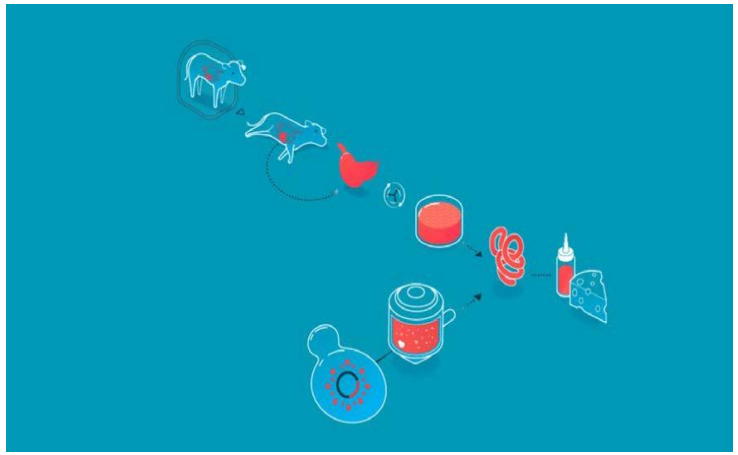
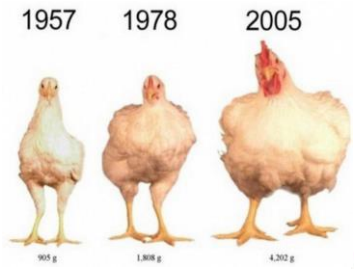
Innovative Foods Part 1: Who Has Jurisdiction?

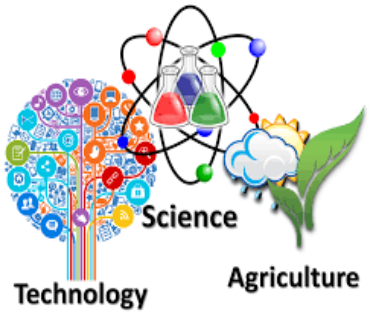
FDLI Food Advertising, Labeling, and Litigation Conference
September 26, 2018



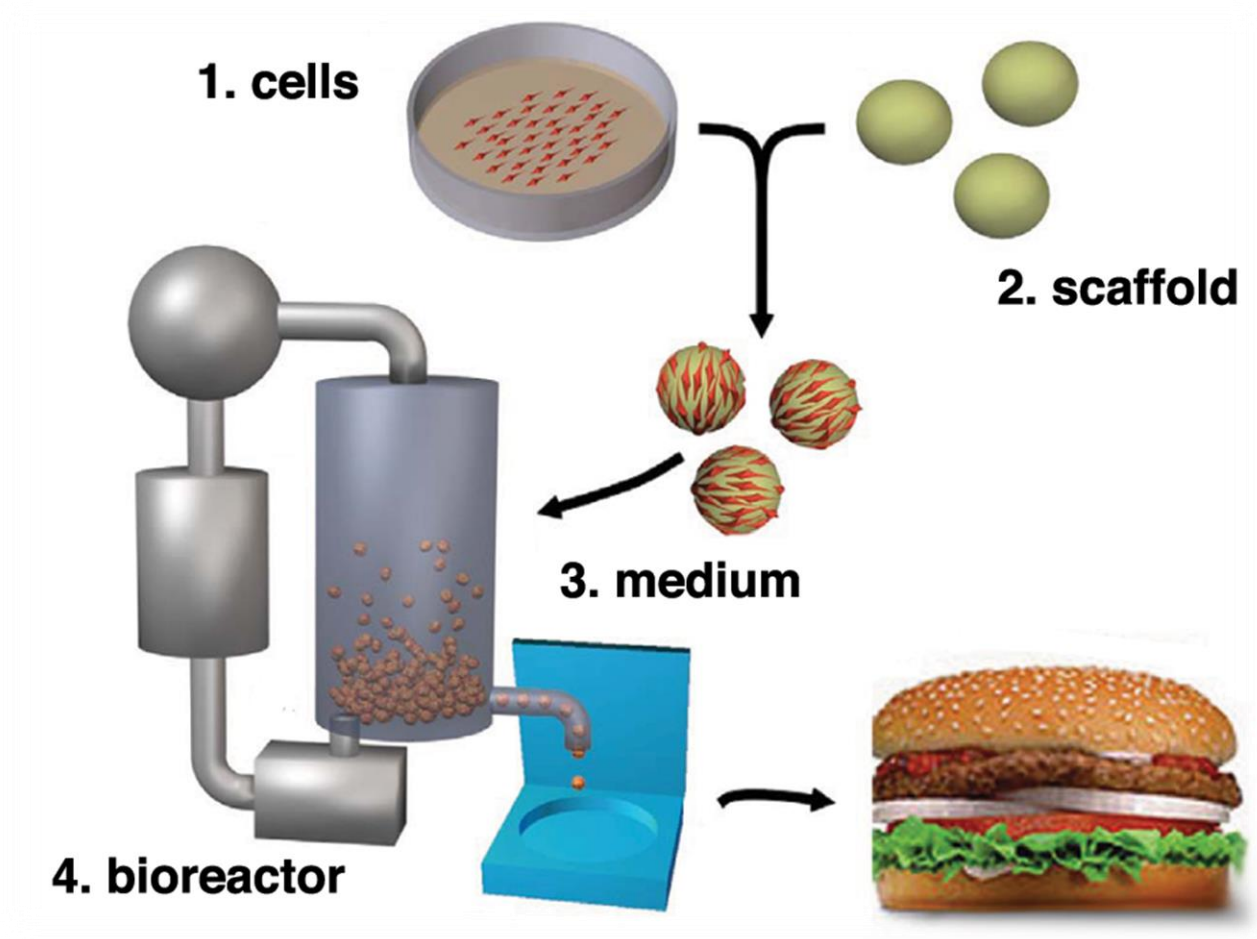
Deepti A. Kulkarni, Sidley Austin LLP
Brian P. Sylvester, Wiley Rein LLP
Moderated by: Stuart Pape, Shareholder, Practice Chair, Polsinelli PC and Planning Committee Chair, Food Advertising, Labeling, and Litigation Conference

Evolving Food System





Cell-Based Meat



The Regulatory Conversation: Who, What, Why?

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
FDA tries to take the reins on regulating cultured meat

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

Who are the relevant regulatory agencies and why?

What will be regulated and by whom?

What is next?

engadget
Lab-grown meat is inevitable. Will we eat it?
With the science coming together, the biggest challenge is getting people on board.

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

THE WALL STREET JOURNAL.
BUSINESS
Sizzling Steaks May Soon Be Lab-Grown
Startups raising funds to produce meat from cells cultivated in bioreactors

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

WIRED

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

The Washington Post
Democracy Dies in Darkness
Why cattle ranchers and tech start-ups are beefing over the meaning of 'meat'

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

Regulatory Agencies: FDA or USDA, or both?

- 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 **live food animals**
- 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**
- 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)

Regulatory Agencies: FDA or USDA, or both?

- 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**
  - 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)

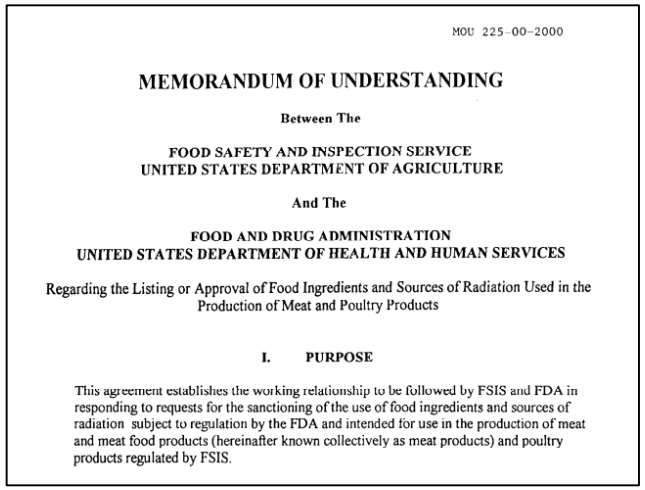
- **Meat food product**

  – "[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 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) (FMIA)

Poultry

- **Poultry**
  - "**[A]ny domesticated bird, whether live or dead.**" 21 U.S.C. 453 (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 those exempted from definition as a poultry product in § 381.15. Except where the context requires otherwise (e.g., in paragraph (b)(42) of this section), this term is limited to articles capable of use as human food."
- **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 and regulates finished products
  - Concurrent evaluation of beef, poultry, and pork protein ingredients (e.g., GRN 168, 313, 314)
  - Congress delegated authority over catfish exclusively

What Will Be Regulated and By Whom?

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?

Manufacturing Process

- Hazard analysis and control measures, GMP
- Preventive controls / HACCP?

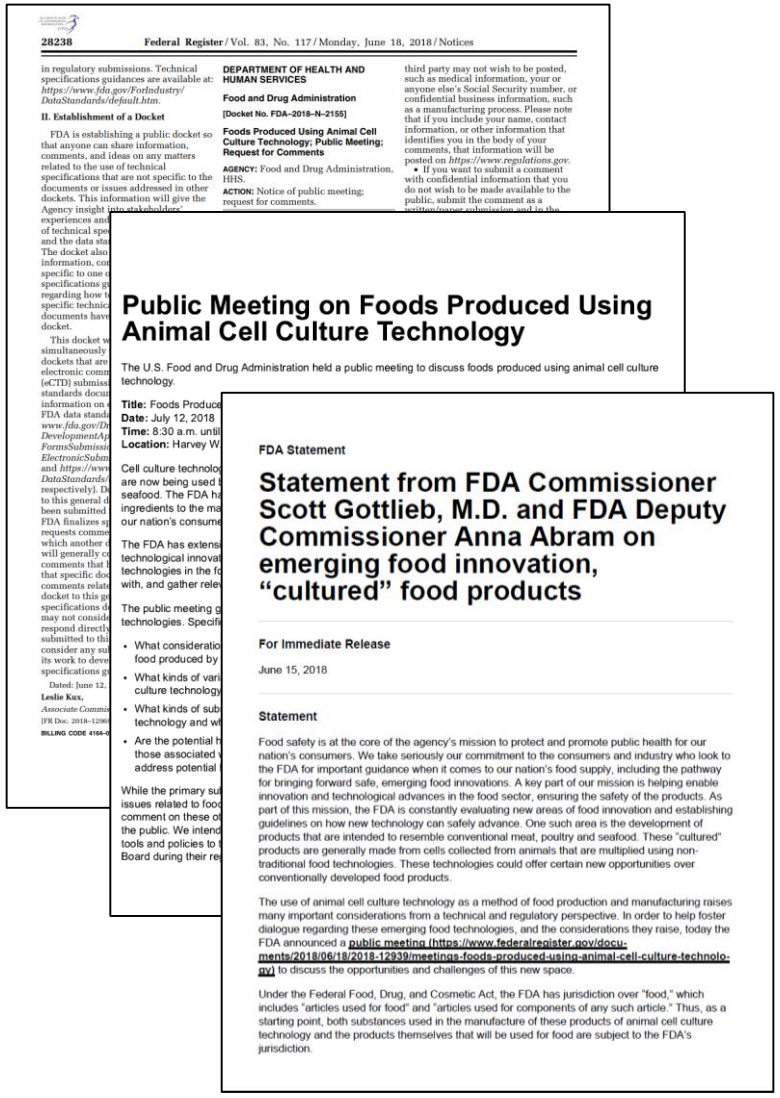
Labeling

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

Facility Inspection

- FDA GMP / FSMA inspection or USDA processing inspection?

Evolving Regulatory Landscape – FDA



28238 Federal Register / Vol. 83, No. 117 / Monday, June 18, 2018 / Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2155]

Foods Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

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.

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

Food safety is at the core of the agency's mission to protect and promote public health for our nation's consumers. We take seriously our commitment to the consumers and industry who look to the FDA for important guidance when it comes to our nation's food supply, including the pathway for bringing forward safe, emerging food innovations. A key part of our mission is helping enable innovation and technological advances in the food sector, ensuring the safety of the products. As part of this mission, the FDA is constantly evaluating new areas of food innovation and establishing guidelines on how new technology can safely advance. One such area is the development of products that are intended to resemble conventional meat, poultry and seafood. These "cultured" products are generally made from cells collected from animals that are multiplied using non-traditional food technologies. These technologies could offer certain new opportunities over conventionally developed food products.

The use of animal cell culture technology as a method of food production and manufacturing raises many important considerations from a technical and regulatory perspective. In order to help foster dialogue regarding these emerging food technologies, and the considerations they raise, today the FDA announced a public meeting (https://www.federalregister.gov/documents/2018/06/18/2018-12939/meetings-foods-produced-using-animal-cell-culture-technology) to discuss the opportunities and challenges of this new space.

Under the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over "food," which includes "articles used for food" and "articles used for components of any such article." Thus, as a starting point, both substances used in the manufacture of these products of animal cell culture technology and the products themselves that will be used for food are subject to the FDA's jurisdiction.

- Held a **public meeting** on July 12 regarding "Foods Produced Using Animal Cell Culture Technology" and opened docket for public comments
- Indicated that it has jurisdiction over products "**intended to resemble conventional meat, poultry, and seafood**" under its broad oversight of "food" and "articles used for components" of food
- Emphasized that it has **unique and relevant expertise** based upon its evaluation of:
  - Microbial, algal, and fungal cells generated by large-scale culture and used as direct food ingredients
  - Foods derived from bioengineered crops
  - Cell culture technology in therapeutic settings
- **Focus on safety**, but did leave door open for labeling

Questions Posed by FDA

Written comments due to FDA by September 25, 2018

Primary focus is safety, but FDA welcomes comments on other issues, including naming

- 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?
- What kinds of substances would be used in the manufacture of foods produced using animal cell culture technology and what considerations would be appropriate in evaluating the safety of these uses?
- Are the potential hazards associated with production of foods using animal cell culture technology different from those associated with traditional food production/processing? Is there a need for unique control measures to address potential hazards associated with production of foods using animal cell culture technology?

Evolving Regulatory Landscape – USDA

POLITICO

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

QUARTZ

FOOD AS POLITICS

US food regulators are fighting over who gets to oversee cell-cultured meat

InsideHealthPolicy
An Inside Washington news service

DAILY NEWS

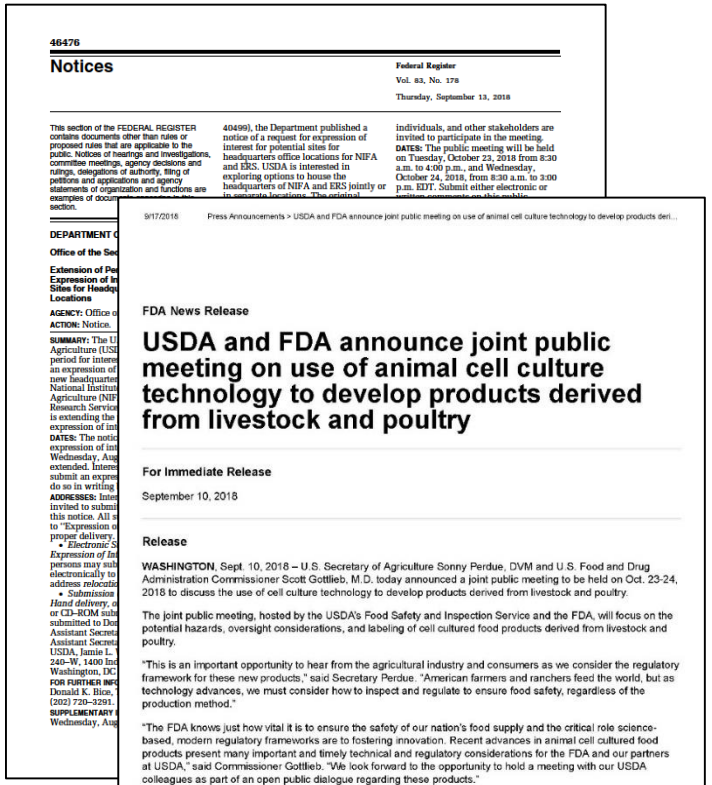
FDA Official: Agency Has Prepared For Cultured Meat Oversight For Years

July 12, 2018

"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. . . According to federal law, ***meat and poultry inspections are the sole purview of USDA, so we expect any product marketed as 'meat' to be USDA's responsibility****. We look forward to working with FDA as we engage the public on this issue."* – USDA Spokesperson

- USDA not officially involved in FDA public meeting
- Strong interest by industry groups and certain political leaders for USDA involvement, particularly with respect to labeling

Evolving Regulatory Landscape – FDA & USDA



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Notices

Federal Register
Vol. 83, No. 178
Thursday, September 13, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of docu... section.

40499), the Department published a notice of a request for expression of interest for potential sites for headquarters office locations for NIFA and ERS. USDA is interested in exploring options to house the headquarters of NIFA and ERS jointly or in separate locations. The original

individuals, and other stakeholders are invited to participate in the meeting.

DATES: The public meeting will be held on Tuesday, October 23, 2018 from 8:30 a.m. to 4:00 p.m., and Wednesday, October 24, 2018, from 8:30 a.m. to 3:00 p.m. EDT. Submit either electronic or

DEPARTMENT

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AGENCY: Office o

ACTION: Notice.

SUMMARY: The U
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Assistant Secreta
USDA, Jamie L.
240–W, 1400 Ind
Washington, DC

FOR FURTHER INFO
Donald K. Bice,
(202) 720–3291.

SUPPLEMENTARY
Wednesday, Aug

9/17/2018 Press Announcements > USDA and FDA announce joint public meeting on use of animal cell culture technology to develop products deri...

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

Release

WASHINGTON, Sept. 10, 2018 – U.S. Secretary of Agriculture Sonny Perdue, DVM and U.S. Food and Drug Administration Commissioner Scott Gottlieb, M.D. today announced a joint public meeting to be held on Oct. 23-24, 2018 to discuss the use of cell culture technology to develop products derived from livestock and poultry.

The joint public meeting, hosted by the USDA's Food Safety and Inspection Service and the FDA, will focus on the potential hazards, oversight considerations, and labeling of cell cultured food products derived from livestock and poultry.

"This is an important opportunity to hear from the agricultural industry and consumers as we consider the regulatory framework for these new products," said Secretary Perdue. "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."

"The FDA knows just how vital it is to ensure the safety of our nation's food supply and the critical role science-based, modern regulatory frameworks are to fostering innovation. 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," said Commissioner Gottlieb. "We look forward to the opportunity to hold a meeting with our USDA colleagues as part of an open public dialogue regarding these products."

The first day of the meeting will focus primarily on the potential hazards that need to be controlled for the safe production of animal cell cultured food products and oversight considerations by regulatory agencies. The second day of the meeting will focus on labeling considerations.

Representatives of industry, consumer groups and other stakeholders are invited to participate in the meeting. Attendees are encouraged to pre-register to attend the meeting. Pre-registration is available at the Meetings and Events page (https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings) on the FSIS website. The

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm619867.htm 1/3

- **Joint public meeting** scheduled for Oct. 23 and 24 regarding "Use of animal cell culture technology to develop products derived from livestock and poultry" and opened docket for public comments (until Nov. 26)
- **FDA Advisory Committee meeting** before FDA Science Board on Oct. 22
- Comes on heels of joint letter from Memphis Meats and NAMI to White House proposing joint FDA-USDA regulatory pathway
- **Focus on safety and labeling**

> *"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 Purdue

> *"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

Joint FDA-USDA Meeting: Safety Considerations

- Most **significant sources of potential hazards** for cell-based meat and poultry v. traditionally produced counterparts and how are they similar and different?
- **Strategies to ensure that all potential hazards are identified and appropriately controlled**
  - Is there an effective and efficient application of pre-market programs to ensure the safety of foods produced by animal cell culture?
  - What type and frequency of inspection will be appropriate for various stages of the manufacture of these products?
  - What type and frequency of inspection will be appropriate for products that combine cell cultured food products and other ingredients?
- FSIS and FDA are actively working to reduce the duplicative and inefficient regulation of establishments and products under both agencies' jurisdiction.
  - How could this be done for products of animal cell culture derived from livestock and poultry?

Joint FDA-USDA Meeting: Labeling

- What factors should be considered in the labeling of products of animal cell culture?
  - Should **standards of identity or criteria for statements of identity be established for these products** to ensure that product names are truthful, not misleading, and sufficiently differentiate cell cultured products from traditional products?
  - Should the **methods by which animal cell cultured products are produced (i.e., the culturing process)** be considered required information for purposes of labeling?
    - If so, what factors should be considered in accurately describing the production methods?
  - Should the **source of the animal cells** (i.e., the species from which the cell line was initiated) be considered required information for the purposes of labeling?
  - What factors should be considered in potentially allowing **health, safety, and other claims** in the marketing of animal cell cultured products?
  - How should **products containing both animal cell cultured products and traditional meat and poultry products** be labeled?

Plant-Based Foods

Recent Developments

- Congressional letter to FDA (December 2016)
  - States that use of the term “milk” for plant-based products is misleading, harmful to dairy industry, and violation of milk standard of identity, which defines milk in relevant part as “lacteal secretion” obtained from dairy cows
- DAIRY PRIDE Act (January 2017)
  - Would have required non-dairy products made from nuts, seeds, plants and algae to no longer be labeled with dairy terms such as milk, yogurt or cheese
  - No action taken
- GFI submitted petition to FDA (March 2017)
  - Requested issuance of regulation clarifying that “new foods may be named by reference to other ‘traditional’ foods in a manner that makes clear to consumers their distinct origins or properties.”
- FDA held Nutrition Innovation Strategy Public Meeting on July 26, 2017
  - Key issue: Modernizing Standards of Identity
  - Dr. Gottlieb reiterated and elaborated on concerns regarding plant-based products using the term “milk” (or other dairy related terms) as part of their name
  - FDA may formally request comments on naming of milk substitutes

What Could Be Next?

Cell-based meat

- Completion of FDA comment period and review of July 12 meeting
- FDA Science Board overview of potential hazards and safety considerations
- Clarification from FDA & USDA regarding regulatory framework and point of entry
- USDA / FSIS decision on U.S. Cattlemen's Petition or naming more generally
- Case-specific determinations
- Continued political interest and legislation (e.g., Federal Ag Appropriations; Missouri law)
- Litigation

Plant-based meat and dairy

- FDA request for comment and issuance of policy statement
- Continued political interest and legislation (e.g., Missouri law)
- Ligitation

Questions?

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