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Food for Thought and Thoughts on Food: What to Expect in 2023

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On this episode, Amaru Sánchez and Bob Hibbert discuss trends you can expect to see in the food and drug space in the coming year. Beginning with the emerging market of cultivated protein, Amaru and Bob cover what is next for the U.S. Department of Agriculture (USDA) in regulating cultivated poultry products, before discussing the Food and Drug Administration's (FDA) Human Foods Program, labelling issues of alternative products, and more.

Practice Areas

FDA and USDA Regulatory Compliance
Food & Drug

Transcript

Bob Hibbert

Hello everyone and greetings from our nation's capital. I'm Bob Hibbert.

Amaru Sanchez

And I'm a Amaru Sanchez.

Bob Hibbert

Welcome back to our podcast Food for Thought and Thoughts for Food. We talk about the regulation thereof by our federal government. And today we're going to go over food and beverage policy trends that we can expect and look forward to in the coming year. Without further ado, let's start with a topic I know, Amaru, is near and dear to your heart. Which is the emerging market for cultivated protein. What's happened there recently and what's going to happen in the upcoming year.

Amaru Sanchez

Yeah, thanks Bob. Definitely a topic that is very near and dear to my heart. And not to kind of pat myself, or ourselves, on the back, as we predicted, 2022 turned out to be a very interesting and a big year for the cultivated protein industry. I think, what everyone knows, is late last year the FDA completed its first pre-market consultation for human food made with culture animal cells. And based on the documents, you know the agency posted, the process took a little - about a year - and this is of course I'm talking about cell cultivated poultry. Since this product is made from cultured cells regulated by USDA, that's their next stop. So they're halfway there but not done.

Of course, there's a few other hoops they need to jump through, including obtaining a grant of inspection for the manufacturing establishment. As well as meeting other USDA regulatory requirements, including the requirements for ensuring sanitation, and developing and implementing hazard analysis and critical control point systems. And then finally obtain prior label approval, which is an interesting one, which we'll talk about labeling a little bit later here. But I'm taking an optimistic view and think that we're going to hear back from USDA in 2023. So, by the end of this year I'm calling it. We're going to have a fully - have underwent both FDA and USDA review – cultivated poultry product on the market. Whether that'll be in a grocery store or restaurant, is still TBD. But, I'm excited for that. I'm also predicting we will see more, or a, consultation from cultivated seafood products.

Bob Hibbert

Yeah, I think, Amaru as you suggest, is really there are three hoops and this this first hoops a big one. And credits due to the people at Upside Foods, who were persistent enough to go through a complicated time-consuming process to cross that threshold. Which, and credits due to FDA as well for engaging in that process, I think in a pretty cooperative manner. Question number two, as you say, is coming under the jurisdiction because it's a poultry product of USDA's Food Safety and Inspection Service. And I think you have some solvable, but, you know, potentially complicated questions of integrating within one continuous process theoretical oversight by FDA as well as FSIS. Although, since FSIS, given its continuous inspection model is going to have someone in the plant on a daily basis, they're really going to be the ones calling the shots. And then last and not least, is what can you call this stuff? And we'll get into that a little bit later.

Amaru Sanchez

And Bob, just a quick follow up with that. This, I think with the formal agreement between FDA and USDA, we know that agencies both have review of this in the pre-market stuff. But moving forward, this will be a dual jurisdiction product. Is that correct?

Bob Hibbert

That is correct. But ultimately when that product leaves the facility it's going to leave with the USDA mark of inspection. Which really indicates that, like I say, it's really - as a practical matter - it's FSIS that's going to be doing the day-to-day oversight of that production.

Amaru Sanchez

And if it does happen in 2023, it's very exciting for both the industry and consumers to finally try these products, not just reading about them. And I think another cause of excitement for the food industry is what the agency has planned following the recent release of the Reagan-Udall Foundation's external evaluation of the FDA Human Food Program. Bob, what are your thoughts on how the agency will handle implementing some of the recommendations in the report?

Bob Hibbert

Well, if we look back to last year, there's longstanding debates as to the appropriate functioning of FDA's food oversight function. It's often said it's a bit of a stepchild within the agency, that tends to have more resources, more focus, on drugs and medical devices. But what really brought that to a head last year, was the problems that they faced within formula where a lot of people thought the agency had dropped the ball. So, what do agencies do when they're under that kind of pressure? "Let's do a study!" So off they went to this Reagan-Udall organization, which gave it a critical look and does what such studies do. It laid out a range of options. Some of them relatively dramatic, such as establishing a whole new food safety agency, but more mundane and - in the end probably more likely – is some form of reorganization, the longstanding argument being that chain of command isn't what it should be and there ought to be someone within the agency with food responsibility that reports directly to the Commissioner of FDA. And that involves internal turf battles with the food people and the Office of Regulatory Affairs and so on. That's the type of recommendation. There's a promise that within the month or so there's going to be some announcement. I think the expectation is that there is going to be that reshuffling and there's going to be more of a food czar, if you will, at FDA. So, we'll see how that plays out. I think the other question is "how much difference does that make?" It's one thing to move around boxes on a flowchart. It's another thing entirely to change an agency's culture, how it operates, and it also goes to the question of resources. What organizations like FDA, when they're under pressure, tend to say is, "Well, we need more resources, we need this, we need more authority, and we need more resources." And re-organizing the flowchart is not going to do either. So, if and when that change is made, we'll see how much or how little difference that makes in terms of how the organization really functions and how the relevant industry is to be regulated. With that, I think that takes us logically to what we just touched upon. Our labeling issues and labeling issues, particularly, as we deal with alternative products like plant-based products. This gets into questions of accurate labeling and also how those fit with long-standard standards of identity that have been on the books for years and many cases are outmoded but, in many cases, don't contemplate some of these product innovations. But what do we think is in store there?

Amaru Sanchez

I'm going to do another of my predictions and I think 2023 will be the year that FDA finally weighs in on the longstanding debate of the labeling of plant-based milk alternatives. After all, the agency included a guidance document on this very topic in their food program guidance under development. And there has been a guidance document regarding the labeling of these products with OMB since March 2022. As you mentioned Bob, you know, there has been sort of an ongoing debate in the food industry as to whether

standards of identity are even necessary and inhibit innovation. And we've actually seen some state-level lawsuits attempting to enforce federal standards of identity, mostly in the state of California. And, generally, these lawsuits have sort of been decided in favor of the plant-based products use of these traditional nomenclature. Of course, you know, the big takeaway from those cases that provided that the label contains sort of a descriptive term to prevent the consumer from you know, being misled essentially. But, you know these issues are not just two FDA regulator products right, Bob? I mean going back to what we initially talked about, USDA regulated cultivated meat and poultry products will need to get their label approved. What can the industry kind of expect in regards to the labor review process for this? You know there's been a few terms being thrown out for these cultivated meat or poultry cultured meat or poultry. Does the agency weigh in on that or will it be one of those whoever is first out of the gate with your approved label, the industry just lines up behind it?

Bob Hibbert

Yeah, well I think those questions run together. I mean I think to back up I've sort of characterized it as something of an easter egg that's sort of embedded in the USDA process. Which is that the food safety and inspection service has very clear federal preemption over its labeling decisions. Something that FDA does not have and some people in FDA would like to have, but do not have as a matter statute. So you have a blackletter law that says that states cannot impose alternate requirements for the labeling of products that are federally inspected within the FSI system. And the fSI system includes private label approval. Again, given my past experience something near and dear to my heart. But, what that means is that at some point, FSIS will have to make a call - whether it's cultivated, cell cultured - whatever the terminology is. I mean the two questions are "What do you – how, if at all, do you differentiate this?" And there are some comments that saying you shouldn't at all. That if it's chicken is chicken, if it's meat, it's meat. But I think, what is more likely, and I think what the industry itself supports is some differentiating language at this point one. Point two is your ability to access traditional terms like burger and hotdog or whatever. But once FSIS makes that determination, it's really a case-by-case decision making system, not unlike the court. Once Company X comes in and says" okay, we'll approve cell cultivated chicken," then they've set a precedent. And unless there's a reason not to, the next guy that comes in is presumably going to get the same treatment. There may or may not be rulemaking attached this, but rulemaking takes forever. And in the meantime, you've got case-by-case precedent that's going to stick and is going to provide an important shield to this industry at least for the products under FSI's Jurisdiction, which does not include seafood with the exception of catfish - which we dont need to get into today. And that's different from, say, some of these plant-based products that are going to face continuing litigation at the state level in certain states that are not particularly friendly to such products and have enacted legislation that really cuts off access to some of that traditional nomenclature. So again, I think here is that FSIS has federal preemption and a case-by-case system and that's going to drive the labeling determinations.

Amaru Sanchez

Yeah, it sounds like USDA is going be pretty busy in 2023. Because, in addition to figuring this out, they're also setting a potentially new safety strategy, right? For certain, more traditional products, and this is the one I'm sort of alluding to here: sort of, you know, pathogen control in certain poultry products. Can you talk a little bit about this relatively new initiative?

Bob Hibbert

Well, USDA has announced that it's in the midst of pursuing a new regulatory framework for the control of salmonella. The incidents of salmonella pathogens in poultry products. Take a step back. I mean the magic word in food law, really all food and drug law, is the word adulterated. If a product is deemed to be adulterated, unwholesome, unsafe for human consumption, it cannot be marketed. And in the FSIS world, that means it not eligible for market inspection. It's not going to leave the plant. For decades, there have been discussions about the potential status of salmonella as an adulterant. And that is worth looking at, really, sort of the big 3 pathogens that have been the focus for the last couple of decades at FSIS. One is e-coli, and certain strains of e-coli that have been deemed to be adulterants. There's also the Listeria Monocytogenes, which is an adulterant of ready to eat products. And in those cases, the agency has had quite a bit of success in driving down those numbers and driving down, more importantly, the food borne illnesses associated with those pathogens. With salmonella, not so much. The incidence rates have remained relatively high. So, this framework sets out to deal with that. There been decades of arguments about that. There was litigation back in the 70s that was knocked down that made that claim. There was litigation around the turn of the century that I happened to personally involved with, that knocked down the notion that so-called salmonella performance standards were - could be - create an enforceable performance standard. But here we are again. There have been petitions since that asked for certain strains to be considered adulterated and FSIS says they're still looking at that. But they're also looking at some sort of potential requirement that incoming flocks would be tested for salmonella before entering the FSIS establishments, the enhancement of more process control requirements within the plant, and, again, the determination that some strains might be considered per se adulterants. That's obviously pretty controversial. There are a lot of comments on the public record both pro and con. But, I think the agency is determined to bite that off in the coming year and we will see what they come up with.

Amaru Sanchez

So, you kind of touched on this towards end of your comment right now. But, if you had to guess, based on your experience and historical parallels with the other pathogens you mentioned, what's a time horizon for some of these things to be finalized? You know, we know if this goes through rule making it could be several years. But I recall with the Jack in the box e-coli issue that it kind of went through a little quicker. What can we expect?

Bob Hibbert

Well, it's a good point of historical reference because you go back to the 1990s, when the FSIS first declared certain strains of e-coli to be adulterants. That was driven by a tragedy. It was driven by an outbreak that came out of fast-food establishments in the state of Washington, which led to serious illness and even deaths of small children. And what tends to happen in that situation, those crises tend to drive quick action. So, you had immediate action by FSIS at that time to declare these strains as adulterants. There were challenges that didn't last very long and that's been on the books ever since. Here we don't have a crisis. We have longstanding concerns about the status of salmonella, but it's a little tougher to point to any emergency rationale for such action. And that suggests a slower, the need for a slower more deliberative process. How slow and how deliberative I think remains to be seen. Moving on, let's get into the interesting, but tricky, world of sustainability that I think is – becomes - the focus of the Federal Trade Commission which has been responsible for the so-called green guides. What can you tell us about that?

Amaru Sanchez

Yeah, so last year, you know, we predicted that the Federal Trade Commission will update and release the Green Guides, which sort of helps marketers ensure that the marketing of their product doesn't cause consumer deception. Particularly around areas of environmental claims. So, while we did not exactly get that right, the FTC did recently announce that is soliciting comments about updating the green guides. This, I think, generally tends to happen every 10 years or so. And in addition to a series of specific questions that the FTC wants the public to weigh in on, they are looking for guidance regarding some very popular claims we have seen, including "compostable," "degradable," and "sustainable." So, why are we talking about this on a food podcast? Well, because as we've seen, consumers and investors are showing an interest in the environmental and sustainability commitments made by food companies. Both sort of legacy as well as new food companies. And the industry has responded. Not only are we seeing more and more companies, both legacy and new companies, make these what's termed environmental, social, governance commitments - or ESG. But we have seen a whole industry develop around ESG data for the food industry. But this is still a very new area and there are a few widely accepted industry standards for claims that FTC is seeking guidance on. Including "climate friendly" and "sustainable." And as we have seen, you know, these claims are increasingly becoming a source of litigation by consumers and interest groups. So, I'm hoping by the end of this year we would get an updated Green Guide that has a little bit more information for companies to ensure that they could at least have better guidance to avoid having some claims be considered deceptive.

Bob Hibbert

Yeah, and just to clarify, that the jurisdiction of the Federal Trade Commission essentially extends in the space to advertising. Whereas FDA and FSIS are focused on labeling. But those are obviously closely linked. What you're going to say in the ad, you might well want to put on the label and vice versa. Defining these terms is easier said than to done. You know, I've had my own experience with terms like "natural" that are still out there. Sort of, sort of defined, but sort of not defined in some places. And it's just terms like that, that are so open ended. Defining them, it's like holding water in your hands. I mean, it's just a challenge having tight enforcement standards But, people want to make those claims. The government doesn't want people to be misled, so it gets dragged into trying to define these elusive terms and the pressure to do that and the desire

of people to sell based on this terminology is only going to increase.

Amaru Sanchez

Absolutely, and we've also seen some increased activity and interest in another federal agency, the Security Exchange Commission, really ramping up and staffing certain task forces that are exclusively looking into these ESG claims. Of course, that's for public companies, but I think that would be a good guide in the sense of that this is an agency priority. So, we may see some hopefully some cross-agency collaboration on ways that the industry can avoid coming on the radar of the SEC, as well as the plaintiffs bar. Another area I think will undoubtedly get some guidance on, in this case from another branch of government, is the Supreme Court's weighing in on California's Proposition 12. We talked about this in the past, but Bob can you give us a quick refresher?

Bob Hibbert

Sure. Well, as I'm sure many of our listeners know, California tends to go its own way in regulatory areas, generally. That includes, in this case, issues involving animal welfare. So, California enacted this Proposition 12, which bans certain animal raising techniques. The use of so-called gestation crates, which confine animals and would apply to pork, eggs, and veal that are sold within the state. If California were imposing those types of requirements only upon facilities within the state, that would be one thing and it wouldn't - whether people liked it or not - it would probably pass legal muster without much controversy. But here what they're doing is they're imposing it on any product to be sold within the state. So, while California doesn't itself have a big pork raising industry, Iowa certainly does. But basically, if people, if pork producers in Iowa, want to sell their products into the state, they will have to conform with the standard if it's held up. So that's worked its way all the way up now to the Supreme Court, which has heard arguments on it. There are other states that have passed or interested in passing similar laws. Massachusetts has enacted similar law. And that's up for grabs at the court. And it really involves a broader question surrounding what's termed the dormant commerce clause. And the argument, to simplify a bit, it boils down to whether the court might consider that to be an unreasonable burden on interstate commerce. That you're gumming up the works of a nationwide marketplace by having one state impose its requirements. But as you saw in the arguments in front of the court, that goes to lots of different directions and doesn't necessarily fit into one political bucket. In other words, if a so-called blue state can enact these types of requirements another so-called red state could come back with other requirements to go in a different direction. So there are issues here that go to the regulation of commerce that transcend the animal welfare concerns. But, this is a big animal welfare issue, obviously. And it would be interesting to see. It's not an if it's a when. I mean it's, there'll be an opinion by the summertime. One way or the other there will be a law of the land and it'll be interesting to see, to what extent, it's more of a dry commerce cause decision versus something that really is influenced by the underlying animal welfare concerns themselves. That remains to be seen.

Amaru Sanchez

Correct. Yeah, I think you mentioned this the justices from quote unquote liberal as well as conservative justices, kind of played this out with some of their questions. You know, what if one state that requires certain firewood to be imported to their state, requires them to use a certain pesticide, you know, is that would that be held up or not? So, there's to your point this hits not just animal welfare but some longstanding state laws. I'll be curious to see how the justices rule in this.

Bob Hibbert

Yeah, I think another question was, I think was from justice Kavanaugh, was "What if there's a law that says you can't sell fruit in our state if it was handled by people who aren't in the country legally?" I mean that just suggests that any sort of hot button political issue can be forced into this paradigm, and you can wind up in lots of interesting directions. So, speaking of interesting directions, I think that's suggested to people that there'll be some interesting issues that unfold this year. For those of you that in addition to being listeners, are also readers, this discussion tracks an article that we put out in the Law360 publication at the beginning of the year and I think we'll have a link up to that in our website, so feel free to take a look at that as well. Otherwise, we appreciate everyone listening, wish everyone a Happy New year and I'm sure we'll have other developments to talk about in the coming year. Any final thoughts Amaru?

Amaru Sanchez

None here, just, ah, looking forward to hopefully another exciting year in the food and beverage industry.

Bob Hibbert.

Amen. Thank you. Bye bye.