HLS Clean Meat Regulatory Roundtable

Harvard Law School, August 9-10, 2018

Event Schedule

Wednesday, August 8, 2018

6:00-8:00	**Welcome Reception**
	Nubar Fireside Lounge at the Sheraton Commander

All Following Sessions & Meals in Lewis 214A & B

Thursday, August 9, 2018

8:30-9:00	Continental Breakfast Available
9:00-9:15	**Welcome / Introduction**
9:15-10:45	**Topic 1 – Regulatory Timing**
10:45-11:00	Break
11:00-12:30	**Topic 2 – Agency Jurisdiction**
12:30-1:30	**Lunch – EU Regulatory Presentation**
1:30-3:00	**Topic 3 – Pre-Market Evaluation**
3:00-3:15	Break
3:15-4:45	**Topic 4 – In-Market Safety**
4:45-5:00	**Concluding Discussion**
5:00-6:00	Cocktail Hour
6:00-8:00	Dinner

Friday, August 10, 2018

8:30-9:00	Continental Breakfast Available
9:00-10:30	**Topic 5 – Labeling, Marketing, Product Identity**
10:30-10:45	Break
10:45-12:15	**Topic 6 – Comments to FDA / Collective Strategies**
12:15-12:30	**Closing Remarks**
12:30-1:30	Lunch (can be taken to go)

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Session Topics

1. Regulatory Timing

If one party rushes through the regulatory door unprepared and hits unexpected hurdles, that could cause substantial setbacks and approval delays for the entire cellular agriculture industry.

What is a realistic timeline for one of the clean meat companies to have a product ready for regulatory approval? Is it possible in a competitive environment for companies within the clean meat sector to cooperate in identifying and adhering to an optimal regulatory pathway or pathways? Will the companies be willing to openly share their timelines with one another? Will investors have an issue with this? Would there be any anti-competitive prohibitions or concerns?

2. Agency Jurisdiction (generally)

The recent public turf war between FDA and USDA highlights the fact that the agency or agencies that oversee the production, inspection, labeling, and/or sale of clean meat will have a critical impact on every aspect of clean meat's emergence and commercialization, and could make or break the nascent industry's chances of disrupting traditional animal protein's dominance.

There are pros and cons to each agency's jurisdiction and while it seems the consensus is that they weigh in favor of FDA jurisdiction both pre-market and in-market, there are several arguments that can be made in favor of USDA jurisdiction in-market: consumer acceptance, reduced risk of consumer fraud class actions (due to preemption), and reduced recall risks.

And even if the FDA controls the pre-market process, this does not mean it will be the agency regulating the products in-market. Shared jurisdiction in-market is also a possibility. It also might be prudent to consider the potential impact of the current Administration's "one food agency" approach.

As an example of the complexity of determining regulatory jurisdiction, we can consider the following four types of clean meat products and the distinctions among how their conventional analogs are currently regulated:

a. Commodity cellular ag products made to replace conventional meat and poultry products (which currently are regulated by USDA).

b. Commodity cellular ag products made to replace conventional seafood products (which currently are regulated by FDA).

c. Value-added cellular ag products made to replace conventional meat and poultry products (which currently are regulated by USDA). How shall this meet the labeling requirements and policy memos for items called "meat lasagna," "meatball," "meat sauce," etc.? Would this be the same requirement, regardless of meat "source," (e.g. percentage of meat in meat lasagna must be 12%, etc.).

d. Value-added cellular ag products made to replace conventional seafood products (which currently are regulated by FDA). Compare, for example, the definition of a "crab cake" which is species-specific and a "fish stick" which is not.

3. Pre-Market Evaluation (jurisdiction & pathway)

Even if FDA were the sole agency to regulate the production and labeling of clean meat products, it is still unclear which regulatory pathway within FDA would be most appropriate, as the agency itself seemed to acknowledge during its July 12 meeting. Generally Recognized as Safe (GRAS) determination would seem to be the consensus, but that still leaves several open questions:

- What are the specific factors that would need to be assessed in establishing safety under FDA's GRAS approach?
- What are key precedents, including those that rely upon substantial equivalence?
- What would be the "ingredient" that would be assessed?
- Is there an adequate basis to assert "general recognition" of safety?
- What kind of data would be submitted?
- Is there a way to exclude animal testing?
- What would this look like if the USDA has jurisdiction instead?
- What about the impact of patents on regulatory efforts? Would patenting different processes or products lead to the need for multiple regulatory approvals?

4. In-Market Safety

Whichever agency is tasked with regulating clean meat must employ a regulatory pathway that adequately ensures the products' short and long-term safety. It also must instill public confidence by virtue of transparency and comfort with both the products' manufacture and the manner in which the agency has established that safety. Public fear of and aversion to genetically-modified foods is well-documented, despite FDA repeatedly assuring that such foods are safe. What are ways that companies, regulators, and interested parties can avoid making the same mistakes and prevent the public from developing an unwarranted aversion to clean meat products?

Hazard Analysis and Critical Control Point (HACCP) is one internationally recognized system for reducing the risk of safety hazards in food. Will HACCP be an appropriate methodology to determine safety for cellular agriculture products? Should the industry proactively create its own "model HACCP" program to determine potential hazards? Both USDA and FDA identify 3 categories of hazards that also are present in this new sector: chemical, biological and physical. What is the best way to identify the industry's critical control points (CCP's) to mitigate this risk?

- What is the framework for ongoing oversight?

- Will both FDA and USDA require continual inspection, or will this be a requirement only for USDA products as is the case now?

- If under an "FDA-only" approach, would the agency have adequate expertise/experience to assess "processing" and would such assessment be performed under FDA's requirements for hazard analysis and risk-based preventive controls?

- If under a dual agency approach, could FDA regulate the "bioprocess" as part of its safety evaluation, with USDA regulating traditional "processing" under its HACCP requirements?

- Could FMIA/PPIA apply under USDA jurisdiction? What would that look like and what would the associated costs be for clean meat producers?

5. Labeling, Marketing, Product Identity

How clean meat products will be labeled, marketed, and advertised are questions of utmost importance to the future of the industry. Both FDA and USDA have statutory mandates to prevent and address consumer deception in food labeling. Yet they take very different approaches to this mandate. How to ensure accurate, informative labeling for products that will be at once familiar to consumers, yet also wholly new and different than their traditional meat counterparts, is still an open question.

Will these products even be allowed to be called "meat"? The use by clean meat companies of customary meat terms to describe their products—chicken, turkey, milk, beef, pork, eggs, etc.—is an area of intense debate and controversy. The disputes over the use of the word "milk" by non-dairy milk alternatives have spilled into the realm of other animal products, with the rise of state and federal regulatory efforts to restrict plant-based and clean/cultured meat companies from using terms like "beef" or "meat" to describe their products. Whether companies that produce clean meat products that are chemically/physically indistinguishable from their traditional counterparts will be allowed to use traditional nomenclature and terms that consumers know and expect is a matter of great consequence.

The importance of regulating with an eye toward consumer perception and preference cannot be overstated, since clean meat products' ability to transform the traditional meat landscape depends entirely on whether people will buy and eat the products.

What is the likely impact of state legislation and the recent petition by the cattlemen's association on this issue? Would either FDA or USDA authorities provide for stronger preemptive effect over state labeling and other requirements pertaining to clean meat?

6. Comments to FDA / Collective Strategies

Should companies within the clean meat sector collaborate on comments to the FDA and present a "unified front" with respect to their opinions on regulatory pathways? Would singular collective or multiple individual action be most impactful on the agency analysis? What are the industry's research needs to comment cogently, and how might this be funded? What are the various models for how proactive cooperation can be accomplished? What is the work product that should come out of this Roundtable?