guard, and I know

it sounds kind of rough, but even in their own practices, the best they've been able to do is to issue guidance. And the guidance that they issued in 2016 speaks to their thinking about some of this emerging manufacturing technologies and science, and what they expect from you. But it's very clear, even when you look at their coordinated outbreak response and evaluation report on this specific tara protein issue, that they weren't able to identify clearly what the cause of this was. In their report, they acknowledged that the only reason they leaned in on the tara protein was because it was a unique ingredient they hadn't seen before that had only been on the market for a couple of years. It was manufactured by a foreign supplier that -- FDA admitted they had never been to that facility. There are just so many things that you can see here that need to be addressed. FDA is very well aware of this, but FDA is scattered in its intention and what it needs to deal with as an agency.

LLB: True, and we're definitely not knocking on FDA because all of our government workers work hard and utilize and optimize the probably limited assets that they receive from the federal government. It's not like nothing has happened in this space. In 2022, for example, FDA published final guidance titled "Best Practices for Convening a GRAS Panel," which I'm sure people have found helpful; that came out on December 21, 2022, replacing draft guidance issued back in 2017. That guidance is understandably intended to assist entities that convene these panels of experts to evaluate independently whether the scientific evidence meets the standard for making a GRAS determination.

Interestingly to me, Karin, FDA received like a whopping 13 comments on this guidance, one of which urged FDA to emphasize that substances really don't require -- at least many substances do not require -- a GRAS panel, noting that GRAS panels have become too burdensome and perhaps they, too, become unwieldy entities. And to your point with regard to food science and data outstripping the capacity of not only FDA, but *private* entities to systematically and regularly review those data in a way that keeps pace with the relentless pace of technological change and data development. With that as background, the question I have is, is the recent issuance of this guidance an endorsement by FDA of a process that some would regard as fundamentally broken and needs an overhaul, or is it simply the agency's attempt to make more scientifically rigorous these GRAS panel reviews?

KFB: When I look at this, I think it's probably more the latter, but I also think that when you look at five years to go from draft to final, that's not unusual. I don't know if there were a lot of revisions. I'm thinking there weren't, but some of that could just be a symptom of priorities within the agency.

LLB: Exactly. Yes.

KFB: But I also -- a guidance is a very powerful tool within FDA. They're the first to say that it's not legally enforceable, but it represents their thinking. When we look at it, it suggests that even if FDA is only seeing, voluntarily, roughly ten percent of these, that it is recommending -- heavily recommending -- that folks consider this and that some of the GRAS notifications that are being voluntarily submitted are not scientifically valid. I think that's their reasoning behind it because they don't really have the power to change it, because it has to go through Congress.

LLB: Right.

KFB: They do have some purview to it. And when they are seeing it, even though they can't officially say, "We approve it," they *can* provide guidance to folks to say, "This is our expectation." But the alternative to some of the comments about "this GRAS process is too

burdensome" -- is the reverse process of actually submitting a food additive petition any less burdensome? I think you could argue one way or the other, but in my mind, FDA's guidance is incredibly helpful and always appreciated, and it does provide you what they are thinking at this time. That's my thoughts on that.

LLB: No. Good thoughts. And the guidance *is* good, and best practices that bear the imprimatur of an FDA or federal government logo on the document is super helpful for legal and commercial purposes. Speaking of enforcement, a question that I had is what enforcement tools *are* available to FDA when *it* becomes aware that a substance fails to meet these GRAS standards? To your knowledge, Karin, does FDA routinely deploy this authority, and in what contexts?

KFB: FDA scientists are allowed to analyze whether there is a basis to conclude that the intended use of a substance is GRAS. They actually have posted a database that contains GRAS substances that they determined were *not* GRAS. There are only about 12 entries there; it's not a popular mechanism.

LLB: Nope. Not a lot.

KFB: No, but when an FDA scientist does actually determine that something is *not* GRAS, and you have gone through this self-affirmation process, essentially that substance now becomes an unapproved food additive. And so that opens up a whole new area for enforcement, because if an unapproved food additive is added to food, that food becomes adulterated under the terms of FDA, and under FSMA, that now grants FDA more authority to engage in looking at that adulterated food product and requiring, voluntarily or mandatorily, a recall.

They would ask for you to recall everything. This is where the risk of -- and there's always risk. I think one of the things that we always talk to our clients about is it doesn't matter which space you're operating under within the food requirements and the laws. It's a risky business because everybody eats. When you talk about introducing a food additive, whether you've done it through something that's already listed in the Code of Federal Regulations, or you've submitted a food additive petition, or you've done self-affirmed GRAS, once it's incorporated into food, food is the subject of several requirements, several laws, including FSMA, which then *does* give FDA authority to intervene.

What you typically see in FDA's intervention is the result of either an inspection or something along those lines, or, as we've talked about, some kind of catastrophic illness has occurred. You don't want to be on the end of the self-affirmed GRAS that resulted in adulterated food because somebody got sick. It's just a very unpleasant experience.

LLB: For sure. You raised such an important point, Karin, which is we're talking about a very narrow sliver of a very complicated space. You have a food additive. If it's not considered a food additive because it's GRAS, you don't have to submit a food additive petition. If you do, you get to bear the burden of the cost, the time, and the uncertainty of the result. But that's just but one piece of this. And there are so many other potential consequences of the risk any manufacturer of a food additive or food material bears when entering the commercial marketplace.

There's the recall -- the possibility of a recall, the possibility of private litigation, of tort actions, by people allegedly sickened by *your* product, the reputational injury. This is just a very small piece of a very complicated patchwork of federal laws and just the possibility of

private litigation derivative of someone's allegation of adverse consequence or injury. It's a tough space to be in, and as you correctly noted, we all must eat. Our furry friends and critters and horses and cows, they have to eat, too. This applies to food for both human and animal consumption.

KFB: Yes, it does.

LLB: Circling back to that *Price* case that we talked about a bit ago and that the problem must be addressed by Congress, administrative agencies are struggling because of resource limitations, exiting know-how and experienced workers that have been at their desks for many years, just that institutional expertise is drifting out the door. We've talked about this on our podcast with regard to EPA. Congress today is not exactly a happy place, or a particularly productive one. Is there any Congressional activity, to your knowledge, under way that touches upon these issues that might right the ship on the GRAS process?

KFB: I am not aware of anything specific to GRAS, especially at the Congressional level. But then, I'll be totally honest. MOCRA, the Modernization of Cosmetics Regulation Act, I think that took a lot of people by surprise, even FDA. That came out of Congress at the end of 2022, but it was attached to an appropriations bill, so, anyone's game here.

Whether certain incidents that have occurred over the past couple of years, especially the infant formula, and now we're dealing with lead in applesauce. That may prompt changes, but would those changes impact this particular aspect? I doubt it because those aren't being linked to GRAS additives. Could we see some changes in food safety as we move into the next year? Could Congress be looking at this? We've already had two major changes to food law over -- from 2011, with FSMA and then the New Era of Smarter --

LLB: -- MOCRA.

KFB: Yes, and the New Era of Smarter Food Safety under Trump. Obama's FSMA rules, which are still being enacted; they're very complicated. There were a lot of aspects of FSMA that have yet to be implemented, and there may be more of a centralized focus. We've seen that with the traceability rules on what's happening right now. I suspect that's probably where you're going to see things. Even when you look at FDA's budget, FDA's budget for 2023 does include an increase toward food safety, but the greater degree of FDA's budget for 2023 for fiscal year is more toward medical, and then a huge investment in pandemic preparedness.

LLB: Right, right. I mean, there are so many challenges to choose among, right? We had this pandemic, which really threw all federal agencies off in terms of planning and the deployment of limited resources to new priorities. It's a tough, tough issue.

I did notice earlier this year in 2023, FDA embarked upon a food chemical safety initiative. Many of us have been very, very interested in what that is all about. Food chemicals covers a lot of territory and bears directly -- or indirectly, depending upon your perspective -- on this issue of GRAS. It's run out of the Center for Food Safety and Applied Nutrition, or CFSAN. Can you tell us a little bit more about what your understanding of this initiative is?

KFB: Sure. FDA notes that it's enhancing its approach to food chemical safety. The areas that they're going to be targeting are some that we've been talking about: expanding their tools, looking at the methods that they use for conducting safety reviews and assessments, prioritizing new and evolving information. But some of that has to do with the *re-*

assessment of chemicals, so taking a look at chemicals because they've got new data, or looking at things that have emerged with all of the data that have come out from other programs or data they themselves have generated, but also then monitoring the food supply chain to ensure that the chemicals that we *are* using are present at levels that are not a risk. This is kind of all part of that chemical safety program, and what they indicate is that they're working to develop a new approach to, not only mine existing data more efficiently, but to prioritize substances for in-depth review.

I look at this as maybe equivalent, but not equivalent, to some of the priority substances under EPA. And that in doing so, the greater funding would help them establish a routine, systematic review of chemicals. And in doing so, what they've done is created the new unified Human Foods Program, and that this would allow them, in their words, to realize the preventive vision of FSMA, so that -- it's a very big space that they're talking about because, to be blunt, there are a lot of chemicals in all aspects of our food supply chain. Looking at and prioritizing based on risk is where they're headed under this new unified Human Foods Program.

LLB: Interestingly, also, as I think some of our listeners know, earlier this year, we learned that former Office of Chemical Safety and Pollution Prevention Assistant Administrator under President Obama, Jim Jones, just a brilliant regulator and friend -- I have so much respect for Jim. He became Deputy Commissioner for [Human] Foods at FDA, which is a new position created after -- and probably in the wake of -- the infant formula tragedy, to which you alluded, as it unfolded last year and earlier this year), although it's a little unclear, because of the newness of this position, I think Jim just joined the ranks of the FDA community midyear, if I'm not mistaken. Karin, you might know better.

KFB: I think it was September.

LLB: September? Wow! That's like yesterday, right?

KFB: September. Yes, exactly.

LLB: It's unsurprising that the expected output of this office remains a little unclear and fuzzy. But given Jim's background -- he has an extensive background in pesticide chemical, ag chemical, both risk evaluation, risk mitigation, and TSCA risk evaluation and risk mitigation. I think certain inferences can be made regarding what he is doing at FDA in this Deputy Commissioner role, but what are *your* thoughts on that?

KFB: I'm very excited to have Jim Jones be part of FDA. He is currently tasked with leading the charge for setting and advancing priorities under the Human Foods Program. We have the new unified Human Foods Program, and then we have Jim now, responsible for leading the charge and setting in advancing priorities. The program areas are to include a wide variety of things: food safety, chemical safety. They're targeting innovative food products, which is exciting to see. And then Jim's experience fits nicely with new agricultural technologies, in the hope of which we will start to bolster, as they say, our resilience in our food supply, because we can all agree that there were, as we talked about the pandemic, there were definitely issues with supply chain and food, but also the acknowledgment of technologies and the globalization. While Jim has been there a short tenure, we have started to see in that the idea of reassessing food additives. Currently there is a proposal to revoke the use of brominated vegetable oil in food. The reason I picked this one out -- because ironically, it was originally GRAS --

LLB: Oh, no kidding?

KFB: Yes, it's been a long -- had a long --

LLB: I missed that.

KFB: It's had a long, sordid history, this one, but it was originally determined to be GRAS in the 1950s, but in the 1970s, it wasn't considered GRAS, but it was a food additive. What you're seeing now is the start of that prioritization of looking at things that have been determined to be GRAS, in evaluating and prioritizing, and then -- if necessary, when we reassess the chemical.

I look forward to seeing where we go from here and what happens also as FDA starts to reorganize a little bit and how that lays out Jim's focus, and then a continued progress toward, hopefully not just revoking everything. That doesn't sound like -- revoking doesn't sound like the right path forward -- but the idea that some attention is going to be placed on this to make things positive.

LLB: Yes, I would agree, especially given this conversation. In addition to what you've already identified, are there other developments or expected initiatives in the new year? I know the Unified Regulatory Agenda came out recently. Anything that our listeners would be interested in knowing about food safety in 2024?

KFB: It seemed like the Unified Agenda aligned with what the Unified Agenda had been. I didn't see anything incredibly shocking. It has been the same Unified Agenda for the last several years. Some of that includes focuses on the food contact notification program, which we didn't really speak to in this, but there has been a long discussion about going back through the food notification program and removing things that are no longer being used in that space.

The rest had a lot to do -- there's a heavy, heavy focus on that traceability rule, because the traceability rule leads back to targeting high-risk food areas. We've seen a lot of outbreaks associated with agricultural foods, like leafy greens and cantaloupe, currently. I didn't see anything new. I did see something pop up this morning about partially hydrogenated vegetable oils and the continued discussion on revoking their use. But that has been part of a long conversation, so it wasn't shocking that that showed up in the *Federal Register* today.

But as we move into 2024, I think you're going to see the continued reshuffling of FDA's offices; the ORA offices (Office of Regulatory Assessment), I believe, are being reworked. I'm curious to see what that looks like at the end and how that then ties into the unified Human Foods Program.

LLB: Yes. Great response, Karin. Thank you. I know we've covered a lot of territory in this conversation, but if our listeners were so inclined, where might more information be had with regard to GRAS?

KFB: We obviously covered this quite a bit. We've delved into this with our clients and our clients' base, so if there is something new and emerging, B&C and Acta would post it on our Firm Clients and Friends memoranda. Our Forecast is going to be out in the beginning of the new year, and that will have some focus areas on what's happening at FDA as a whole, not just specific to this area.

And then I encourage folks to try to navigate the FDA web page. Quite interesting how they lay it out. There's a lot of information there. It's not always easy to find. If there's something specific you're trying to locate, feel free to reach out. We can help you. But that's kind of -- the *Federal Register* we follow all the time, so hopefully with that, we provide enough resources for folks that are interested in this.

LLB: Wonderful. Thank you, Karin, and thank you for a really excellent conversation on generally recognized as safe. It's been an evolving concept, subject to a lot of conversation, a lot of litigation. And I suspect 2024, we will see additional developments in this space, so I urge our listeners to watch for them. Thank you so much.

KFB: Thank you.

LLB: Thanks again to Karin for speaking with me today about the ever-fluid concept of GRAS. FDA's expected in 2024 to address a range of issues, and GRAS may well be one of them, if Congress does not act first.

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