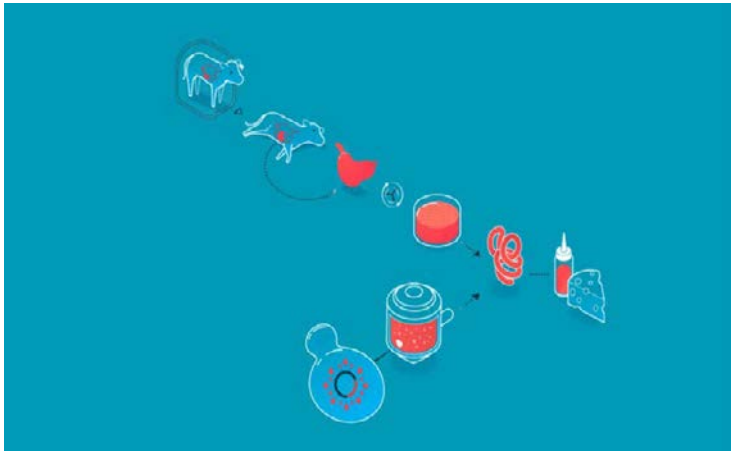
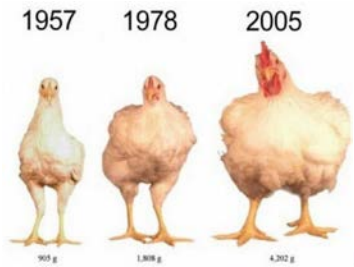
Controversy Panel: Cell Cultured Meat

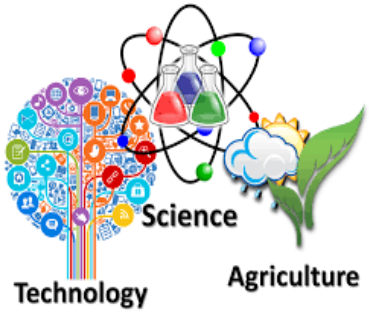
Food Policy Impact Conference
February 12, 2019



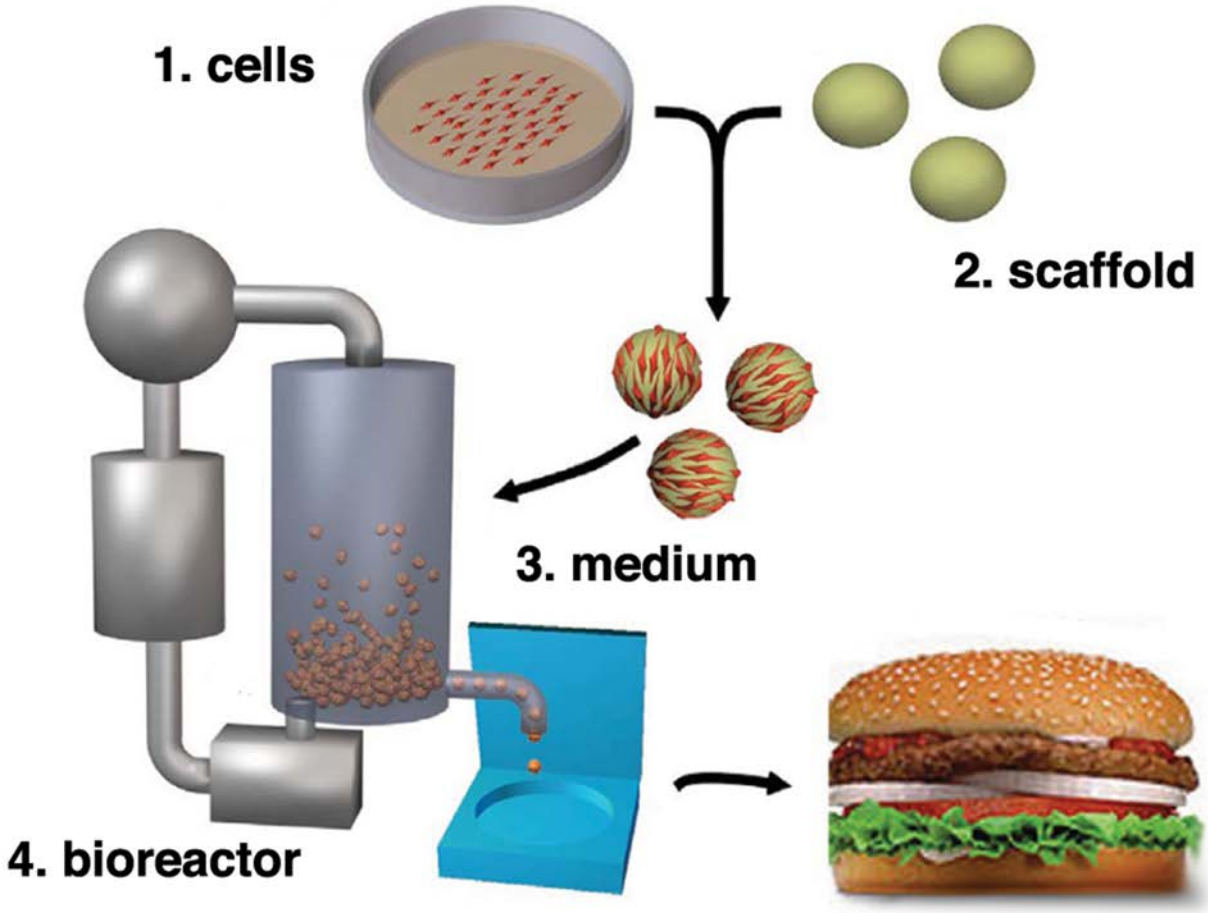
Jessica Almy, Good Food Institute
Deepti A. Kulkarni, Sidley Austin LLP
Brian Ronholm, Arent Fox LLP

Evolving Food System





Cell-Based Meat



The Regulatory Conversation: Who, What, Why, and How?

Forbes

Federal Agencies Hammer Out A Plan To Regulate Cell-Based Meats

The Atlantic

SCIENCE

The Farcical Battle Over What to Call Lab-Grown Meat

The FDA held a public meeting to talk about it, but no one could agree on what to call it.

Science

Artificial chicken grown from cells gets a taste test—but who will regulate it?

engadget

Lab-grown meat is inevitable. Will we eat it?

With the science coming together, the biggest challenge is getting people on board.

Who are the relevant regulatory agencies and why?

What will be regulated, by whom, and how?

What is next?

THE HILL

Meat lobby wants USDA to ban 'clean meat' makers from calling their products meat

CNN

How close are we to a hamburger grown in a lab?

WHAT *IS* MEAT, ANYWAY? LAB-GROWN FOOD SETS OFF A DEBATE

THE WALL STREET JOURNAL.

BUSINESS

Sizzling Steaks May Soon Be Lab-Grown

Startups raising funds to produce meat from cells cultivated in bioreactors

WIRED

Forbes

There's The Beef But Where's The Cow?

The Washington Post

Democracy Dies in Darkness

Why cattle ranchers and tech start-ups are beefing over the meaning of 'meat'

Regulatory Agencies: FDA

- Regulates **“food” and food ingredients** under Federal Food, Drug, and Cosmetic Act
- Determines **safety of new food ingredients including in plant-based foods, seafood, and meat and poultry products**
- Regulates **food products of biotechnology including GE animals**
- Assessed safety of **animal cloning and labeling**
- Regulates **microbial, algal, and fungal cells generated by large-scale culture** and used as direct food ingredients; **animal cell culture technology in therapeutic settings**; and **processing, manufacture, and packaging of seafood** (except catfish)
- Regulates **safety and labeling of “non-specified” red meats** (e.g., bison and venison) and **“non-specified” birds** (e.g., wild turkey) and products with minimal amounts of meat/poultry (e.g., multi-ingredient foods containing ≤ 3% raw meat/poultry or ≤ 2% cooked meat/poultry

Regulatory Agencies: USDA

- Regulates **“meat and meat food products”** and **“poultry and poultry products”** under Federal Meat Inspection Act and Poultry Products Inspection Act except:
  - multi-ingredient foods containing ≤ 3% raw meat/poultry or ≤ 2% cooked meat/poultry
  - non-specified meats or birds
- Regulates **establishments that slaughter and/or process meat and poultry products**
  - 2/3 of facilities inspected by USDA are processing facilities
  - Processing activities include mixing, grinding, fabrication, preblending, patty formation, stuffing, mechanical tenderization, cooking/smoking, etc.
- Determines safety, wholesomeness, and accuracy of **labeling**
- Determines **suitability of ingredients** used in meat and poultry products
- Reviews other new technologies for safety and suitability

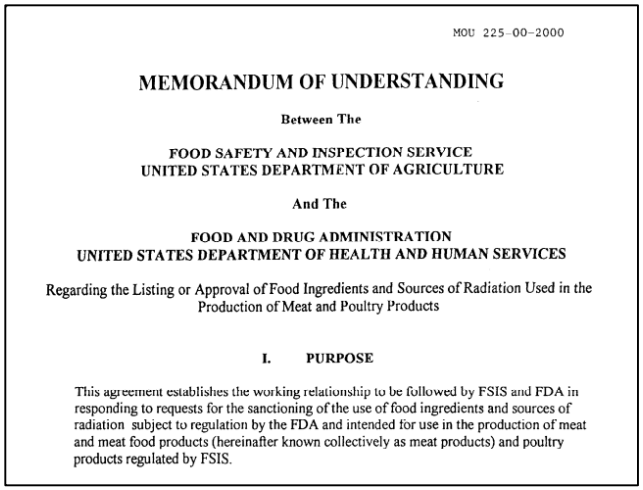
Meat

- **Meat**
  - "The **part of the muscle of any cattle, sheep, swine, or goats** that is skeletal or that is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels that normally accompany the muscle tissue and that are not separated from it in the process of dressing." 9 CFR § 301.2 (FMIA regulations)
- **Meat food product**
  - "[A]ny 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 [USDA]. . ." 21 U.S.C. § 601(j) (FMIA)

Poultry

- **Poultry**
  - "**[A]ny domesticated bird, whether live or dead.**" 21 U.S.C. § 453(e) (PPIA)
  - "Any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs, also termed young pigeons from one to about thirty days of age), whether live or dead." 9 CFR § 381.1 (PPIA regulations)
- **Poultry product**
  - **"[A]ny poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof**, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by [USDA] . . ." 21 U.S.C. § 453(f)
- **Poultry food product**
  - "Any product capable of use as human food which is **made in part from any poultry carcass or part thereof**, excepting those exempted from definition as a poultry product in § 381.15." 9 CFR 381.1

Regulatory Agencies: FDA or USDA, or both?



MOU 225-00-2000

MEMORANDUM OF UNDERSTANDING

Between The

FOOD SAFETY AND INSPECTION SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE

And The

FOOD AND DRUG ADMINISTRATION
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products

I. PURPOSE

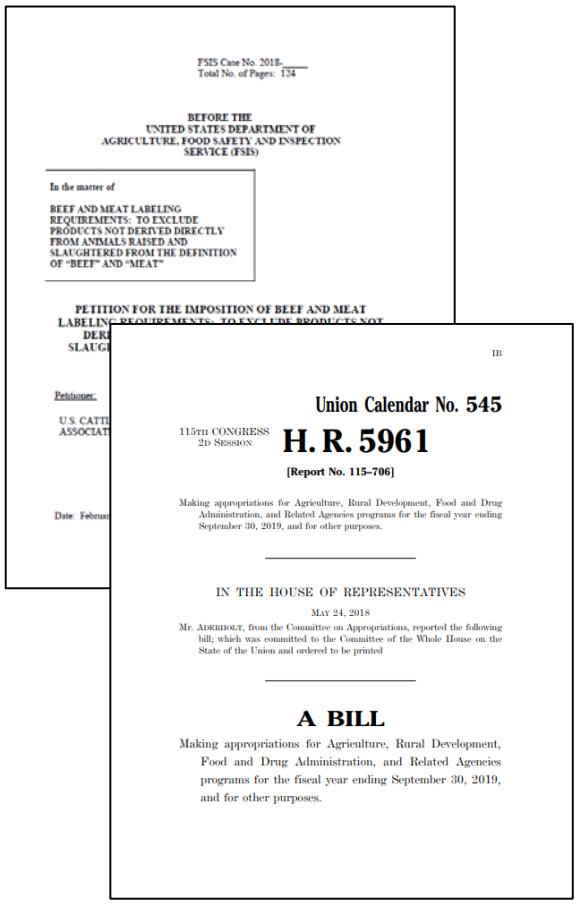
This agreement establishes the working relationship to be followed by FSIS and FDA in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by the FDA and intended for use in the production of meat and meat food products (hereinafter known collectively as meat products) and poultry products regulated by FSIS.

More than 25% of GRAS notices filed with FDA have involved substances in products in meat and poultry products, and have undergone concurrent evaluation by USDA/FSIS

Current Framework & Key Precedents

- New ingredients in meat or poultry
  - **FDA evaluates safety** and **USDA consults on suitability**
  - Stems from FDA's "food additive" authority
  - For ingredients of biological origin, evaluation is primarily a **comparative assessment**
- Finished meat & poultry product labeling
  - **Typically regulated by USDA**
- Other relevant precedents
  - FDA evaluated safety and labeling of food from animal clones and progeny; USDA/FSIS deferred to FDA determination
  - Concurrent evaluation of beef, poultry, and pork protein ingredients (e.g., GRN 168, 313, 314)
  - Congress delegated authority over catfish to USDA

Evolving Regulatory Landscape: Winter-Spring 2018



FSIS Case No. 2018-____
Total No. of Pages: 124

BEFORE THE
UNITED STATES DEPARTMENT OF
AGRICULTURE, FOOD SAFETY AND INSPECTION
SERVICE (FSIS)

In the matter of

BEEF AND MEAT LABELING
REQUIREMENTS: TO EXCLUDE
PRODUCTS NOT DERIVED DIRECTLY
FROM ANIMALS RAISED AND
SLAUGHTERED FROM THE DEFINITION
OF "BEEF" AND "MEAT"

PETITION FOR THE IMPOSITION OF BEEF AND MEAT

Petitioner:

U.S. CATTLEMEN'S ASSOCIATION

Date: February

IB

Union Calendar No. 545

115TH CONGRESS
2D SESSION

H. R. 5961

[Report No. 115–706]

Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2019, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 24, 2018

Mr. ADERHOLT, from the Committee on Appropriations, reported the following bill; which was committed to the Committee of the Whole House on the State of the Union and ordered to be printed

A BILL

Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2019, and for other purposes.

Feb. 9, 2018

- U.S. Cattlemen's Association (USCA) submits petition to USDA asking FSIS to establish meat labeling requirements that exclude products that are **not "from cattle that have been born, raised, and harvested in the traditional manner"**
- Receives over 6,150 comments

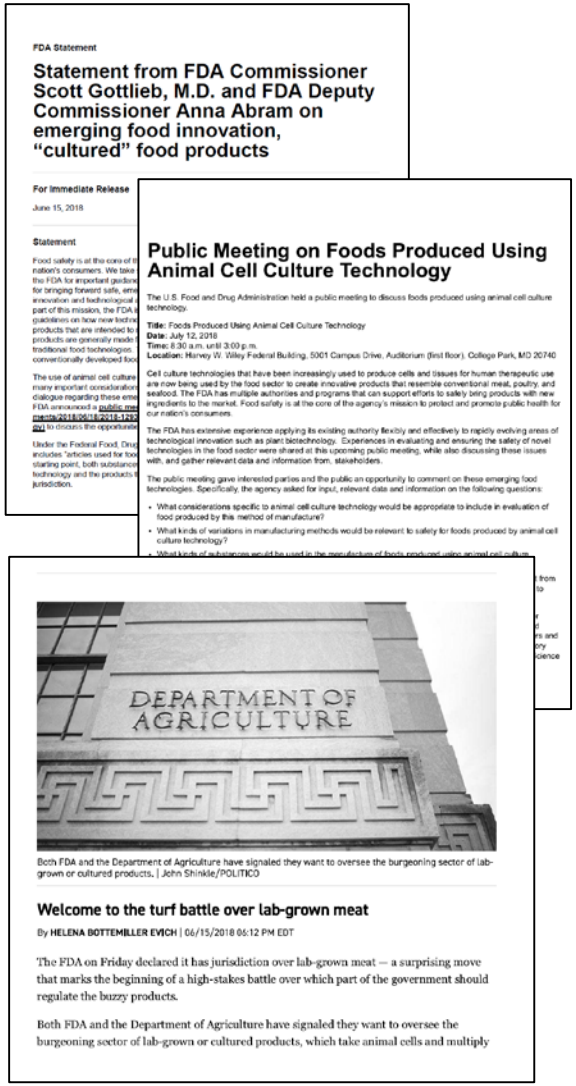
Apr. 18, 2018

- Before House Approps. Comm., Secretary Perdue, in response to questions on cell-based meat, indicates that meat and poultry and products labeled as such are **under the sole purview of USDA**

May 24, 2018

- FY19 House Approps. Comm.-reported bill (HR 5961) has language **directing USDA to exclusively regulate cell-based meat**

Evolving Regulatory Landscape: Summer 2018



FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner Anna Abram on emerging food innovation, "cultured" food products

For Immediate Release

June 15, 2018

Statement

Public Meeting on Foods Produced Using Animal Cell Culture Technology

The U.S. Food and Drug Administration held a public meeting to discuss foods produced using animal cell culture technology.

Title: Foods Produced Using Animal Cell Culture Technology
Date: July 12, 2018
Time: 8:30 a.m. until 3:00 p.m.
Location: Harvey W. Wiley Federal Building, 5001 Campus Drive, Auditorium (first floor), College Park, MD 20740

Cell culture technologies that have been increasingly used to produce cells and tissues for human therapeutic use are now being used by the food sector to create innovative products that resemble conventional meat, poultry, and seafood. The FDA has multiple authorities and programs that can support efforts to safely bring products with new ingredients to the market. Food safety is at the core of the agency's mission to protect and promote public health for our nation's consumers.

The FDA has extensive experience applying its existing authority flexibly and effectively to rapidly evolving areas of technological innovation such as plant biotechnology. Experiences in evaluating and ensuring the safety of novel technologies in the food sector were shared at this upcoming public meeting, while also discussing these issues with, and gather relevant data and information from, stakeholders.

The public meeting gave interested parties and the public an opportunity to comment on these emerging food technologies. Specifically, the agency asked for input, relevant data and information on the following questions:

- What considerations specific to animal cell culture technology would be appropriate to include in evaluation of food produced by this method of manufacture?
- What kinds of variations in manufacturing methods would be relevant to safety for foods produced by animal cell culture technology?

Both FDA and the Department of Agriculture have signaled they want to oversee the burgeoning sector of lab-grown or cultured products. | John Shinkle/POLITICO

Welcome to the turf battle over lab-grown meat

By HELENA BOTTEMILLER EVICH | 06/15/2018 06:12 PM EDT

The FDA on Friday declared it has jurisdiction over lab-grown meat — a surprising move that marks the beginning of a high-stakes battle over which part of the government should regulate the buzzy products.

Both FDA and the Department of Agriculture have signaled they want to oversee the burgeoning sector of lab-grown or cultured products, which take animal cells and multiply

June 15, 2018

- FDA issues statement on cell-cultured meat **announcing oversight under broad "food" authority and public meeting**
- USDA responds stating: ***"FDA's claim of jurisdiction over food — and anything used in food — is so overly broad that it implies that USDA doesn't have a role. . . meat and poultry inspections are the sole purview of USDA, so we expect any product marketed as 'meat' to be USDA's responsibility."***

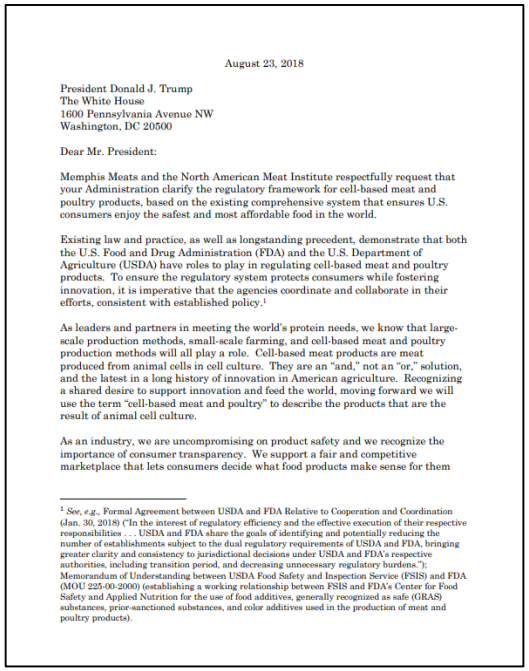
July 12, 2018

- FDA holds **public meeting** on "Foods Produced Using Animal Cell Culture Technology"
- FDA indicates jurisdiction over products **"intended to resemble conventional meat, poultry, and seafood"**
- FDA emphasizes **unique and relevant expertise** based upon oversight of foods developed using biosystems, foods derived from bioengineered crops, cell culture technology in therapeutic settings
- **Focuses on safety, but leaves door open for labeling**

Evolving Regulatory Landscape: Summer 2018 (cont'd)

Meat Institute, Memphis Meats Tell White House Both FDA and USDA have Roles in Regulating Cell-based Meat and Poultry Products.

Thursday, August 23, 2018



August 23, 2018

President Donald J. Trump
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

Memphis Meats and the North American Meat Institute respectfully request that your Administration clarify the regulatory framework for cell-based meat and poultry products, based on the existing comprehensive system that ensures U.S. consumers enjoy the safest and most affordable food in the world.

Existing law and practice, as well as longstanding precedent, demonstrate that both the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have roles to play in regulating cell-based meat and poultry products. To ensure the regulatory system protects consumers while fostering innovation, it is imperative that the agencies coordinate and collaborate in their efforts, consistent with established policy.[1]

As leaders and partners in meeting the world's protein needs, we know that large-scale production methods, small-scale farming, and cell-based meat and poultry production methods will all play a role. Cell-based meat products are meat produced from animal cells in cell culture. They are an "and," not an "or," solution, and the latest in a long history of innovation in American agriculture. Recognizing a shared desire to support innovation and feed the world, moving forward we will use the term "cell-based meat and poultry" to describe the products that are the result of animal cell culture.

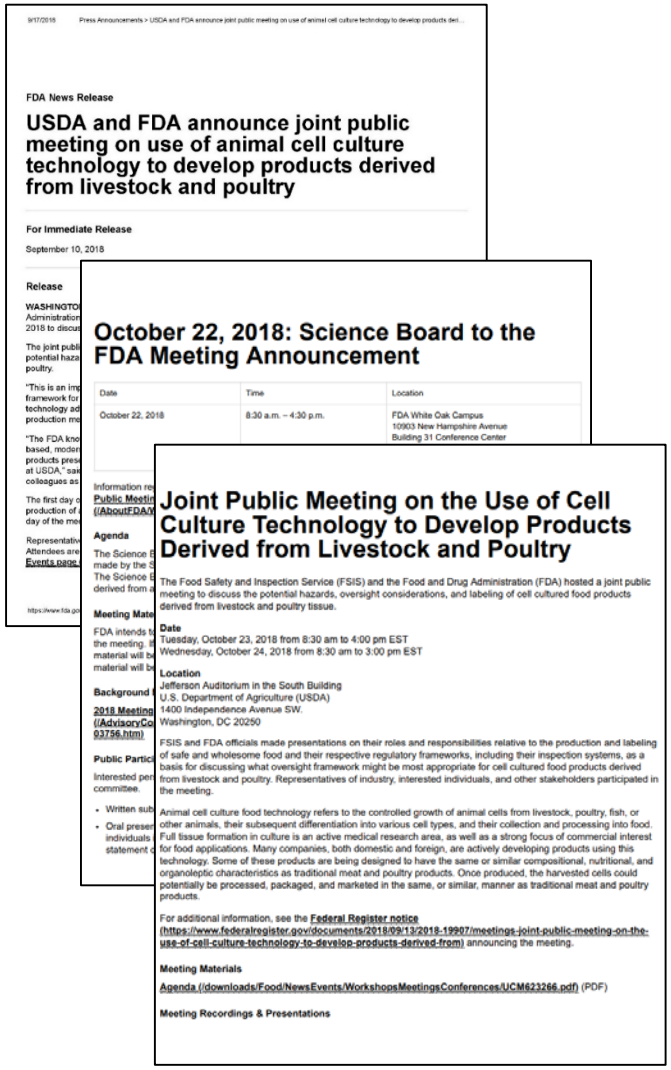
As an industry, we are uncompromising on product safety and we recognize the importance of consumer transparency. We support a fair and competitive marketplace that lets consumers decide what food products make sense for them

[1] *See, e.g.*, Formal Agreement between USDA and FDA Relative to Cooperation and Coordination (Jan. 30, 2018) ("In the interest of regulatory efficiency and the effective execution of their respective responsibilities . . . USDA and FDA share the goals of identifying and potentially reducing the number of establishments subject to the dual regulatory requirements of USDA and FDA, bringing greater clarity and consistency to jurisdictional decisions under USDA and FDA's respective authorities, including transition period, and decreasing unnecessary regulatory burdens."); Memorandum of Understanding between USDA Food Safety and Inspection Service (FSIS) and FDA (MOU 225-00-2000) (establishing a working relationship between FSIS and FDA's Center for Food Safety and Applied Nutrition for the use of food additives, generally recognized as safe (GRAS) substances, prior-sanctioned substances, and color additives used in the production of meat and poultry products).

Aug. 23, 2018

- **Memphis Meats & NAMI submit letter to President** asking Administration to clarify the regulatory framework
- *"Existing law and practice, as well as longstanding precedent, demonstrate that both" FDA and USDA "have roles to play in regulating cell-based meat and poultry products. . ."*
- **Calls for FDA to have oversight over pre-market safety evaluations, and for USDA to regulate thereafter, applying relevant findings from FDA's safety evaluation**
- *"Such a regulatory framework is not new and plays into the strengths and experience of FDA and USDA"*

Evolving Regulatory Landscape: Fall 2018



FDA News Release

USDA and FDA announce joint public meeting on use of animal cell culture technology to develop products derived from livestock and poultry

For Immediate Release

September 10, 2018

October 22, 2018: Science Board to the FDA Meeting Announcement

Date	Time	Location
October 22, 2018	8:30 a.m. – 4:30 p.m.	FDA White Oak Campus 10903 New Hampshire Avenue Building 31 Conference Center

Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) hosted a joint public meeting to discuss the potential hazards, oversight considerations, and labeling of cell cultured food products derived from livestock and poultry tissue.

Date
Tuesday, October 23, 2018 from 8:30 am to 4:00 pm EST
Wednesday, October 24, 2018 from 8:30 am to 3:00 pm EST

Location
Jefferson Auditorium in the South Building
U.S. Department of Agriculture (USDA)
1400 Independence Avenue SW.
Washington, DC 20250

FSIS and FDA officials made presentations on their roles and responsibilities relative to the production and labeling of safe and wholesome food and their respective regulatory frameworks, including their inspection systems, as a basis for discussing what oversight framework might be most appropriate for cell cultured food products derived from livestock and poultry. Representatives of industry, interested individuals, and other stakeholders participated in the meeting.

Animal cell culture food technology refers to the controlled growth of animal cells from livestock, poultry, fish, or other animals, their subsequent differentiation into various cell types, and their collection and processing into food. Full tissue formation in culture is an active medical research area, as well as a strong focus of commercial interest for food applications. Many companies, both domestic and foreign, are actively developing products using this technology. Some of these products are being designed to have the same or similar compositional, nutritional, and organoleptic characteristics as traditional meat and poultry products. Once produced, the harvested cells could potentially be processed, packaged, and marketed in the same, or similar, manner as traditional meat and poultry products.

For additional information, see the Federal Register notice (https://www.federalregister.gov/documents/2018/09/13/2018-19907/meetings-joint-public-meeting-on-the-use-of-cell-culture-technology-to-develop-products-derived-from) announcing the meeting.

Meeting Materials
Agenda (/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM623266.pdf) (PDF)

Meeting Recordings & Presentations

Sept. 10, 2018

- **USDA & FDA announce joint public meeting on use of animal cell culture technology to develop products derived from livestock and poultry**
- "*American farmers and ranchers feed the world, but as technology advances, we must consider how to inspect and regulate to ensure food safety, regardless of the production method.*" ~ Secretary Perdue
- *"Recent advances in animal cell cultured food products present many important and timely technical and regulatory considerations for the FDA and our partners at USDA."* ~ Commissioner Gottlieb

Oct. 22, 2018

- FDA holds advisory committee **meeting before FDA Science Board** on potential hazards and nutritional considerations

Oct. 23-24, 2018

- **FDA & USDA hold joint public meeting**
- Requests comment on numerous issues relating to premarket review, inspection, safety, and labeling

Evolving Regulatory Landscape: Fall-Winter 2018

FDA Statement

Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the regulation of cell-cultured food products from cell lines of livestock and poultry

For Immediate Release

November 16, 2018

Statement

Last month, the U.S. Department of Agriculture and the U.S. Food and Drug Administration held a public meeting to discuss the use of livestock and poultry cell lines to develop cell-cultured food products. At this meeting, stakeholders shared valuable perspectives on the regulation needed to both foster these innovative food products and maintain the highest standards of public health. The public comment period will be extended and will remain open through December 26, 2018.

After several thoughtful discussions between our two Agencies that incorporated this stakeholder feedback, we have concluded that both the USDA and the FDA should jointly oversee the production of cell-cultured food products derived from livestock and poultry. Drawing on the expertise of both USDA and FDA, the Agencies are today announcing agreement on a joint regulatory framework wherein FDA oversees cell collection, cell banks, and cell growth and differentiation. A transition from FDA to USDA oversight will occur during the cell harvest stage. USDA will then oversee the production and labeling of food products derived from the cells of livestock and poultry. And, the Agencies are actively refining the technical details of the framework, including robust collaboration and information sharing between the agencies to allow each to carry out our respective roles.

This regulatory framework will leverage both the FDA's experience regulating cell-culture technology and living biosystems and the USDA's expertise in regulating livestock and poultry products for human consumption. USDA and FDA are confident that this regulatory framework can be successfully implemented and assure the safety of these products. Because our agencies have the statutory authority necessary to appropriately regulate cell-cultured food products derived from livestock and poultry the Administration does not believe that legislation on this topic is necessary.

###

Agri Pulse

USDA, FDA will jointly regulate cell-cultured meat

Nov. 16, 2018

- FDA & USDA issue **joint statement concluding that both agencies will oversee cell-based meat and poultry**
- *"Drawing on the expertise of both USDA and FDA, the Agencies are today announcing agreement on a **joint regulatory framework wherein FDA oversees cell collection, cell banks, and cell growth and differentiation. A transition from FDA to USDA oversight will occur during the cell harvest stage. USDA will then oversee the production and labeling of food products derived from the cells of livestock and poultry."***
- *"Agencies are actively refining the technical details of the framework, including robust collaboration and information sharing . . ."*
- *"Because our agencies have the statutory authority necessary to appropriately regulate cell-cultured food products . . . **the Administration does not believe that legislation on this topic is necessary**."*

Evolving Regulatory Landscape: Today

General support for joint framework, though labeling remains a hotly debated issue

Open questions regarding premarket process, transfer of oversight, inspection, and labeling and claims

Agencies have indicated that they intend to issue further details soon

"*This regulatory framework* ***plays to the respective strengths of both USDA and FDA, while continuing to foster innovation and assure a safe and reliable food system*** *. . . We look forward to providing additional input . . .*" ~ Dr. Uma Valeti, CEO, Memphis Meats

"*We're* ***pleased the agencies have initiated the steps to work together on regulating cell-based meat products*** *. . .*" ~ Mark Dopp, Senior VP, Reg. & Scientific Affairs, NAMI

"*We are* ***pleased that Secretary Perdue and Commissioner Gottlieb are so swiftly moving forward on cell-based meat and that they are aware of the importance of this industry to the U.S. economy****. . .*" ~ Jessica Almy, Dir. of Policy, GFI

"*. . .* ***that USDA would have primary jurisdiction over the most important facets of lab-produced fake meat is a step in the right direction****, but there is still a lot of work to do on this issue to ensure that real beef producers and consumers are protected and treated fairly.*" ~ Collin Woodall, Senior VP, Govt. Affairs, NCBA

"*USCA is* ***encouraged by today's statement from the USDA and FDA on a joint regulatory framework*** *. . . Now that we have settled on the jurisdiction of these products, it's* ***time to move on to ensuring a truthful and transparent label for consumers****.*" ~ USCA

What Will Be Regulated, By Whom, and How?

FDA: Pre-Market Safety

- Substances used in manufacturing (e.g., animal cells, growth medium, scaffold)
- Assessment of whether manufacturing changes or affects identity, conditions of use, purity, toxicity, or safety
- Identity, history of safe use, common knowledge of safety, technical effect and intended use, margin of exposure
- Consultation process, food additive / GRAS process, process similar to LACF/AF?

FDA & USDA?: Manufacturing / Processing

- Hazard analysis and preventive controls, GMP
- HACCP, SSOPs?

USDA: Labeling

- Product name (e.g., qualifies as “meat” or “poultry” products?)
- Other mandatory labeling
- Other claims

FDA & USDA?: Facility Inspection

- FDA GMP / FSMA inspection or USDA processing inspection?
- Can USDA conduct processing inspection and consult with FDA as needed?

What Could Be Next?

Federal

- Clarification from FDA & USDA regarding regulatory framework, including point of entry, premarket process, inspection, and labeling
- USDA / FSIS decision on USCA petition or naming more generally
- Case-specific determinations
- Continued political interest and legislation (e.g., Appropriations)
- Litigation

State

- Missouri passed law prohibiting “misrepresenting a product as meat that is not derived from harvested production livestock or poultry”
- 14 other state bills pending
- Litigation

Other

- Investment and development outside the U.S.

Questions?

Jessica Almy
jessicaa@gfi.org
202.670.1686

Deepti A. Kulkarni
dkulkarni@sidley.com
202.736.8805

Brian Ronholm
Brian.Ronholm@arentfox.com
202.715.8478