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OPPORTUNITIES IN FOOD AND AGRICULTURAL TECH

Robert G. Hibbert

May 22, 2019

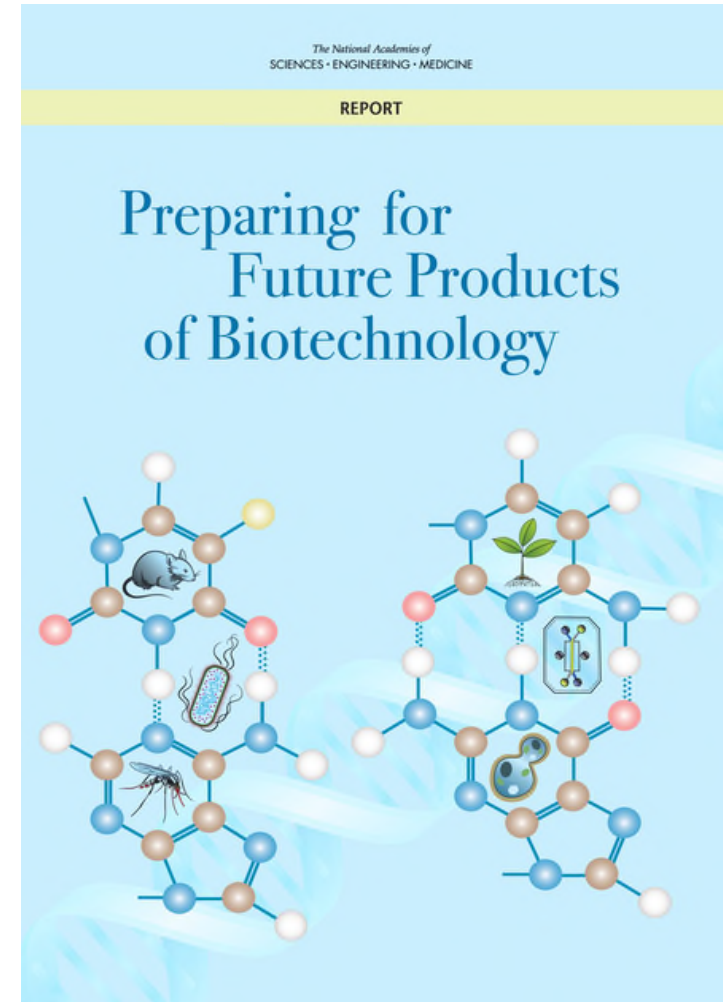
Agenda

- Understand the breadth of the new and innovative food products likely to emerge in the next 5-10 years
- Understand the current regulatory paradigm applicable to such products
- Highlight some of the major challenges for companies in this space

**NEW AND INNOVATIVE FOOD
PRODUCTS LIKELY TO
EMERGE IN THE NEXT 5-10
YEARS**

National Academy of Sciences

- In July 2015, the Office of Science and Technology Policy in the Executive Office of the President initiated an effort to modernize the U.S. regulatory system for biotechnology products
- An ad hoc committee identified “animal cell culture-derived products” as likely to be in the marketplace within the next 5-10 years



Examples of animal cell culture-derived products?

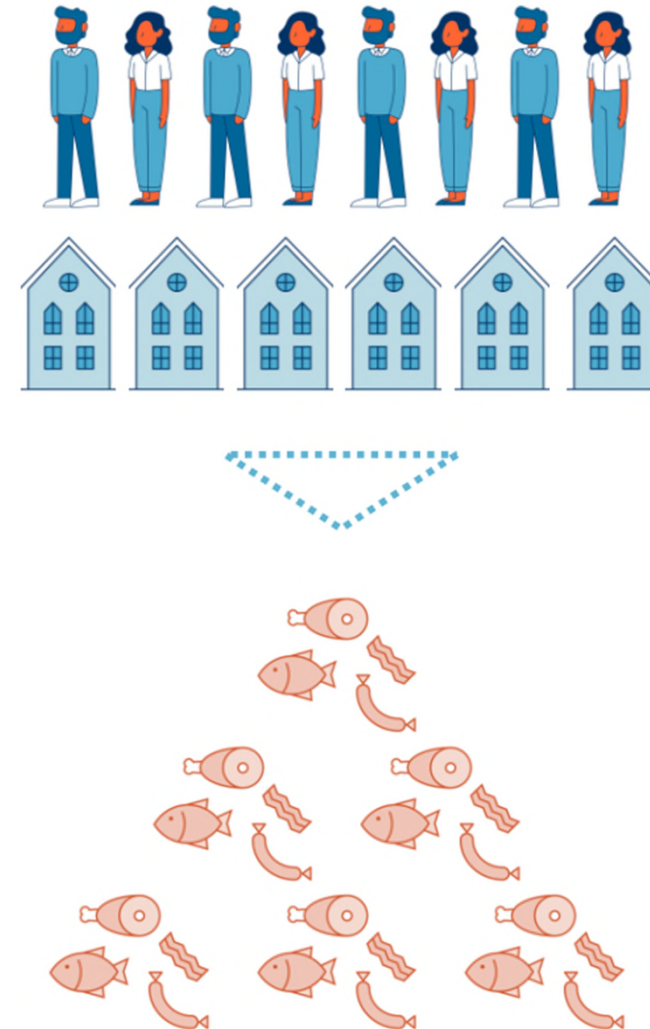
- Cowless leather
- Animal-free milk
- Chickenless eggs
- Cell-cultured meat (CCM aka “clean meat”)
 - Beef
 - Chicken
 - Fish



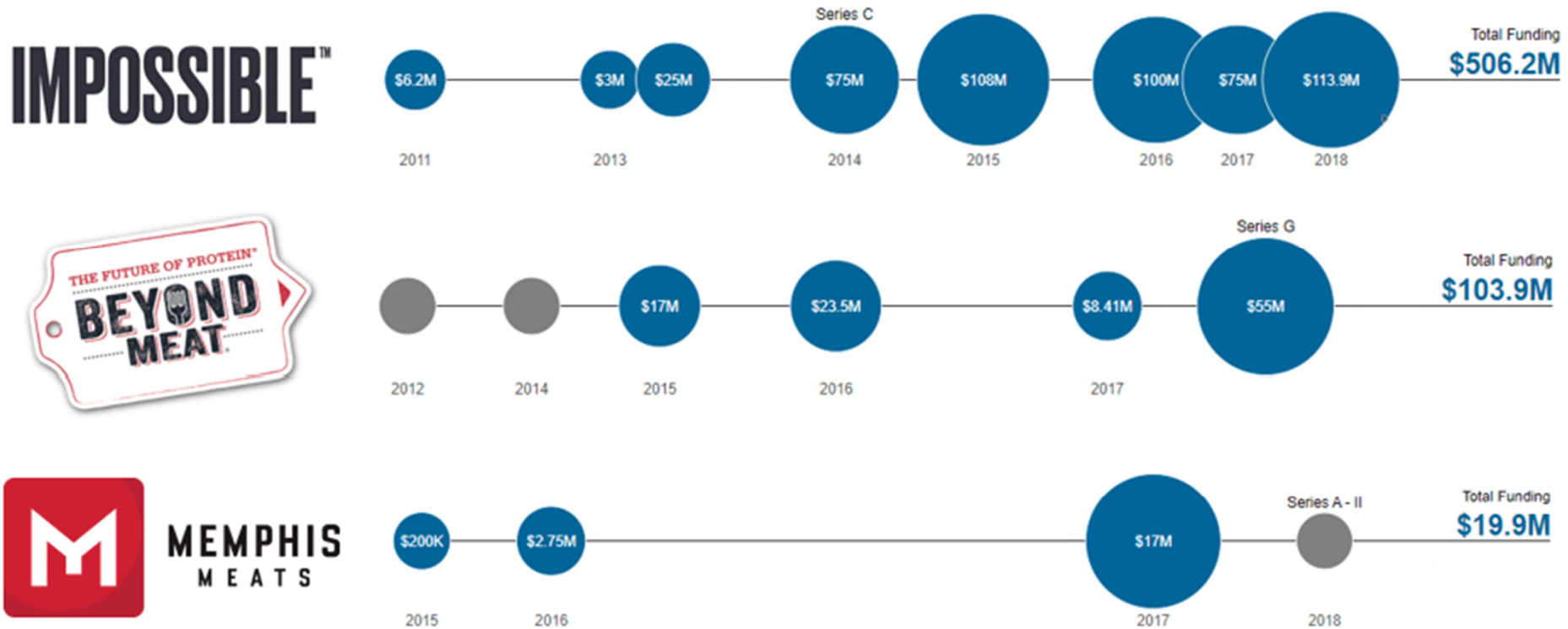
Source: Food and Drug Law Institute, Laws and Regulations Concerning Cell-Cultured Meat and Cellular Agriculture, <https://www.fdli.org/2018/02/update-laws-regulations-concerning-cell-cultured-meat-cellular-agriculture/>.

Feeding a Growing Global Population

- 30% of global human calorie consumption comes from meat products
- World's population is expected to surge to 9.6B by 2050, leading to a 61% increase in food production
- This increasing demand begs the question of how society will sustainably feed future generations



Meat Substitutes Financing History 2012-2019 (1/10/19)



CBINSIGHTS

Notable Venture Capital Investment

 **IndieBio investments across meatless ecosystem**
2015 – 2019 YTD (1/10/19)



 **New Crop Capital investments across meatless ecosystem**
2015 – 2017 YTD (11/6/17)



CURRENT REGULATORY PARADIGM

Legal Landscape

- **USDA/FSIS**

- Federal Meat Inspection Act (FMIA) (21 U.S.C. §§ 601-695)
 - **“Meat food product”** defined as:
 - any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. (21 U.S.C. 601(J))
 - “Meat” defined as the part of the muscle of any cattle, sheep, swine or goats which is skeletal or which is found in the tongue, diaphragm, heart or esophagus... (9 C.F.R. 301.2).”

- **FDA**

- Federal Food, Drug and Cosmetic Act (FD&C Act) authorizes FDA to regulate all foods through post-marketing mechanisms such as inspections, testing, and enforcing adulteration and misbranding standards and good manufacturing practices. Primary jurisdiction ceded to FSIS for meat and meat food products.

Agency Jurisdiction

USDA/FSIS?

- **Argument for:**
 - Inherent characteristics of cell-cultured meat is, at the cellular-level, actual meat
- **Argument against:**
 - Skeletal and Carcass
- **Significance:**
 - Industry and consumers are accustomed to USDA's mark of inspection and grading

FDA?

- **Argument for:**
 - FDA has broad authority regulate foods
 - General experience with new food ingredients
- **Argument against:**
 - Inherent characteristics of cell-cultured meat is, at the cellular-level, meat
 - FDA does not have experience with issues associated with meat products
- **Significance:**
 - No mark of inspection or grading

FDA / USDA Framework

- **Issued March 7, 2019**
- **Premarket Review** – FDA to design and implement consultation and review process
- **Inspection Oversight** – USDA / FSIS oversees production, continuous inspection requirement (meat and poultry) FDA inspection for Seafood
- **Labeling** – FSIS (meat and poultry) FDA (Seafood)

Remaining Regulatory Challenges

- **Premarket Review**

- Specific details of process
- Data requirements and timeline
- Nature of acceptance

- **Inspection Oversight**

- Compatibility with traditional model / HACCP paradigm
- Inspected and passed status

- **Labeling**

- State labeling initiatives
- Federal preemption (FSIS)
- Lack of express preemption (FDA)

Biography



Robert G. Hibbert

robert.hibbert@morganlewis.com

Washington, D.C.

T +1.202.739.5611

F +1.202.739.3001

Robert G. Hibbert advises clients in the food and agricultural industries on federal regulation, particularly relating to the US Department of Agriculture (USDA), as well as the US Food and Drug Administration (FDA). Clients seek his counsel on labeling, advertising, recalls, food safety compliance, animal health, and new product development issues. Bob's experience with civil litigation in federal court includes successful challenges to the scope of USDA jurisdiction and authority over major segments of the food processing industry.

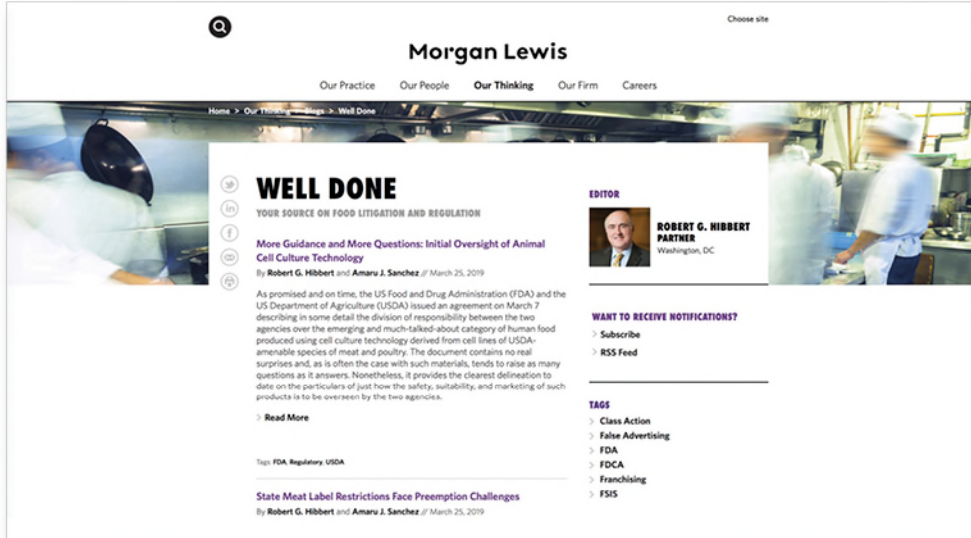


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More Guidance and More Questions: Initial Oversight of Animal Cell Culture Technology
By Robert G. Hibbert and Amaru J. Sanchez / March 25, 2019

As promised and on time, the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) issued an agreement on March 7 describing in some detail the division of responsibility between the two agencies over the emerging and much-talked-about category of human food produced using cell culture technology derived from cell lines of USDA-amenable species of meat and poultry. The document contains no real surprises and, as is often the case with such materials, tends to raise as many questions as it answers. Nonetheless, it provides the clearest delineation to date on the particulars of just how the safety, suitability, and marketing of such products is to be overseen by the two agencies.

[Read More](#)

Tags: FDA, Regulatory, USDA

State Meat Label Restrictions Face Preemption Challenges
By Robert G. Hibbert and Amaru J. Sanchez / March 25, 2019

EDITOR
ROBERT G. HIBBERT
PARTNER
Washington, DC

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