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A CONVERSATION WITH

When agencies team up: A conversation with Emily Strunk, senior associate in Mayer Brown's D.C. practice

By Lisa M. Keefe on 5/21/2019

Months after the Food & Drug Administration and USDA outlined their much-anticipated agreement for how the cell-based meat industry would be regulated in the United States, nothing has been forthcoming in terms of further details. Meanwhile, the companies in this space have continued to herald their advancements: Israeli company Aleph Farms recently raked in another $12 million in funding from such investors as Cargill Inc., and several companies now are promising commercially available products by the end of 2019.

The Analogue Dish checked in with Emily Strunk, a senior associate in the Litigation & Dispute Resolution group in Mayer Brown's Washington D.C. office, where she focuses on regulatory matters and consumer protection issues. She has experience parsing regulatory law across nearly a dozen agencies in the U.S. and abroad, with a specialty in gaps or gray areas in the law that emerge when new technologies hit the market. With a communications background, she has developed a niche in the area of labeling.

Analogue Dish: What does the agreement between the FDA and the USDA bode for the future of the meat market specifically? What is known and what is as yet unknown?

EMILY STRUNK: Federal agencies have had joint jurisdiction over various technologies a long time. Then new technology arrives and they have to figure it all out again.

One thing this agreement makes clear is where in the process FDA will have oversight and where USDA will pick it up. Until there's a higher degree of confidence in exactly how it's going to work, agencies like to keep it

broad so they don't make promises they can't keep.

As it is, the agreement's done a pretty good job of setting up the process. It makes sense that this is a first step.

AD: You say that the agencies are keeping the agreement broad, but what are the areas where the way forward is murkiest?

STRUNK: I think the biggest question is labeling. How will these products be marketed to consumers? Will it include some understanding that this is not a traditional hamburger?

As I've seen other [regulatory matters] progress, [both agencies will] try to do their best to apply the existing framework to the new technology. From FDA's perspective, they're approaching it from a food additive standpoint. I think people were surprised when the new technology came out — it all seemed a little 'Star Trek' — but FDA has done a good job of figuring out where it fits into its existing regulatory framework.

Labeling will be at USDA, and because at USDA the labels have to go through a pre-approval process, the process is more resistant to outside critique and lawsuits, particularly in the area of consumer class action suits. We see this in the suits against the use of the term 'natural' all the time. Plaintiffs' lawyers drop cases against USDA-regulated products but continue cases against the FDA-regulated products.

Another aspect is, will they call it out on the label as being a non-traditional hamburger, for example? It *is* meat and that's what they're selling at the end of the day.

AD: What conclusions can be drawn from other food labeling disputes, like plant-based milks?

STRUNK: With the non-dairy milks [regulated by FDA], there is somewhat of a public health argument because of the nutritional differences.

USDA also does less with standards of identity. They have the authority to define meat as being something that requires an animal, but it's hard to predict whether they will or not. If they call it 'meat' there may be some information on the label describing its origins. When you look at how consumers feel about it, the feelings around this are, as of now, a little bit stronger against cell-based meat technology. It's similar to the way they feel about foods labeled 'GMO' or 'non-GMO'.

USDA may decide that it's important to label cellular-based meat products from a consumer perspective, and also from the producer perspective (to distinguish it from meat from an animal). Particularly in states that have an economic interest in animal-based meat products, it would not be unlikely to see some action on this issue going forward in those states.

AD: How does this play out on a canvas where Congress also is trying to get involved?

STRUNK: The way it stands right now if Congress doesn't take further action, the agencies just move forward. They keep talking, and will probably likely see some guidance documents if they decide that no special

regulations are needed to implement this. It's easier to issue guidance documents rather than new regulations.

Given the regulatory mechanisms that each of the agencies has in place, if there is no need for more regulation then it just creates an extra bureaucratic headache.

Now, if Congress legislates one way or another then the agencies would have to see how they'd have to apply the new law.

AD: And where the states are trying to get a piece of the action?

STRUNK: On a state-by-state basis, it's hard to put in place labeling requirements that are different or in addition to what the federal authorities require on USDA products compared with FDA products, because of USDA's pre-approval process. And once USDA makes a decision on labeling cell-based meat proteins, the states really have to go with what FSIS puts on the label.

The cell-based meat sector still has a lot of challenges. The product isn't even in the marketplace yet. It remains to be seen whether the texture and taste pass muster with consumers. In fact, there's a lot that has yet to be seen.